

Office on Women's Health Report to the White House Council on Women and Girls

TO: White House Council on Women and Girls
FROM: Department of Health and Human Services
DATE: November 2009

Executive Summary

The Department of Health and Human Services (HHS) is the United States government's principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves. With more than 59,000 employees, HHS improves the lives of women and girls through the administration of over 300 programs in research, direct clinical service delivery, educational and training programs, disease prevention and health promotion strategies, advocacy, and policy development.

HHS Employees

While HHS understands its responsibility to advance the health of the nation, it also recognizes its significant role in championing the health and well-being of its workforce. The Department strives to maintain a supportive and positive workplace environment that promotes as well as exemplifies the importance of health and work-life balance. By empowering the HHS workforce with the tools to establish a good work-life balance, as well as providing resources and services in health and wellness, HHS enables its employees to enjoy healthier and happier lives, greater job satisfaction, and increased work productivity.

The HHS workforce comprises over 59,000 employees, including permanent employees (full-time and part-time), the Commissioned Corps, the Senior Executive Service, and Senior Executive Service equivalent. Women represent 64.5% of the HHS workforce, a proportion that is substantially higher than the overall federal workforce (44%).¹ Acknowledging the significant representation of women in the Department, HHS has responded in addressing the unique health and work-life support needs of its female employees, in addition to its entire workforce, with the goal of improving the lives of women, families, and all employees.

The Department provides a variety of WorkLife programs, clinical services, wellness-fitness services, and benefits to its employees. The Office of Human Resources in the Office of the Assistant Secretary for Administration and Management and Federal Occupational Health provide leadership in overseeing and managing these programs, in collaboration with the agencies themselves. The goal is to ensure that employees have the resources needed to balance their home and work life by offering WorkLife options and access to information, consultation, referral services, direct clinical services, and wellness facilities. Many of these services specifically impact the health and work-life balance of female employees.

¹ HHS Analysis of Workforce Demographics FY 2008, Office of Diversity Management and EEO, Office of the Assistant Secretary for Administration and Management.

HHS Programs and Policies

The Department sponsors many programs through its agencies and offices, including programs addressing specific diseases and health conditions and those that focus on cross-cutting needs for women and girls. The disease-specific programs encompass areas such as cancer, cardiovascular health, diabetes, chronic fatigue syndrome, HIV/AIDS, lupus, substance abuse, and mental health. The breadth of cross-cutting programs includes adolescent health, aging, data collection, health information, health promotion/disease prevention, minority health, and violence prevention.

HHS also conducts health policy analysis on a vast range of topics, including disease-specific issues and access to care/coverage, care giving, disability, global health, human trafficking, reproductive care, and rural health. Recently, in May 2009, the Department released the report *Roadblocks to Health Care: Why the Current Health Care System Does Not Work for Women* that highlighted the many challenges that women face in our current health care system.

HHS Infrastructure

The Department has maintained a dedicated focus on women and girls' health for over two decades, with leadership by the Coordinating Committee on Women's Health, the Office on Women's Health and several HHS agency offices dedicated to women's health issues.

- HHS Coordinating Committee on Women's Health (CCWH): Established in 1983 with a mission to provide department-wide leadership to address the health, safety, and quality of life for women and girls. Chaired by the Deputy Assistant Secretary for Health (Women's Health) and comprised of senior-level representatives from each of the HHS agencies and offices.
- HHS Office on Women's Health (OWH): Established in 1991 to support the Public Health Service Coordinating Committee on Women's Health Issues. Now serves as the coordinator for women's health efforts across HHS. Led by the Deputy Assistant Secretary for Health (Women's Health), OWH supports a Regional Women's Health Coordinator and a support position in each of the 10 HHS regional offices.
- Agency Offices of Women's Health: Four HHS agencies maintain offices on women's health:
 - National Institutes of Health (Office of Research on Women's Health);
 - Centers for Disease Control and Prevention (Office of Women's Health);
 - Food and Drug Administration (Office of Women's Health); and
 - Health Resources and Services Administration (Office of Women's Health).

Opportunities

HHS has made important contributions to improving the health of women and girls through its leadership, resources and programs and policies focusing on education/awareness, research, disease prevention and health promotion, and direct clinical services. The primary opportunities for this Administration include the following:

- Addressing the unique needs of women and girls in health reform;

- Examining HHS’s current portfolio to identify gaps in knowledge or services and to ensure all program and policies are informed by the best available science;
- Developing an HHS-wide, comprehensive women and girls’ health strategy; and
- Collaborating and coordinating efforts with other federal departments to address non-clinical determinants of health for women and girls, including educational, economic, and environmental determinants.

The White House Council on Women and Girls can provide leadership and recommendations across each of these areas, and help to ensure that HHS programs and policies align with the priorities of the White House.

A. Introduction

The Department of Health and Human Services (HHS) is the United States government's principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves. With more than 59,000 employees, HHS improves the lives of women and girls through the administration of over 300 programs in research, direct clinical service delivery, educational and training programs, advocacy, and policy development.

History of HHS Involvement in Women and Girls' Health

For over 25 years, HHS has recognized the importance of the achievement of women and girls through its focus on women's health. In 1983, the Assistant Secretary for Health at HHS appointed a Public Health Service (PHS) Task Force on Women's Health Issues to "identify those women's health issues that are important in our society today and to lay out a blueprint for meshing those issues with the priorities of the Public Health Service."² After two years of study, the Task Force issued Volume I of *Women's Health: Report of the Public Health Task Force on Women's Health Issues* in 1985, which included their findings and a series of recommendations to address women's health. In response to the recommendations, the PHS Coordinating Committee on Women's Health was created in 1986 to facilitate intradepartmental communication.

Acknowledging the success of the PHS Coordinating Committee on Women's Health and the importance of women's health issues, HHS established the Office on Women's Health (OWH) to improve the health of American women by advancing and coordinating a comprehensive women's health agenda throughout the Department to address prevention and health care service delivery, research, public and health care professional education, and career advancement for women in the health professions and in scientific careers.

The position of Deputy Assistant Secretary for Health (Women's Health) was created in 1993, and that individual both directs the Office on Women's Health and chairs the HHS Coordinating Committee on Women's Health (CCWH). CCWH has had many successes in its more than 20 year history, advancing the women's health agenda throughout the Department and to the American public. Select accomplishments include *The Healthy Woman – A Complete Guide for All Ages*, National Women's Health Week, Minority Women's Health Summits, the Women's Health Time Capsule, *A Century of Women's Health 1900-2000*, Town Hall Meetings and Congressional briefings, and most recently the Summit for Action: The Health of Women & Girls Beyond 2010.

² Public Health Service Task Force on Women's Health Issues, *Women's Health: Report of the Public Health Service Task Force on Women's Health Issues, Volume I*. Public Health Reports, 1985. 100(1): p. 73-106.

The first office devoted to women's health in HHS was the Office of Research on Women's Health (ORWH) at the National Institutes of Health. This office was established in September 1990 via statute within the NIH Office of the Director to serve as the focal point for women's health research at the NIH. Since the establishment of the NIH ORWH and HHS OWH, three other Offices of Women's Health have been created – at the Centers for Disease Control and Prevention, the Food and Drug Administration, and the Health Resources and Services Administration.

Over the last 20 years, HHS has and continues to address a broad range of women's health issues through its many agencies and offices, such as cardiovascular health, breast and gynecologic cancers, domestic violence, adolescent health, substance abuse, mental health, reproductive and sexual health, osteoporosis, minority health, tobacco cessation, diabetes, obesity, HIV/STDs, general health promotion and disease prevention, and quality of care (*see Appendix*). In addition to these issues, HHS is also tackling the topic of health care reform and women. On May 13, 2009, HHS Secretary Kathleen Sebelius hosted a roundtable discussion with women small business owners on the urgent need for health reform. At the meeting, Secretary Sebelius released the HHS report *Roadblocks to Health Care: Why the Current Health Care System Does Not Work For Women*, which highlights the many challenges that women face in our current health care system (*see Appendix*).

HHS Agencies and Impact on Women and Girls

Within the Department, HHS has several agencies that promote and advance the health of the nation at-large, while also directly impacting the health, well-being, and livelihood of women and girls.

Administration for Children and Families (ACF) - www.acf.hhs.gov/

- Administers federal programs that promote the economic and social well-being of families, children, individuals, and communities. Empowers women and girls and strengthens communities through programs such as supporting domestic violence victims and their dependents, child care assistance, helping needy families with children, and school readiness.

Administration on Aging (AoA) - www.aoa.gov/

- Helps elderly individuals maintain their dignity and independence in their homes and communities through comprehensive, coordinated, and cost effective systems of long-term care, and livable communities across the U.S. Noting that older women outnumber older men, are more likely to live alone, and have a lower median income, AoA provides for supportive and nutrition services, caregiver support, and Alzheimer's Disease supportive services.

Agency for Healthcare Research and Quality (AHRQ) - www.ahrq.gov/

- Improves the quality, safety, efficiency, and effectiveness of health care through health services research. Strives to enhance the response of the health care system to women's needs; understand differences between the health care needs of women and men; understand and eliminate disparities in health care; and empower women to make better health care decisions.

Agency for Toxic Substances and Disease Registry (ATSDR) - www.atsdr.cdc.gov/

- Serves the public by using the best science, taking responsive public health actions, and providing trusted health information to prevent harmful exposures and disease related to toxic substances. Provides leadership in preventing and mitigating exposures to hazardous wastes and toxic substances that may affect women's health and the public's health at-large.

Centers for Disease Control and Prevention (CDC) - www.cdc.gov/

- Serves as the national focus for developing and applying disease prevention and control, environmental health, and health promotion and health education activities designed to improve the health of the people of the U.S. Promotes wellness and prevention through a broad array of programs such as breast and gynecologic cancer screening, sexual and reproductive health, cardiovascular disease risk reduction, and healthy lifestyles.

Centers for Medicare & Medicaid Services (CMS) - www.cms.hhs.gov/

- Ensures effective, up-to-date health care coverage and promotes quality care for beneficiaries. Provides coverage for prevention and intervention measures in women's and girls' health, such as the immunizations including human papilloma virus, breast and cervical cancer screening and treatment, and regulation of laboratory testing of Pap smears.

Food and Drug Administration (FDA) - www.fda.gov/

- Protects the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. Given that women and girls are regular consumers of products regulated by FDA, such as contraceptives, diabetes and high blood pressure medications, mammography, food products, and cosmetics, the agency's mission serves to protect their health and the public's health at-large.

Health Resources and Services Administration (HRSA) - www.hrsa.gov/

- Provides national leadership, program resources and services needed to improve access to comprehensive, culturally competent, quality health care. Women and girls represent a significant subset of the population served by HRSA, receiving services such as primary care (including prenatal care) at HRSA-supported health centers, coordinated HIV services, parenting and lactation support initiatives, and training health care professionals.

Indian Health Service (IHS) - www.ihs.gov/

- Serves as the principal federal health care provider and health advocate for American Indians and Alaska Natives with the goal to raise their physical, mental, social, and spiritual health to the highest level through comprehensive, culturally acceptable personal and public health services. Implements programs such as domestic violence and sexual assault services, education, and training, nurse midwifery programs, tobacco cessation, healthy nutrition.

National Institutes of Health (NIH) - www.nih.gov/

- Supports science as the nation's medical research agency in pursuit of fundamental knowledge and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability. Research funded by NIH seeks to understand the causes, diagnosis, prevention, and cure of human diseases and has provided clues and insights into sex and gender factors that impact health and disease, leading to the development of the most appropriate preventive and therapeutic approaches for the health of girls and women. Additionally, the NIH is committed to training the next generation of scientists to ensure sustained scientific advancement.

Office for Civil Rights (OCR) - www.hhs.gov/ocr

- Promotes and ensures that all persons have equal access and the opportunity to participate in and receive services from all HHS-funded programs without facing unlawful discrimination on the basis of race, color, national origin, disability, age, and gender, and that the privacy of their health information is protected. Through prevention and elimination of unlawful discrimination and by protecting the privacy of individually identifiable health information, OCR assists HHS carry out its overall mission of improving the health and well-being of all people affected by its many programs.

Office of Public Health and Science (OPHS) - <http://www.hhs.gov/ophs/index.html>

- Provides for the delivery of public health services through several offices, such as the Office of the Surgeon General, the Regional Health Administrators, the Office of Disease Prevention and Health Promotion, the Office of HIV/AIDS Policy, the Office of Minority Health, the Office of Population Affairs, the Office on Women's Health, and the President's Council on Physical Fitness and Sports.

Substance Abuse and Mental Health Services Administration (SAMHSA) - www.samhsa.gov/

- Builds resilience and facilitates recovery for people with or at risk for mental or substance use disorders. Provides resources and services in areas such as pregnancy and substance abuse, suicide prevention, mental illness treatment, behavioral health and wellness, and services in the aftermath of trauma or violence.

Women's Health Infrastructure in HHS

HHS has had a dedicated focus on women and girls' health for over two decades, through leadership by the departmental Office on Women's Health, the Coordinating Committee on Women's Health, and several HHS agency Offices of Women's Health. In addition to these entities, many of the other HHS agencies have dedicated staff or committees who provide leadership on their agencies' programs and policies related to women and girls.

Office on Women's Health (OWH)

www.womenshealth.gov and www.girlshealth.gov

- Established in 1991 to improve the health of American women by advancing and coordinating a comprehensive women's health agenda throughout HHS to address health care prevention and service delivery, research, public and health care professional education, and career advancement for women in the health professions and in scientific careers. Led by the Deputy Assistant Secretary for Health (Women's Health), OWH supports a Regional Women's Health Coordinator and a support position in each of the 10 HHS regional offices.
 - Coordinates and promotes collaborations among HHS agencies and offices
 - Provides information on research, prevention, and services to assist decision-makers
 - Identifies, develops, and supports model programs and innovations in women's health
 - Educates health and wellness professionals and consumers

Coordinating Committee on Women's Health (CCWH)

- Established in 1983 to safeguard and improve the health and well-being of all women and girls in the United States. Provides department-wide leadership to address the health, safety, and quality of life for women and girls. CCWH works strategically to improve awareness, increase collaboration, advance evidence-based programs and policies, support sex and gender-specific initiatives and address gaps and disparities in women's health. Chaired by the Deputy Assistant Secretary for Health (Women's Health), CCWH is comprised of senior-level representatives from each of the Federal agencies and offices within the Department (*see Appendix*).

Agency Offices of Women's Health

Four HHS agencies maintain offices of women's health that function to provide leadership and coordinate women's health related activities within their respective agencies.

Centers for Disease Control and Prevention Office of Women's Health

- Established in 1994 and located in the Office of Strategy and Innovation within the Office of the Director. Mission: to promote and improve the health, safety, and quality of life for women.
 - Provides a forum for collaboration by agency staff; women's health coordinators in the regions, states, and territories; other federal agencies; academic institutions; and partners in private and public organizations

- Serves as an advocate for women's health issues and stimulates research, disease prevention programs, and policy development
- Informs women, public health practitioners, workplace health and safety professionals, health care providers, and others about matters related to women's health
- Communicates information and research findings to raise awareness about issues and populations with public health needs
- Participates in campaigns and other activities to encourage healthful behaviors by women.

Food and Drug Administration Office of Women's Health

- Established in 1994 and located in the Office of Science and Health Coordination in the Office of the Commissioner. Mission: 1) to protect and advance the health of women through policy, science, and outreach and 2) to advocate for participation of women in clinical trials.
 - Promotes integrative and interactive approach regarding women's health issues across all the organizational components of the FDA
 - Develops research agenda to identify and understand sex differences in FDA regulated products
 - Promotes the development of drugs, biologics and medical devices for the treatment of women's unmet medical needs in areas such as auto-immune diseases, obesity, and ovarian cancer
 - Funds intramural and extramural research and collaborates with other scientific constituents to achieve mission
 - Forms partnerships with government and non-government entities, including consumer groups, health advocates, professional organizations, and industry, to promote FDA's women's health objectives

Health Resources and Services Administration Office of Women's Health

- Established in 1996 and currently located in the Maternal and Child Health Bureau. Mission: to work across all HRSA programs to ensure that women across the lifespan receive comprehensive, culturally competent, quality health care.
 - Coordinates and supports sex/gender-specific disease prevention and health promotion activities within HRSA and HHS
 - Supports educational and information dissemination efforts on topics related to sex/gender specific health issues
 - Serves as the HRSA liaison with other Federal and non-Federal individuals and organizations working on women's health policy and programs
 - Provides mentorship experiences for scholars and interns and encourages staff development opportunities

National Institutes of Health Office of Research on Women's Health

- First office devoted specifically to women's health in HHS. Established in 1990 via statute and located in the Division of Program Coordination, Planning, and Strategic Initiatives within the NIH Office of the Director.
 - Ensures the participation of women in clinical research funded by the NIH

- Establishes the research agenda for women's health including expanding the context of women's health beyond the reproductive system and reproductive years
- Expands and promotes research on the health of women and girls across the many components of the NIH
- Promotes the recruitment, retention, advancement and reentry of girls and women in biomedical careers
- Provides outreach for matters related to inclusion as well as research education to the extramural community and women's advocacy organizations

Other Agencies' Infrastructure on Women's Health

The remaining HHS agencies also have staff that work on women's health issues and participate in the HHS Coordinating Committee on Women's Health.

Administration for Children and Families

- Has liaison that participates in Coordinating Committee on Women's Health

Administration on Aging

- Has liaison that participates in Coordinating Committee on Women's Health

Agency for Healthcare Research and Quality

- Senior Advisor for Women's Health and General Research who coordinates agency activities pertaining to research on women's health and participates in HHS Coordinating Committee on Women's Health

Centers for Medicare & Medicaid Services

- Has liaison that participates in Coordinating Committee on Women's Health

Indian Health Service

- Office of Clinical and Preventive Services provides national consultation and leadership, including one full-time employee (FTE) focused on maternal and child health and an employee who dedicates ½-FTE on women's health issues. Women's health and maternal and child health consultants and advocates provide services throughout the Indian Health System.

Substance Abuse and Mental Health Services Administration

- Position of Associate Administrator for Women's Services and the Advisory Committee for Women's Services (ACWS) were created via statute in 1992
- Associate Administrator for Women's Services oversees the agency's women's health service activities
- Advisory Committee for Women's Services (ACWS) advises SAMHSA's Associate Administrator for Women's Services on appropriate activities to be undertaken by the agency with respect to women's substance abuse and mental health services, collects and reviews data, and improves the collection of data on women's health

- SAMHSA Women’s Coordinating Committee (SWCC) is legislatively mandated under the Children’s Act of 2000 to: 1) identify the need for women’s services and make an estimate of funds needed for each fiscal year; 2) identify needs regarding the coordination of services for women; 3) encourage support from all agencies in the Administration for women’s services; and 4) assure the unique needs of minority women are recognized and addressed within the Administration
- Has liaison that participates in HHS Coordinating Committee on Women’s Health

HHS Funding on Women’s Health

The Moyer Material, which is a supplement to HHS’s Congressional Budget Justifications, reports funding levels on specific areas within the Department. In 1994, women’s health funding became a focus area in the Moyer Report. As demonstrated in the table below, in FY 2009, HHS allocated greater than \$100 billion to women’s health-related programs and initiatives throughout the Department (*see Appendix*).

WOMEN'S HEALTH					
Program Level (Dollars in Millions)					
	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
Agency					
FDA	27.3	34.4	39.4	46.6	47.8
HRSA	1,801.3	1,913.1	1,924.7	1,986.3	2,019.9
IHS	153.1	159.6	166.1	171.8	178.5
CDC	1,042.7	1,006.6	1,013.8	1,051.8	1,063.2
NIH	3,458.0	3,485.3	3,514.5	3,626.9	3,682.6
SAMHSA	548.6	539.0	573.6	607.5	623.4
AHRQ	49.4	50.2	50.3	50.3	50.3
CMS	76,477.0	81,887.0	86,622.0	92,645.0	98,478.0
ACF	202.9	204.5	200.9	204.3	218.2
AoA	677.5	692.0	706.5	744.2	744.1
OS/OPHS	80.3	44.9	44.7	48.7	47.2
Total, HHS	84,518.2	90,016.7	94,856.5	101,183.3	107,153.2

Future Direction

Under the new leadership of HHS Secretary Kathleen Sebelius, the Department is poised to provide effective leadership in advancing the lives of women and girls. With a strong history of dedication to women’s health, HHS will move forward with innovative strategies to positively impact women and girls.

This report to the White House Council on Women and Girls will provide information on HHS programs and policies that impact women and girls, the Department’s initiatives to improve the lives of women in the HHS workforce, and recommendations for the Department’s future direction. The report outline is as follows:

- Programs That Improve the Lives of the Federal Workforce
- Programs That Improve the Lives of America’s Women and Girls
- Overarching Recommendation

B. Programs That Improve the Lives of the Federal Workforce

As the principal agency for protecting the health of all Americans and providing essential human services, HHS not only understands its responsibility to advance the health of the nation, but also its significant role in championing the health and well-being of its own workforce. The Department strives to maintain a supportive and positive workplace environment that promotes as well as exemplifies the importance of health and work-life balance. By empowering the HHS workforce with the tools to establish a good work-life balance, as well as providing resources and services in health and wellness, HHS enables its employees to enjoy healthier and happier lives, greater job satisfaction, and increased work productivity.

HHS Employees

The size of the permanent HHS workforce (full-time and part-time, Commissioned Corps, Senior Executive Service, and Senior Executive Service equivalent) has been stable over the past six years. In FY 2008, the HHS workforce was 59,324 employees. Women account for nearly 64.5% of the HHS workforce, a proportion that is substantially higher than the proportion in the overall federal workforce (44%). Yet, there is a lower representation of women at higher ranks in both the civilian workforce and uniformed service and in positions of executive leadership. Furthermore, there is a lower percentage of minority women compared to white women at higher grades and in executive leadership positions.

Relevant Statistics:

- Female employees are the majority in each of HHS agencies
- Female employees outnumber male employees in GS-1 through GS-14; however, male employees outnumber female employees in GS-15 and the Senior Executive Service (SES)
- 58% of the SES workforce are men; 42% are women
- Minority women outnumber white women in GS-1 through GS-8; however, white women exceed minority women in GS-9 through GS-15 and SES
- White women account for 78% of all women in SES
- Commissioned Corps (FY 2009)
 - Men and women are essentially equal in representation (women = 49%)
 - Women have equal or greater representation in Commissioned Corps Rank 1-5
 - At Commissioned Corps Rank 6 and above, men outnumber women
 - Women outnumber men as nurses and dietitians; however, men outnumber women as medical officers, engineers, and environmental health officers

HHS Work-Life Balance and Health/Wellness Programs

The Department provides a variety of WorkLife programs, clinical services, wellness-fitness services, and benefits to its employees. The goal is to ensure that employees have the resources needed to balance their home and work life by offering WorkLife options and access to information, consultation, referral services, direct clinical services, and wellness facilities. Some of the services specifically impact women's health and female employees; however, the other services address all employees' health and work-life balance. The Office of Human Resources in the Office of the Assistant Secretary for Administration and Management and Federal Occupational Health (FOH) provide leadership in overseeing and managing these programs, as well as leadership through the agencies themselves.

The WorkLife programs vary by agency and may include:

- **Alternative Work Schedules:** Alternative Work Schedule (AWS) allows employees to establish their arrival and departure times based on the schedule selected as approved by their supervisor. This arrangement may allow employees to better balance personal and work commitments and schedules. The HHS agencies offer AWS, and employees may establish these schedules in consultation with their supervisors. Implementation of AWS is a matter of management and supervisory discretion that is dependent on the job requirements of the employee and functions of the agency.
- **Child Care Subsidy Program and Daycare Centers:** HHS provides a child care subsidy tuition program for employees with dependent children (ages birth through 12 or under 18 if disabled). The program is operated on a first-come, first-served basis and covers employees nationwide and in overseas locations. Child care may be full-time or part-time care; center-based or home-based; and includes before and after school programs and daytime summer programs for school-aged children. The child care provider must be licensed and/or regulated by state and/or local authorities.³ Some of the agencies also provide access to on-site or near-site child care centers for employees, as well as child care referral services.
- **Employee Assistance Program:** Through Federal Occupational Health (FOH) and other contract providers, HHS provides access to comprehensive, integrated, and personalized information and referrals through the Employee Assistance Program (EAP). The services are free and confidential. EAP provides professional, confidential counseling and referral services for employees and their dependents who may be experiencing personal problems that may be affecting their quality of life or their ability to perform on the job. The program offers assessments, referrals, short-term counseling, and follow-up for employees experiencing family and marital problems, substance abuse, stress, depression, and any other emotional and life challenges. Services are generally available 24 hours a day/7 days a week.⁴ An additional component of EAP is the Work/Life Program, which helps HHS employees, and family members better manage daily responsibilities and life events, such as parenting, caregiving, prenatal care, education, retirement planning, financial and legal concerns, and professional work/life consultation.

³ Office of Human Resources, WorkLife Programs, HHS Intranet <http://intranet/ohr/worklife/index.html>.

⁴ Office of Human Resources, WorkLife Programs, HHS Intranet, <http://intranet/ohr/worklife/index.html>.

- **Lactation Support:** Certain HHS agencies offer a lactation support program, providing mothers and mothers-to-be with counseling and participation in breast-feeding classes and discussion groups. Many of the agencies have lactation rooms available. Such support reflects the agencies' commitment to increasing breastfeeding rates in the U.S. to improve public health.^{5,6}
- **Telecommuting/Teleworking:** HHS agencies offer telecommuting to employees to work part of the time at a location other than their official duty station (e.g., their home). Implementation of telecommuting is a matter of management and supervisory discretion that is dependent on the job requirements of the employee and functions of the agency.
- **Clinical Services:** Federal Occupational Health's Clinical Services Division delivers Clinical, Wellness/Fitness, Health Promotion, Smoking Cessation, Law Enforcement, Medical Surveillance, Medical Employability and Automated External Defibrillator (AED) Program Services to over half a million Federal employees. FOH has provided clinical services to many of HHS's agencies since its inception in 1946. Clinical Health Center Services include mammograms, cervical cancer screening, lactation program, osteoporosis screening, immunizations, health screenings (e.g., blood pressure, diabetes, cholesterol, vision, hearing, tuberculosis, glaucoma), and educational lectures.
- **Wellness-Fitness Services:** Federal Occupational Health (FOH) and many of the HHS agencies offer wellness and fitness services to HHS employees throughout the Department. FOH has provided onsite wellness/fitness centers, fitness education, fitness assessments, and personal training at various HHS agencies since the 1980s. Many HHS agencies have also assumed leadership in promoting health and wellness among their employees through programs such as yoga, health fairs, nutrition education, and health education resources via the intranet.

Relevant Statistics

HHS employee participation in the many WorkLife Programs varies by agency. Included in the Appendix of this report is a chart summarizing the WorkLife Programs in each agency, as well as relevant statistics.

⁵ Centers for Disease Control and Prevention, www.cdc.gov/breastfeeding/index.htm.

⁶ Office of Disease Prevention and Health Promotion, Healthy People 2010, www.healthypeople.gov/default.htm.

Evaluation/Feedback Mechanism

Every year HHS employees have an opportunity to share their views on their work environment by participating in the HHS Annual Employee Survey Process. In the odd numbered years, the Department offers the HHS Human Capital Survey, and in even numbered years, the Department participates in the Federal Human Capital Survey (FHCS), administered by the Office of Personnel Management (OPM). Each annual cycle provides valuable trend data to give the Department a better understanding of the HHS work environment and guide planning for future improvement initiatives. The Office of the Assistant Secretary for Administration and Management provides leadership in the Department on human resources policy, including work-life balance initiatives. The Department is currently conducting in-depth analysis of the 2008 survey results to determine where improvements have been realized and where action is needed. The next employee survey will be approximately October/November 2009.⁷

Below is a snapshot of HHS results from the 2008 Federal Human Capital Survey administered by the Office of Personnel Management in August and September 2008. The survey includes questions that assess employee satisfaction with work-life programs. Almost 40% (39.2%) of all HHS employees completed the survey; with all HHS agencies having participation rates of 33.3% or higher. 65% of the survey respondents were female employees.

⁷ Office of Human Resources, Federal Human Capital Survey (FHCS) – 2008, HHS Intranet <http://intranet/ohr/fhcs/2008.html>.

**2008 Federal Human Capital Survey
HHS Overall (FHCS & Assessor Results)
Surveys Returned: 26,121**

Demographics			
D-1. Where do you work?		D-7. What is your pay category/grade?	
Headquarters	51%	Federal Wage System	2%
Field	49%	GS 1-6	8%
		GS 7-12	35%
D-2. What is your supervisory status?		GS 13-15	44%
Non-Supervisor	64%	Senior Executive Service	1%
Team Leader	16%	Senior Level (SL) or Scientific or Professional (ST)	1%
Supervisor	13%	Commissioned Corps	6%
Manager	6%	Administratively Determined Rates	1%
Executive	2%	Other	3%
D-3. Are you:		D-8. How long have you been with the Federal Government (excluding military service)?	
Male	35%	Less than 1 year	2%
Female	65%	1 to 3 years	12%
D-4. Are you Hispanic or Latino?		4 to 5 years	9%
Yes	5%	6 to 10 years	21%
No	95%	11 to 14 years	9%
D-5. Please select the racial category or categories with which you most closely identify.		15 to 20 years	18%
American Indian or Alaska Native	16%	More than 20 years	30%
Asian	7%	D-9. How long have you been with your current agency?	
Black or African-American	17%	Less than 1 year	3%
Native Hawaiian or Other Pacific Islander	0%	1 to 3 years	17%
White	57%	4 to 5 years	11%
Two or more races (Not Hispanic or Latino)	3%	6 to 10 years	24%
D-6. What is your age group?		11 to 20 years	26%
25 and under	1%	More than 20 years	19%
26-29	3%	D-10. Are you considering leaving your organization within the next year, and if so, why?	
30-39	19%	No	68%
40-49	30%	Yes, to retire	5%
50-59	35%	Yes, to take another job in the Federal Government	19%
60 or older	12%	Yes, to take another job outside the Fed. Government	4%
		Yes, other	5%
		D-11. I am planning to retire:	
		Within one year	3%
		Between one and three years	9%
		Between three and five years	11%
		Five or more years	77%

**2008 Federal Human Capital Survey
HHS Overall (FHCS & Assessor Results)
Surveys Returned: 26,121**

This is a summary-by-question of your organization's responses to the 2008 Federal Human Capital Survey. This summary displays results by Positive, Neutral, Negative, and where applicable, Do Not Know or No Basis to Judge responses. As shown below, for each response scale two responses are categorized as "Positive," one response is categorized as "Neutral," and two are categorized as "Negative."

Positive Responses		Neutral Responses	Negative Responses		Do Not Know/No Basis to Judge
<i>Strongly Agree</i>	<i>Agree</i>	<i>Neither Agree nor Disagree</i>	<i>Disagree</i>	<i>Strongly Disagree</i>	
<i>Strongly Agree</i>	<i>Agree</i>	<i>Neither Agree nor Disagree</i>	<i>Disagree</i>	<i>Strongly Disagree</i>	<i>Do Not Know</i>
<i>Very Satisfied</i>	<i>Satisfied</i>	<i>Neither Satisfied nor Dissatisfied</i>	<i>Dissatisfied</i>	<i>Very Dissatisfied</i>	
<i>Very Satisfied</i>	<i>Satisfied</i>	<i>Neither Satisfied nor Dissatisfied</i>	<i>Dissatisfied</i>	<i>Very Dissatisfied</i>	<i>No Basis to Judge</i>
<i>Very Good</i>	<i>Good</i>	<i>Fair</i>	<i>Poor</i>	<i>Very Poor</i>	

69. How satisfied are you with paid vacation time?

	<i>Positive</i>	<i>Neutral</i>	<i>Negative</i>
Governmentwide (official FHCS weighted)	87.7%	7.7%	4.7%
Health and Human Services (official FHCS weighted)	84.4%	9.9%	5.7%
Health and Human Services (unofficial ASB unweighted)	84.7%	9.4%	5.9%

70. How satisfied are you with paid leave for illness (for example, personal), including family care situations (for example, childbirth/adoption or eldercare)?

	<i>Positive</i>	<i>Neutral</i>	<i>Negative</i>
Governmentwide (official FHCS weighted)	84.3%	9.4%	6.3%
Health and Human Services (official FHCS weighted)	82.0%	10.5%	7.5%
Health and Human Services (unofficial ASB unweighted)	81.7%	10.6%	7.7%

71. How satisfied are you with child care subsidies?

	<i>Positive</i>	<i>Neutral</i>	<i>Negative</i>	<i>DNK/NBJ</i>
Governmentwide (official FHCS weighted)	9.1%	23.0%	4.2%	63.7%
Health and Human Services (official FHCS weighted)	9.4%	21.0%	4.8%	64.8%
Health and Human Services (unofficial ASB unweighted)	8.8%	20.2%	4.8%	66.2%

72. How satisfied are you with work/life programs (for example, health and wellness, employee assistance, eldercare, and support groups)?

	<i>Positive</i>	<i>Neutral</i>	<i>Negative</i>	<i>DNK/NBJ</i>
Governmentwide (official FHCS weighted)	28.5%	24.4%	7.4%	39.7%
Health and Human Services (official FHCS weighted)	33.4%	23.3%	6.9%	36.3%
Health and Human Services (unofficial ASB unweighted)	32.6%	22.8%	7.1%	37.6%

73. How satisfied are you with telework/telecommuting?

	<i>Positive</i>	<i>Neutral</i>	<i>Negative</i>	<i>DNK/NBJ</i>
Governmentwide (official FHCS weighted)	22.6%	20.3%	13.7%	43.3%
Health and Human Services (official FHCS weighted)	36.1%	18.5%	16.0%	29.4%
Health and Human Services (unofficial ASB unweighted)	35.4%	17.8%	16.2%	30.6%

74. How satisfied are you with alternative work schedules?

	<i>Positive</i>	<i>Neutral</i>	<i>Negative</i>	<i>DNK/NBJ</i>
Governmentwide (official FHCS weighted)	46.9%	17.0%	12.7%	23.4%
Health and Human Services (official FHCS weighted)	51.8%	15.3%	11.1%	21.8%
Health and Human Services (unofficial ASB unweighted)	51.0%	14.7%	11.6%	22.7%

Note: The official FHCS weighted data refers to only the HHS Full-Time employee population; whereas the unofficial ASB (Assessment Services Branch/OPM) data refers to the All Employee population including Full Time, Part Time, Title 42, and Commissioned Corps employees.

C. Programs That Improve the Lives of America's Women and Girls

Through the Office of the Secretary and 11 agencies, HHS sponsors hundreds of programs that cover a wide spectrum of activities that improve the lives of America's women and girls. In FY 2009, HHS allocated greater than \$100 billion to women's health-related programs and initiatives throughout the Department.

Reflecting the unique missions of each of the HHS agencies, program highlights include:

- Health and social science research
- Disease prevention
- Food and drug safety
- Health insurance for elderly and disabled Americans, as well as low-income individuals, through Medicare and Medicaid
- Health information technology
- Financial assistance and services for low-income families
- Maternal and child health
- Pre-school education and services
- Child abuse and domestic violence prevention
- Substance abuse prevention and treatment
- Services for older Americans
- Comprehensive health services for Native Americans
- Faith-based and community initiatives
- Medical preparedness for emergencies

In the Appendix of this report are detailed summaries of each of the HHS agencies' programs addressing 1) education and/or careers in science, 2) financial literacy, 3) work-life balance, and 4) health and human services. The following information is a broad overview of the Department's approach to these four topic areas.

Program Descriptions:

Education and/or Careers in Science

HHS provides numerous educational and career development opportunities that promote the academic achievement and career advancement of women and girls. Many of these opportunities serve to enhance exposure to possible careers in science, the health professions, public health, and research, as well as afford mentorship opportunities to ensure retention and success in these fields.

HHS University sponsors programs that recruit individuals outside of the federal government to participate in internship or fellowship opportunities. It also fosters the career development of HHS employees by offering Department-wide programs that focus on topics including:

- General leadership and management training
- Mentoring programs tailored to specific levels of General Schedule employees and the Senior Executive Service

- Supervisory and managerial skills training tailored to years of experience (e.g., first-line supervisors vs. mid-level managers)

Furthermore, HHS agencies sponsor many intramural and extramural programs that address education and careers in science. The array of programs targets populations throughout the educational and career pipeline of pre-school students through career professionals. Examples include:

- Internships or fellowships in research, public health, policy, and clinical fields
- School readiness and academic achievement programs
- Career development awards in biomedical and public health fields
- Mentoring programs
- Teacher instruction in math and science

Financial Literacy

The Department sponsors programs that enhance the financial literacy of women and girls. Internally HHS hosts financial and retirement planning seminars and provides relevant resources to its employees. Externally the Department targets financial literacy and economic stability programming towards specific populations, of which women represent an important component such as:

- Low-income and disadvantaged individuals/families
- Older individuals, with specific programs for older women
- Racial and ethnic minority communities
- Women-owned small businesses

Work-Life Balance

Paralleling the Department's initiatives to improve the work-life balance of its employees, HHS agencies also promote programs addressing work-life balance among America's women.

Examples include:

- Caregiver support programs
- Lactation resources for working mothers
- Lactation program toolkits for businesses who employ women of childbearing age

Health and Human Services

As the government's principal agency for protecting the health of all Americans and providing essential human services, HHS sponsors hundreds of programs through its agencies and offices, including programs addressing specific diseases and health conditions and those that focus on cross-cutting needs for women and girls.

Disease-specific programs encompass areas such as breast and gynecologic cancer, cardiovascular disease, diabetes, obesity, sexually transmitted infections (including HIV/AIDS), lupus, osteoporosis, substance abuse, and behavioral health. The breadth of cross-cutting programs includes adolescent health, aging, data collection, health information, health promotion and disease prevention, minority health, and violence prevention.

HHS also conducts health policy analysis on a vast range of topics, including disease-specific issues and access to care and health care coverage, caregiving, disability, global health, human trafficking, reproductive health, and rural health. Recently, in May 2009, the Department released the report *Roadblocks to Health Care: Why the Current Health Care System Does Not Work for Women* that highlighted the many challenges that women face in our current health care system.

a. Relevant Statistics

Included in the Appendix of this report are detailed summaries of each of the HHS agencies' programs that include relevant statistics for the programs where applicable.

b. Evaluation/Feedback Mechanism

Included in the Appendix of this report are detailed summaries of each of the HHS agencies' programs that include evaluation/feedback mechanisms for the programs where applicable.

D. Overarching Recommendations

HHS is the government's principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves. The Department recognizes the awesome role that it plays in improving the lives of women and girls, through education and career development, financial literacy, work-life balance, health and wellness, research, and advocacy. Although HHS has made great strides in its over 20 year history of being a leader in women's health, it is committed to expanding and accelerating related efforts in this Administration. In developing next steps, HHS will benefit from the experience and expertise of its own health officials as well as input and guidance from external stakeholder groups.

The HHS Coordinating Committee on Women's Health has already begun the process of developing a strategic blueprint to address women and girls' health. In July 2009, the Committee hosted a *Summit for Action: The Health of Women and Girls Beyond 2010*. This Summit represented phase III of a year-long initiative to develop a new women's health agenda. Phase I and II consisted of data-gathering from expert interviews, web-based discussions and review/synthesis of women's health literature. In this last phase III, the Committee invited approximately 100 thought leaders to participate in a series of working sessions over the 2-day conference. The Committee will use the gathered information from each phase to develop recommendations for a "comprehensive, compelling, and forward-driven action agenda" to improve the health of women and girls. The findings and recommendations from the Summit will help to inform departmental strategy in the current Administration.

The HHS agenda will focus on a number of health programs and policies, some of which may be disease-specific and others that are cross-cutting in nature. With regards to the latter, health disparities will certainly be one area of focus. A compelling body of evidence has demonstrated significant health disparities among women of different socioeconomic status, race/ethnicity, age, disability, and geographic location. In efforts to advance and promote women and girls'

health, HHS must incorporate the needs of those subpopulations that are disproportionately affected or disadvantaged, and design targeted mechanisms to reduce and eventually eliminate those disparities.

In addition to the focus on disparities, HHS will also deliberate on a more comprehensive definition of women's health that captures the totality of health concerns and needs among women across the lifespan. The traditional scope of women's health has been limited to reproductive and sexual health concerns, neglecting important causes of morbidity and mortality that significantly impact women (e.g., cardiovascular disease) and may affect them disproportionately more so than men. Related, HHS will also ensure that all of its women's health initiatives reflect the best science and sound policy, reflecting a broader Administrative directive.

More immediately, HHS is mindful of the implications and the impact of health reform on women's health. In May 2009, HHS Secretary Kathleen Sebelius released the report *Roadblocks to Health Care: Why the Current Health Care System Does Not Work For Women*. The report highlighted the following: 1) women are more vulnerable to high health care costs than men; 2) the current health insurance framework leaves too many women uncovered; and 3) higher costs and inadequate benefits make the individual insurance market an unreliable choice for women. As we move forward with health reform, the Department will strive to reduce and ultimately eradicate the many barriers that women face in the current health care system. Strengthening primary care will be particularly important for enhancing women and girls' health through prevention and wellness.

Finally, as noted by the Council, even as HHS focuses on a health agenda for women and girls at large, it must serve as a "role model employer" for its own female employees. Working women continue to represent a growing proportion of the workforce, and achieving the right balance of career and family is often difficult. In addition to supporting and expanding existing work-life programs, HHS will conduct further study of challenges posed by potential conflict in work-life balance to identify and implement innovative strategies for the future.

Across each of these areas, HHS will aggressively seek opportunities for greater collaboration and coordination within its own agencies, across federal Departments and with external partners. Continued leadership and support from the White House Council on Women and Girls will be critical to the success of this effort.

APPENDIX

**U.S. Department of Health and Human Services Report
White House Council on Women and Girls**

November 2009

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Department of Health and Human Services
Coordinating Committee on Women's Health
The CCWH Profile

Background:

The Department of Health and Human Services Coordinating Committee on Women's Health (CCWH) was established in 1983 to safeguard and improve the health and well-being of all women in the United States. The CCWH works strategically to improve awareness, increase collaboration, advance evidence-based programs and policies, support sex and gender-specific initiatives and address gaps and disparities in women's health.

The CCWH is chaired by Dr. Wanda K. Jones, the Deputy Assistant Secretary for Health (Women's Health) and is comprised of senior-level representatives from each of the Federal agencies and offices within the Department. The CCWH representatives foster critical linkages among research, education, training, prevention, safety, and care and service systems to improve the health status of women and girls.

Vision: All women and girls lead safe and healthy lives.

Mission: Provide Department-wide leadership to address the health, safety and quality of life for women and girls.

Objectives:

- Recommend and provide guidance on women's health policy, programming and evaluation efforts;
- Collaborate and coordinate initiatives with Federal and non-Federal partners;
- Identify and develop a coordinated response to emerging issues that affect women and girls' health and well-being; and
- Deliver science-based and culturally competent health information and resources.

Select CCWH Accomplishments:

- Beyond 2010 Women's Health Summit and Action Agenda
- *The Healthy Woman – A Complete Guide for All Ages*
- Minority Women's Health Summits
- National Women's Health Week
- Town Hall Meetings and Congressional Briefings
- Women's Health Time Capsule and *A Century of Women's Health 1900-2000*

**U.S. Department of Health and Human Services
Coordinating Committee on Women's Health**

Office of the Secretary (OS)

Office on Disability (OD)

Office of the Assistant Secretary for Resources and Technology (ASRT)

Office of the Assistant Secretary for Planning and Evaluation (ASPE)

Office of Global Health Affairs (OGHA)

Office of Public Health and Science (OPHS)

Office on Women's Health (OWH)

Office of Disease Prevention and Health Promotion (ODPHP)

Office of HIV/AIDS Policy (OHAP)

Office of Intergovernmental Affairs (OIA)

Office of Minority Health (OMH)

Office of Population Affairs (OPA)

President's Council on Physical Fitness and Sports (PCPFS)

Regional Offices (Regions 1 – 10)

Administration on Aging (AoA)

Center for Program Operations

Administration on Children and Families (ACF)

Office of Planning, Research and Evaluation

Agency for Healthcare Research and Quality (AHRQ)

Office of the Director; Women's Health and Gender Research

Centers for Disease Control and Prevention (CDC)

Office of Women's Health

Centers for Medicaid and Medicare Services (CMS)

Office of External Affairs and Center for Medicaid and State Operations

Food and Drug Administration (FDA)

Office of Women's Health

Health Resources and Services Administration (HRSA)

Office of Women's Health

Indian Health Service (IHS)

Office of Clinical and Preventive Services

National Institutes of Health (NIH)

Office of Research on Women's Health (ORWH)

Substance Abuse and Mental Health Services Administration (SAMHSA)

Office of Policy Planning and Budget

HHS Health Policy Topics

Access to Care
 Cancer/Breast Cancer
 Cardiovascular Health
 Care Giving
 Data Analysis by Gender
 Diabetes
 Disability
 Domestic Violence/Violence Against Women
 Female Genital Mutilation/Cutting
 Girls in Sports
 Global Health
 Health Insurance
 Health Literacy
 Health Professions/ Interdisciplinary Training
 Healthy Marriage
 HIV/AIDS
 HPV Vaccination
 (Human Papilloma virus)
 Human Trafficking
 Inclusion in Research
 Lupus
 Medicaid
 Medicare
 Mental Health
 Obesity
 Physical Activity
 Plan B Contraception
 Preconception Care
 Prevention
 Rural Health
 SCHIP/CHIPRA
 (State Children's Health Insurance Program/Children's Health
 Insurance Program Reauthorization Act)

 Substance Abuse
 Tobacco/Smoking

Agency/Office

CMS, AHRQ, HRSA
 CDC, CMS, AHRQ, OPHS
 CDC, NIH, OPHS, AHRQ, HRSA
 AoA
 AHRQ, HRSA, NIH, CDC
 CDC, NIH, FDA, OPHS, ASPE, IHS
 ACF, OD, OSG, ACF
 CDC, OPHS, ACF, IHS, HRSA, AHRQ
 OPHS
 OPHS, CDC
 OPHS, CDC, ASPE, OGHA
 CMS, AHRQ
 OPHS, HRSA, CDC
 NIH, HRSA, OPHS
 ACF, ASPE, HRSA
 HRSA, CDC, OPHS

 CDC, FDA, OPA

 ACF, OPHS
 NIH, CDC, FDA
 NIH, OPHS, HRSA, CDC
 CMS, ASPE
 CMS
 SAMHSA, OSG, OPHS, HRSA
 CDC, OPHS, NIH, OSG, HRSA
 OPHS, CDC, HRSA
 FDA
 ACF, CDC, OPHS, HRSA
 ACF, CDC, HRSA, OPHS, OSG
 OPHS, HRSA

 CMS

 SAMHSA
 CDC, FDA, HRSA, OSG

ACF = Administration for Children & Families
 AoA = Administration on Aging
 AHRQ = Agency for Healthcare Research & Quality
 ASPE = Asst Secretary for Planning and Evaluation
 CDC = Centers for Disease Control and Prevention
 CMS = Centers for Medicare & Medicaid Services
 FDA = Food and Drug Administration
 HRSA = Health Resources and Services Administration

IHS = Indian Health Service
 NIH = National Institutes of Health
 OD = Office on Disability
 OGHA = Office of Global Health Affairs
 OPA = Office of Population Affairs
 OPHS = Office of Public Health and Science
 OSG = Office of the Surgeon General
 SAMHSA = Substance Abuse and Mental Health Services Administration

WOMEN'S HEALTH

Program Level
(Dollars in Millions)

	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
Food and Drug Administration					
Cancer	22.7	24.3	34.1	40.6	41.7
Breast Cancer (non-add)	21.4	10.9	19.3	24.5	24.6
Cross-cutting Categories	4.6	10.1	5.3	6.0	6.1
Office of Women's Health (non-add)	4.1	4.0	5.3	6.0	6.0
Total, FDA	27.3	34.4	39.4	46.6	47.8
Health Resources and Services Administration					
Reproductive Health (MCH Block Grant/Healthy Start)	317.4	330.2	319.6	320.9	320.9
Pregnancy/Prevention/Maternal Health (non-add)	317.4	330.2	319.6	320.9	320.9
Infectious Diseases	36.6	35.9	36.8	38.4	38.4
AIDS/HIV (non-add) - Ryan White Title IV	36.6	35.9	36.8	38.4	38.4
Cross-cutting Categories	1,447.4	1,547.0	1,568.3	1,627.0	1,660.6
Treatment & Prevention Services (non-add)	1,363.0	1,487.4	1,505.2	1,559.7	1,591.1
Education/Training for Health Care Providers (non-add)	84.0	59.3	62.8	67.0	69.2
Office on Women's Health (non-add)	0.4	0.3	0.3	0.3	0.3
Total, HRSA	1,801.3	1,913.1	1,924.7	1,986.3	2,019.9
Indian Health Service					
Cancer	15.9	17.0	17.7	17.3	17.6
Breast Cancer (non-add)	14.4	15.6	16.2	15.9	16.2
Colorectal Cancer (non-add)	1.4	1.4	1.4	1.4	1.4
Reproductive Health	134.4	139.8	145.6	151.7	158.1
Pregnancy/Prevention/Maternal Health (non-add)	134.1	139.5	145.4	151.5	157.8
Other (non-add)	0.3	0.3	0.3	0.3	0.3
Substance Abuse	2.0	2.0	2.0	2.0	2.0
Alcohol (non-add)	2.0	2.0	2.0	2.0	2.0
Cross-cutting Categories	0.8	0.8	0.8	0.8	0.8
Office of Women's Health (non-add)	0.8	0.8	0.8	0.8	0.8
Total, IHS	153.1	159.6	166.1	171.8	178.5

WOMEN'S HEALTH

Program Level
(Dollars in Millions)

	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
Centers for Disease Control and Prevention					
Cancer	251.3	234.3	240.8	259.0	258.9
Breast Cancer (non-add)	121.4	112.2	113.0	116.0	115.9
Reproductive Cancers (non-add)	86.6	79.5	85.6	88.0	88.0
Other: lung/colorectal/other neoplasms (non-add)	43.4	42.6	42.3	55.0	55.1
Cardiovascular/Pulmonary	30.0	28.7	32.2	34.2	34.2
Reproductive Health	41.5	41.0	46.0	46.0	51.2
Pregnancy/Prevention/Maternal Health) (non-add)	40.6	40.2	46.0	45.0	51.0
Aging	0.8	0.8	0.8	0.8	0.8
Metabolism/Endocrinology	81.7	78.5	80.1	83.1	83.3
Diabetes (non-add)	38.7	38.1	35.5	36.7	36.8
Obesity/Nutrition (non-add)	30.2	27.6	26.0	26.4	26.5
Other: WISEWOMAN (non-add)	13.0	12.9	18.6	20.0	20.0
Substance Abuse	65.8	64.5	54.0	55.0	55.0
Behavioral Studies/Programs	77.0	73.9	74.4	84.0	84.0
Violence (non-add)	77.0	73.9	74.4	84.0	84.0
Mental Health	1.0	0.9	0.6	0.6	0.6
Infectious Diseases	249.4	246.0	249.0	249.0	249.0
AIDS/HIV (non-add)	105.8	113.8	121.0	121.0	121.4
Immune Disorders	7.2	7.1	8.3	8.7	8.7
Neurologic, Muscular & Bone	6.6	6.3	6.2	6.1	6.1
Ophthalmic, Otolaryngologic, & Oral	8.5	8.4	9.1	9.9	9.9
Health Effects of the Environment	4.0	4.1	3.7	3.7	4.5
Cross-cutting Categories	217.9	212.0	208.6	211.7	217.0
Health Statistics & Data Collection	58.9	57.9	57.0	56.8	57.0
Office on Women's Health	0.4	0.4	0.4	0.4	0.4
Global Health	158.6	153.7	151.2	154.4	159.6
Total, CDC	1,042.7	1,006.6	1,013.8	1,051.8	1,063.2

WOMEN'S HEALTH

Program Level
(Dollars in Millions)

	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
National Institutes of Health 47/					
Cancer	972.0	1,002.2	972.9	1,001.2	1,028.6
Breast Cancer (non-add)	656.0	684.3	656.1	676.4	695.2
Cardiovascular/Pulmonary	411.0	439.8	410.5	419.3	424.2
Reproductive Health	355.0	367.1	354.6	368.1	371.3
Pregnancy/Prevention/Maternal Health) (non-add)	176.0	183.3	176.5	212.4	214.9
Aging	292.0	294.6	292.4	299.2	302.1
Metabolism/Endocrinology	243.0	270.6	243.4	243.8	242.1
Diabetes (non-add)	82.3	66.6	66.2	65.9	62.2
Obesity (non-add)	150.3	184.1	183.3	183.2	163.4
Substance Abuse	275.0	192.8	274.9	282.1	285.5
Behavioral Studies/Programs	25.0	24.0	24.7	28.3	25.9
Violence (non-add)	7.0	7.6	7.2	7.4	7.5
Mental Health	101.0	78.7	100.6	101.3	105.5
Autism (non-add)	2.8	6.8	6.8	6.8	6.8
Infectious Diseases	307.0	368.3	307.2	314.1	318.2
AIDS/HIV (non-add)	146.0	226.7	146.1	143.6	159.0
Immune Disorders	136.0	127.0	135.7	137.6	138.9
Neurologic, Muscular & Bone	219.0	120.6	219.2	224.5	226.4
Kidney and Urologic	36.0	50.9	35.6	35.7	35.6
Ophthalmic, Otolaryngologic, & Oral	28.0	48.5	27.9	28.7	29.1
Health Effects of the Environment	3.0	9.2	2.5	2.7	2.7
Cross-cutting Categories	55.0	91.0	112.2	140.3	146.5
Total, NIH 48/	3,458.0	3,485.3	3,514.5	3,626.9	3,682.6

WOMEN'S HEALTH

Program Level
(Dollars in Millions)

	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
Substance Abuse and Mental Health Services Administration					
Substance Abuse	483.2	473.5	483.4	499.3	519.5
Prevention (non-add)	101.3	101.4	102.0	105.4	104.0
Treatment (non-add)	381.9	372.2	381.4	393.9	415.5
Behavioral Studies/Programs	0.7	0.7	-	-	-
Violence (non-add)	0.7	0.7	-	-	-
Mental Health	64.7	64.8	90.2	108.2	103.9
Prevention (non-add)	15.8	18.1	24.6	23.5	23.5
Treatment (non-add)	48.9	46.7	65.5	84.6	80.3
Total, SAMHSA	548.6	539.0	573.6	607.5	623.4
Agency for Healthcare Research and Quality					
Cancer	0.3	0.7	1.1	0.7	0.6
Breast Cancer (non-add)	0.1	0.5	0.9	0.6	0.6
Cardiovascular/Pulmonary	0.2	0.0	0.2	-	-
Heart Disease (non-add)	0.2	0.0	0.2	-	-
Reproductive Health	0.6	0.1	-	-	-
Hysterectomy (non-add)	0.5	-	-	-	-
Pregnancy/Prevention/Maternal Health (non-add)	0.1	0.1	-	-	-
Metabolism/Endocrinology	0.6	0.4	-	-	-
Diabetes (non-add)	0.6	0.4	-	-	-
Behavioral Studies/Programs	0.4	0.4	-	-	-
Violence (non-add)	0.1	0.1	-	-	-
Tobacco use cessation (non-add)	0.3	0.3	-	-	-
Mental Health (Depression/mood disorders)	0.9	0.6	0.4	0.4	-
Neurologic, Muscular & Bone	0.0	0.2	-	-	-
Kidney and Urologic	-	-	-	-	-
Cross-cutting Categories	46.4	47.7	48.6	49.2	49.7
Total, AHRQ	49.4	50.2	50.3	50.3	50.3

WOMEN'S HEALTH

Program Level
(Dollars in Millions)

	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
Centers for Medicare & Medicaid Services					
Cancer	11,924.0	12,801.0	13,605.0	14,560.0	15,473.0
Breast Cancer (non-add) 49/	700.0	750.0	850.0	940.0	1,010.0
Cardiovascular/Pulmonary	37,674.0	40,444.0	42,985.0	46,002.0	48,885.0
Aging	9,123.0	9,793.0	10,408.0	11,139.0	11,837.0
Metabolism/Endocrinology	4,445.0	4,771.0	5,071.0	5,427.0	5,767.0
Diabetes (non-add) 50/	3,927.0	4,215.0	4,480.0	4,795.0	5,095.0
Liver Disease (non-add)	518.0	556.0	591.0	632.0	672.0
Mental Health (Depression) 51/	3,781.0	3,848.0	3,679.0	3,881.0	4,150.0
Infectious Diseases (Septicemia)	2,792.0	2,997.0	3,186.0	3,409.0	3,623.0
Kidney and Urologic 52/	6,738.0	7,233.0	7,688.0	8,227.0	8,743.0
Total, CMS	76,477.0	81,887.0	86,622.0	92,645.0	98,478.0
Administration for Children and Families					
Reproductive Health	75.3	73.8	68.4	66.1	80.0
Pregnancy/Prevention/Maternal Health (non-add) 53/	75.3	73.8	68.4	66.1	80.0
Substance Abuse (Prevention, Treatment) 54/	-	-	-	-	-
Behavioral Studies/Programs	127.6	127.7	125.5	131.0	131.0
Violence (non-add) 55/	127.6	127.7	125.5	131.0	131.0
Cross-cutting Categories	0.0	3.0	7.0	7.2	7.2
Homelessness (non-add) 56/	0.0	3.0	7.0	7.2	7.2
Total, ACF	202.9	204.5	200.9	204.3	218.2

WOMEN'S HEALTH

Program Level
(Dollars in Millions)

	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
Administration on Aging					
Aging	7.5	7.5	7.3	7.3	7.3
Alzheimer's (non-add)	7.5	7.5	7.3	7.3	7.3
Metabolism/Endocrinology	532.3	546.7	562.9	599.4	599.4
American Recovery and Reinvestment Act (non-add)				69.8	
Behavioral Studies/Programs	137.8	137.9	136.2	137.4	137.4
Violence (non-add)	15.2	15.2	15.5	16.1	16.1
Caregiving (non-add)	121.7	121.8	119.8	120.5	120.5
Total, AoA	677.5	692.0	706.5	744.2	744.1
Office of the Secretary/Office of Public Health & Science					
Cancer	0.1	0.2	0.1	0.1	0.1
Cardiovascular/Pulmonary	1.1	-	-	-	-
Reproductive Health	31.7	0.5	0.1	0.5	0.6
Pregnancy/Prevention/Maternal Health (non-add)	30.3	0.0	-	-	-
Metabolism/Endocrinology	0.3	0.0	0.1	0.1	0.1
Diabetes (non-add)	0.1	-	-	-	-
Obesity (non-add)	0.2	0.0	0.1	0.1	0.1
Substance Abuse	0.1	0.0	0.2	0.2	0.2
Behavioral Studies/Programs	2.8	0.1	0.3	1.8	1.8
Violence (non-add)	2.8	0.1	0.3	1.8	1.8
Infectious Diseases	6.7	5.2	5.2	4.7	7.2
AIDS/HIV (non-add)	6.3	5.2	5.2	4.7	7.2
Immune Disorders	0.0	0.0	0.0	0.0	0.0
Cross-cutting Categories	37.5	38.9	38.9	41.5	37.2
Treatment & Prevention Services (non-add)	4.8	5.4	2.8	2.8	2.6
Education/Training for Health Care Providers (non-add)	0.7	0.9	0.9	0.9	0.9
Cultural Influences (non-add)	1.2	1.1	1.1	1.1	0.0
Offices on Women's Health (non-add)	30.7	31.4	34.1	36.7	33.7
Total, OS/OPHS	80.3	44.9	44.7	48.7	47.2

WOMEN'S HEALTH

Program Level
(Dollars in Millions)

	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
Category					
Cancer	13,186.3	14,079.7	14,871.6	15,878.9	16,820.5
Breast Cancer (non-add)	1,513.2	1,573.4	1,655.5	1,773.4	1,862.2
Cardiovascular/Pulmonary	38,116.3	40,912.5	43,428.0	46,455.5	49,343.4
Reproductive Health	955.9	952.6	934.3	953.3	982.1
Pregnancy/Prevention/Maternal Health (non-add)	773.8	767.2	755.8	795.8	824.6
Aging	9,423.3	10,095.9	10,708.5	11,446.3	12,147.2
Metabolism/Endocrinology	5,302.8	5,667.2	5,957.5	6,353.4	6,691.8
Substance Abuse	826.0	732.8	814.5	838.5	862.2
Behavioral Studies	371.4	364.7	361.0	382.5	380.1
Violence (non-add)	230.5	225.3	222.8	240.3	240.3
Mental Health	3,948.6	3,993.0	3,870.8	4,091.5	4,360.0
Infectious Diseases	3,391.6	3,652.4	3,784.3	4,015.1	4,235.8
AIDS/HIV (non-add)	294.7	381.6	309.1	307.7	326.0
Immune Disorders	143.2	134.1	144.0	146.3	147.6
Neurologic, Muscular and Bone	225.6	127.1	225.3	230.6	232.5
Kidney and Urologic	6,774.0	7,283.9	7,723.6	8,262.7	8,778.6
Ophthalmic, Otolaryngologic, and Oral	36.5	56.9	37.0	38.6	39.0
Health Effects of the Environment	7.0	13.3	6.2	6.4	7.2
Cross-cutting Categories	1,809.5	1,950.6	1,989.8	2,083.7	2,125.1
Women's Health Total, HHS	84,518.2	90,016.7	94,856.5	101,183.3	107,153.2

WOMEN'S HEALTH

Program Level
(Dollars in Millions)

	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
Agency					
FDA	27.3	34.4	39.4	46.6	47.8
HRSA	1,801.3	1,913.1	1,924.7	1,986.3	2,019.9
IHS	153.1	159.6	166.1	171.8	178.5
CDC	1,042.7	1,006.6	1,013.8	1,051.8	1,063.2
NIH	3,458.0	3,485.3	3,514.5	3,626.9	3,682.6
SAMHSA	548.6	539.0	573.6	607.5	623.4
AHRQ	49.4	50.2	50.3	50.3	50.3
CMS	76,477.0	81,887.0	86,622.0	92,645.0	98,478.0
ACF	202.9	204.5	200.9	204.3	218.2
AoA	677.5	692.0	706.5	744.2	744.1
OS/OPHS	80.3	44.9	44.7	48.7	47.2
Total, HHS	84,518.2	90,016.7	94,856.5	101,183.3	107,153.2

FY 2010 HHS Cross-cut Endnotes

- 47/ Estimates for NIH are exclusive of overlap and will not agree with funding reported for total NIH spending on individual disease areas.
- 48/ Funding represents sex/gender specific research and does not include many expenditures for women's health that are basic science studies or studies that include both men and women.
- 49/ These amounts reflect estimated Medicare benefit outlays for screening and diagnostic mammograms and the Federal share of Medicaid costs for screening mammograms.
- 50/ Costs for diabetes patients, not directly related to diabetes, are excluded.
- 51/ Mental Health includes Medicare and Federal Medicaid costs.
- 52/ Costs for kidney disease patients, not directly related to kidney disease, are excluded.
- 53/ In the discretionary and mandatory FY 2006 to FY 2009 Abstinence Education programs and FY 2010 Teen Pregnancy Prevention, both female and male youth are included in the target population. Therefore, we assume that half of the funding in these programs supports the number of girls and women receiving program benefits.
- 54/ Promoting Safe and Stable Families did not have a separate priority area for substance abuse women's health. Therefore, we can not assume that half of its funding accommodated women's health; no estimate should have been included in the FY 2009 Moyer Material.
- 55/ Estimates are based on the amount of funding for the National Health Resource Center on Domestic Violence.
- 56/ In FY 2006, the Runaway and Homeless Youth's Transitional Living Program provided services to maternity group homes. There was not a separate priority area for maternity group home services. Therefore, estimates are based on the number of grantees receiving funding for maternity group home services.

ROADBLOCKS TO HEALTH CARE:

Why the Current Health Care System *does not* work for *Women*

Overwhelmed by Health Care Costs

Women are more vulnerable to high health care costs than men.

Women's reproductive health requires more regular contact with health care providers, including yearly pap smears, mammograms, and obstetric care.

Women are also more likely to report fair or poor health than men (9.5% versus 9.0%).¹

While rates of chronic conditions such as diabetes and high blood pressure are similar to men, women are twice as likely to suffer from headaches, more likely to experience joint, back or neck pain.² These chronic conditions often require regular and frequent treatment and follow-up care.

A Patchy System of Health Insurance

The current health insurance framework leaves too many women uncovered.

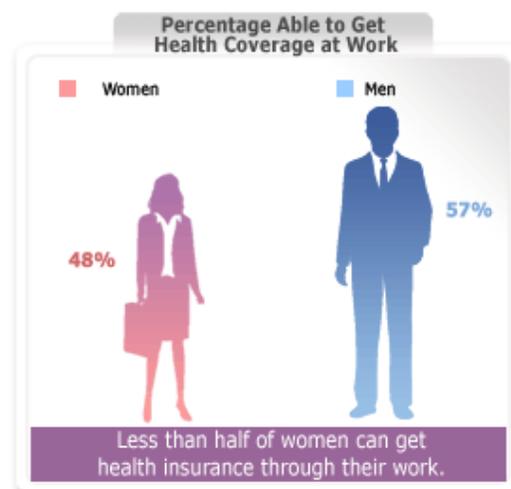
Twenty-one million women and girls went without health insurance in 2007, and another 14 million relied on coverage through the individual insurance market.³

Women are less likely to be employed full-time than men (52% versus 73%), making them less likely to be eligible for employer-based health benefits themselves. In fact, less than half of women have the option of obtaining employer-based coverage on their own.⁴

Even when they work for an employee that offers coverage, one in six is not eligible to take it, often because they are part-time workers. They end up either covered through a spouse (41%), purchasing insurance directly through the individual market (5%), on public programs (10%), or uninsured (38%).⁵

And even among women with the option to get health coverage through their employer, they are twice as likely as men to go on their spouse's plan (15% versus 7%).⁶

This dynamic has several effects. Single women are twice as



Source⁴

likely to be uninsured than married women (24% versus 12%).⁷

Married women in the 55 to 64 age group are particularly vulnerable to a discontinuity of coverage as their spouses go on Medicare. Among this age group, there is a drop in dependent employer-sponsored coverage from 39% to 34%.⁸

When employer-based coverage is not an option, some women turn to the individual insurance market. In the 55 to 64 age group, the decline in employer-based coverage is coupled with a rise in the purchase of individual insurance from 5% to 8%. This trend is not seen with men.⁹

The Failure of the Individual Insurance Market

Higher costs and inadequate benefits make the individual insurance market an unreliable choice for women.

Important state and federal laws that protect individuals with employer-sponsored insurance do not apply to health insurance sold in the individual market. These include anti-discrimination protections in the Civil Rights Act of 1964¹⁰ and the Pregnancy Discrimination Act of 1978,¹¹ as well as the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which prohibits covered employers from charging different premiums or denying coverage based on age or health status.¹²

In contrast, in the individual insurance market, many states allow insurance companies to calculate premiums based on an individual’s characteristics such as existing health problems, age, and gender.¹³

Data from e-health insurance show that there is a wide variation in premiums by state, by plan, and by age and gender of the policyholder. A search for single coverage plans with similar underlying benefits for a nonsmoker living in a large city found premiums that ranged from \$700 to all the way to \$8000.¹⁴

In particular, women are often charged higher premiums than men during their reproductive years. Holding other factors constant, a 22 year old woman can be charged one and a half times the premium of a 22 year old man. This difference largely disappears – and sometimes reverses – by age 64.¹⁵

The high cost of health insurance in the individual market



Source¹⁵

impedes a woman's ability to obtain coverage at a time when she needs it most. Of the 8 million middle-income nonelderly women who do not have employer-sponsored coverage, more than half remain uninsured and only a fifth obtain insurance through the individual market. In comparison, more than one-third of high-income women without employer-sponsored insurance manage to purchase individual coverage – but 43% still go uncovered.¹⁶

Beyond cost, the coverage in the individual market is woefully inadequate. A recent survey by the National Women's Law Center found that the vast majority of individual market health insurance policies did not cover maternity care (a limited number of insurers sell a separate maternity "rider.")¹⁷

Moreover, it is still legal in 9 states for insurers to reject applicants who are survivors of domestic violence.¹⁸

The Price of Access

As a result, women are more likely than men to experience difficulty accessing care.

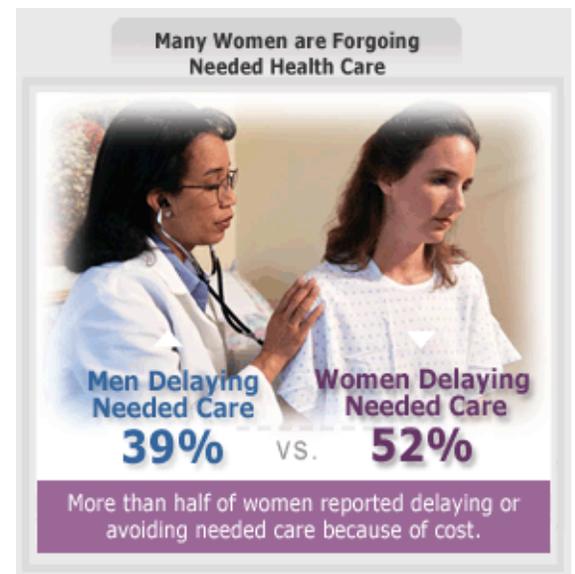
In a recent national survey, more than half of women (52%) reported delaying or avoiding needed care because of cost, compared with 39% of men.¹⁹

Women face a higher financial burden from medical care than men. Nearly one-third of women aged 50 to 64 are in households that have spent more than 10% of their income on health care, compared with one quarter of men of similar age.²⁰

Almost half of women report problems paying medical bills, compared with 36% of men, and one-third of women were forced to make a difficult tradeoff such as using up their savings, taking on debt, or giving up basic necessities.²¹

Comprehensive health care reform is needed to level the playing field, and make health care accessible and affordable for all women.

Sources



Source¹⁹

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Data analysis provided by the Center for Financing, Access and Cost Trends, Agency for Healthcare Research and Quality, and the Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services.

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Summary

HHS Programs That Improve the Lives of the Federal Workforce

ALTERNATIVE WORK SCHEDULES (AWS)

Program Description: An Alternative Work Schedule allows employees to establish their arrival and departure times based on the schedule selected as approved by their supervisor. This arrangement may allow employees to better balance personal and work commitments and schedules. The HHS agencies offer AWS, and employees may establish these schedules in consultation with their supervisors. Implementation of AWS is a matter of management and supervisory discretion that is dependent on the job requirements of the employee and functions of the agency.

Relevant Statistics: Statistics on HHS employee participation in AWS are largely not available, as AWS is not required reporting to the Office of Personnel Management. AWS arrival bands allow employees with children the flexibility of either arriving later or departing earlier from work to coincide with school or daycare schedules. Currently, employees within HHS have the availability to use flexible bands as established by their respective OPDIVs.

Evaluation/Feedback Mechanism: AWS is evaluated across the Department via the HHS Annual Employee Survey process (described Section B 1(a) below).

CHILD CARE SUBSIDY PROGRAM AND DAYCARE CENTERS

Program Description: HHS provides a child care subsidy tuition program for employees with dependent children (ages birth through 12 or under 18 if disabled). The program is operated on a first-come, first-served basis and covers employees nationwide and in overseas locations. Child care may be full-time or part-time care; center-based or home-based; and includes before and after school programs and daytime summer programs for school-aged children. The child care provider must be licensed and/or regulated by state and/or local authorities.¹

Agency	ACF	AoA	AHRQ	ATSDR	CDC
Program Description	No child care subsidy program available	Child care subsidy program available	No child care subsidy program available	No child care subsidy program available	1) Child care center 2) Child care resource and referral service 3) Child care subsidy program available
Relevant Statistics	N/A	No employees are currently enrolled in this program	N/A	N/A	Child care subsidies provided for 69 employees and 93 children
Evaluation/Feedback Mechanism	N/A	First Financial Associates administers program	N/A	N/A	Federal Employee Education and Assistance Fund administers child care subsidy program

¹ Office of Human Resources, WorkLife Programs, HHS Intranet <http://intranet/ohr/worklife/index.html>

CHILD CARE SUBSIDY PROGRAM AND DAYCARE CENTERS, CONT

Agency	CMS	FDA	HRSA	IHS	NIH	SAMHSA
Program Description	1) On-site daycare at Central Office 2) No child care subsidy program available	Child care subsidy program available	Child care subsidy program available	No child care subsidy program available	1) Child care subsidy program available 2) Child care resource and referral services program	Child care subsidy program available
Relevant Statistics	89 employees with children enrolled at daycare center	Approximately 50 employees participating in the child care subsidy program	No employees participated in program in the last year	N/A	1) 104 employees receive child care subsidy (133 children of NIH employees). 95% enrollees are single mothers 2) 450 child care spaces on campus 3) 139 employees served in child care referral service (80% callers female)	
Evaluation/Feedback Mechanism	Office of Operations Management through Director of Division of Operations Management and Administrative Services Group provide program oversight	First Financial Associates administers program	Federal Employee Education and Assistance Fund administers program	N/A	1) Federal Employee Education and Assistance Fund administers child care subsidy 2) Office of Research Services oversees Child Care Resource and Referral Services 3) Proposal to construct additional child care center on Bethesda campus	First Financial Associates administers program

EMPLOYEE ASSISTANCE PROGRAM (EAP)

Program Description: Through Federal Occupational Health (FOH) and other contract providers, HHS provides access to comprehensive, integrated, and personalized information and referrals through the Employee Assistance Program (EAP). The services are free and confidential. EAP provides professional, confidential counseling and referral services for employees and their dependents who may be experiencing personal problems which may be affecting their quality of life or their ability to perform on the job. The program offers assessments, referrals, short-term counseling, and follow-up for employees experiencing family and marital problems, substance abuse, stress, depression, and any other emotional and life challenges. Services are generally available 24 hours a day/7 days a week.²

Program	Employee Assistance Program	WorkLife Program*
Program Description	1) Confidential counseling services (depression, stress management, traumatic events, parenting, work-life balance, domestic violence) 2) Financial and legal services 3) Website: www.FOH4You.com with educational resources	1) Provides information, referrals, and consultation services for employees to better manage work-life balance. Topics: adult care, child care, education, financial and legal concerns, prenatal care and adoption, relocation 2) Available kits: Prenatal Kit, Child Safety Kit, Eldercare Kit, and College Kit. 3) Mothers at Work Program available on website
Relevant Statistics	Oct 2008-Mar 2009: 392 HHS employees used EAP services (70.4% female, 29.6% male)	Same as EAP (column to left)
Evaluation/Feedback Mechanism	Survey Results (Oct 2008-Mar 2009): 1) 86% satisfied with help received on 800# 2) 98% satisfied with feasibility of getting the EAP services needed 3) 98% satisfied with EAP counselor 4) 92% satisfied with how EAP helped solve problem 5) 96% satisfied with overall service received 6) 100% would recommend EAP to other employees Director of EAP Services oversees program.	Same as EAP (column to left)

*FOH WorkLife Program is a component of the Employee Assistance Program.

² Office of Human Resources, WorkLife Programs, HHS Intranet, <http://intranet/ohr/worklife/index.html>

LACTATION SUPPORT

Program Description: Certain HHS agencies offer a lactation support program, providing mothers and mothers-to-be with counseling and participation in breast-feeding classes and discussion groups. Many of the agencies have lactation rooms available. Such support reflects the agencies' commitment to increasing breastfeeding rates in the U.S. to improve public health.^{3,4}

Agency	ACF	AoA	AHRQ	CDC	CMS
Program Description	New lactation room opened January 2009	Lactation support is provided upon request	Lactation room available	Lactation Support Program implemented in 1996 which provides education, support and lactation room, and breast feeding consultation	Lactation rooms available in the Central Office CMS Health Unit
Relevant Statistics	3 employees use the lactation room on a regular basis	No employees currently using this program	N/A	28 lactation rooms at different CDC facilities with over 200 female employees enrolled in the lactation program	Jan 2009 – July 2009: lactation rooms have been used on 2,462 occasions
Evaluation/Feedback Mechanism	Office of Management Resources, Office of the Administration oversees the lactation room. Deputy Assistant Secretary provided leadership in establishing the facility.	Office of Management Analysis and Resources provides leadership		Potential future programs 1) Goal of having a lactation room in every CDC building 2) Create dual-station lactation rooms 3) Promote focused programs for staff in field locations and lower grade positions	Office of Operations Management through Director of Division of Operations Management and Administrative Services Group provide leadership in overseeing the lactation rooms

³ Centers for Disease Control and Prevention, www.cdc.gov/breastfeeding/index.htm

⁴ Office of Disease Prevention and Health Promotion, Healthy People 2010, www.healthypeople.gov/default.htm

LACTATION SUPPORT, CONT

Agency	FDA	HRSA	IHS	NIH	SAMHSA
Program Description	Lactation room available at the Parklawn Building (created approximately 2002)	Lactation room available	Lactation room available since July 2006	Lactation Program 1) Breastfeeding education classes 2) Telephone support while on maternity leave 3) Return-to-work consultations 4) Lactation rooms available at multiple NIH buildings	N/A
Relevant Statistics	No employees are currently participating in lactation program	N/A	N/A	1) 28 lactation rooms available 2) 375 participants to date in FY09	N/A
Evaluation/Feedback Mechanism	Center Director, Assistant Director and Office Manager oversee the lactation program	Program administered by Federal Occupational Health and run through the Health Unit	N/A	Survey feedback: 96% respondents would recommend program to coworker; 97% said program improves work-life balance	Developing plan and identifying resources to create a lactation room

TELECOMMUTING/TELEWORKING

Program Description: Telecommuting allows employees to work part of the time at a location other than their official duty station (e.g., their home).

Agency	ACF	AoA	AHRQ	CDC	CMS
Program Description	Telework started in 1996 in regional offices and 1998 in central office	Telework program available	Telework program is available	Telework available since 1995	Telework program available
Relevant Statistics	1) 339/1257 employees telework (27%) 2) 19 at least 3 days/wk 3) 249 1-2 days/wk 4) 71 at least once/month	1) 15/106 employees telework (14%) 2) 13 1-2 days/wk 3) 2 at least once/month	1) 152/294 employees telework (52%) 2) 110 1-2 days/wk 3) 42 at least once/month 4) Women = 71% of telework participants	1) 1722/9532 employees telework (18%) 2) 146 at least 3 days/wk 3) 1556 1-2 days/wk 4) 20 at least once/month	1) 2742/4387 employees telework (63%) 2) 59 at least 3 days/wk 3) 606 1-2 days/wk 4) 2077 at least once/month
Evaluation/Feedback Mechanism	Office of Management Resources, Office of Administration oversees telework program	Office of Management Analysis and Resources provides leadership		1) Will possibly create a Telework Management Officer position for program administration. 2) May develop agency specific telework training for employees and managers 3) May develop electronic telework registration and tracking system	1) CMS has agency-wide use of laptop computers which may increase participation in telework 2) Director of Office of Operations Management and Office of Information Services oversee telework program

TELECOMMUTING/TELWORKING, CONT.

Agency	FDA	HRSA	IHS	NIH	OS	SAMHSA
Program Description	Telework program available	Telework program available	Telework program available since 1998	Telework program available	Telework program available	Telework program available
Relevant Statistics	1) 2670/9082 employees telework (29%) 2) 110 at least 3 days/wk 3) 1960 1-2 days/wk 4) 600 at least once/month	1) 291/1461 employees telework (20%) 2) 6 at least 3 days/wk 3) 275 1-2 days/wk 4) 10 at least once/month 5) 2008 – 67 male employees, 238 female employees teleworked	1) 73/14,498 employees telework (0.5%) 2) 40 at least 3 days/wk 3) 24 1-2 days/wk 4) 9 at least once/month	1) 3309/16,967 employees telework (20%) 2) 145 at least 3 days/wk 3) 1639 1-2 days/wk 4) 1525 at least once/month	1) 1326/7332 employees telework (18%) 2) 59 at least 3 days/wk 3) 932 1-2 days/wk 4) 335 at least once/month	1) 146/520 employees telework (28%) 2) 1 at least 3 days/wk 3) 45 1-2 days/wk 4) 100 at least once/month
Evaluation/Feedback Mechanism			Low participation due to majority of employees providing direct patient care	Director of Office of Human Resources and Associate Director for Management provide leadership	Deputy Assistant Secretary for Human Resources provides leadership	

CLINICAL SERVICES

Program Description: FOH’s Clinical Services Division and other contract providers deliver Clinical, Wellness/Fitness, Health Promotion, Smoking Cessation, Law Enforcement, Medical Surveillance, Medical Employability and Automated External Defibrillator (AED) Program Services to over half a million Federal employees. FOH has provided clinical services to many of HHS’s agencies since its inception in 1946.

Program	FOH Clinical Services
Program Description	Clinical Health Center Services (sample of services provided): 1) Mammograms 2) Screenings (blood pressure, diabetes, cholesterol, vision, hearing, glaucoma, tuberculosis, cardiac risk profile, colon cancer, cervical cancer) 3) Lactation support services 4) Osteoporosis screening 5) Immunizations 6) HIV education and screening 7) Educational lectures (healthy heart, women’s wellness, men’s wellness, podiatry)
Relevant Statistics	Oct 2008-Mar 2009: FOH provided 19,610 encounters for various clinical encounters for HHS employees. >25% for blood pressure screenings.
Evaluation/Feedback Mechanism	Client satisfaction surveys with clinical services overall above 97% Director of Clinical Services oversees the program

WELLNESS-FITNESS SERVICES

Agency	FOH*	AHRQ	CDC	CMS	NIH	SAMHSA
Program Description	1) On-site fitness centers 2) Group exercise classes 3) Personalized exercise prescriptions 4) Body composition analysis 5) Muscular strength/endurance measurements 6) Cardiovascular and strength training equipment 7) Virtual fitness programs	1) Physical activities (yoga, pilates, dance, wellness center) 2) Weight watchers (nutrition counseling) 3) Wellness Program 4) Wellness Room for employees to relax	1) CDC/ATSDR Women's-Network-Listserv to promote healthy lifestyles among employees 2) 5 fitness facilities 3) Nutrition and weight management seminars 4) Chronic disease management classes	1) Annual Holistic Health Fair 2) Health and Wellness Seminars 6 times/year	1) NIH Yoga Week – 6 free yoga sessions at various locations on NIH campus. 12 presentations on benefits of yoga. 2) NIH Conditioning and Relaxation (CORE) Week – teach employees about different modes of physical activity, techniques for stress management and healthy living	1) PeopleFirst – employee-led, work/life balance and human capital initiative 2) Health and Wellbeing Program – empower employees to improve health through healthy lifestyle 3) Health and Wellness Committee (with Fitness, Nutrition, Wellbeing, Health Literacy, and Safety Subcommittees)
Relevant Statistics	Oct 2008-Mar 2009: Provided wellness services to 1808 HHS employees (1112 female employees and 696 male employees)	Average participation in wellness program is 5 employees/class	>50% employees participate in CDC health promotion offerings	1) >500 employees attend annual Holistic Health Fair 2) Approx 25 employees attend Health and Wellness Seminars	>1300 attendees at Yoga Week. Participation in NIH Fitness Center yoga classes increased by 20%.	1) PeopleFirst – 13 physical fitness activities organized (>125 participants) 2) >20 employees participate SAMHSA team in Marine Corps Marathon
Evaluation/Feedback Mechanism	Satisfaction scores 4.7/5.0. Director of Clinical Services oversees program.	Surveys conducted of Wellness Program	Plans to launch listserv by end of year 2009.	Director of Division of Operations Management, Administrative Services Group provides leadership of program	Plan to expand into NIH Mind-Body Week (Sept 8-11, 2009)	

** Federal Occupational Health (FOH) provides onsite wellness/fitness centers, fitness education, fitness assessments, and personal training at various HHS agencies since the 1980's. FOH provides leadership on Department-wide HHS wellness and fitness services.*

Detailed Summaries of HHS Programs by Agency/Office

**Programs That Improve Lives of Federal Workforce
Programs That Improve Lives America's Women and Girls
Overarching Recommendations**

Federal Occupational Health

A. Executive Summary:

Federal Occupational Health (FOH) is pleased to provide information to the White House Council on Women and Girls. Specifically, FOH will highlight several occupational health programs that improve the lives of the federal workforce that are related to clinical services, such as worksite health clinics and wellness/fitness centers; and the Employee Assistance Program to include Work/Life services.

FOH, a service agency within the Department of Health and Human Services (HHS), provides occupational health and wellness services exclusively to federal employees. FOH was created by Congress in 1946 by an amendment to the Public Health Service Act (42 USC), and is a non-appropriated, fully reimbursable agency. Our mission is to improve the health, safety, and productivity of the federal workforce.

FOH is one of the largest providers of occupational health services to the federal government providing Clinical, Wellness/Fitness, Employee Assistance Program (EAP), Work/Life, and Environmental Health and Safety services to more than 360 departments and agencies; reaching 1.5 million federal employees nationally and internationally. As a federal agency, FOH is uniquely positioned to seamlessly coordinate and deliver multi-faceted programs across the country, including some of the most remote corners of the United States. Our federal workforce is composed of Commissioned Corps officers of the U.S. Public Health Service (USPHS), civil servants and contractors who are primarily direct service providers.

FOH Facts:

- FOH manages and operates over 300 occupational health centers across the country providing clinical services to over a half a million federal employees.
- FOH provides over 250,000 immunizations, 46,000 pre-placement, periodic and medical surveillance exams customized to meet our agencies' needs, and over 2,500 consultations with federal managers on an annual basis.
- FOH manages, equips and/or staffs 40 federal Wellness/Fitness centers nationwide.
- FOH manages one of the largest Employee Assistance Programs (EAPs) in the country with approximately 125 onsite counselors and over 17,000 affiliate counselors located in federal work sites in all 50 states and Puerto Rico.
- FOH provides a wide range of Environmental Health Services from indoor air quality assessments to asbestos and lead monitoring.

B. Programs That Improve the Lives of the Federal Workforce:

FOH will highlight several programs that improve the lives of the HHS Federal workforce from its many occupational health services to include clinical health centers, wellness/fitness centers, Employee Assistance Program, and Work/Life services.

1.1 Program Description - Clinical Services:

FOH's Clinical Services Division delivers Clinical, Wellness/Fitness, Health Promotion, Smoking Cessation, Law Enforcement, Medical Surveillance, Medical Employability and Automated External Defibrillator (AED) Program Services to over half a million Federal employees. FOH has provided clinical services to many of HHS's agencies since its inception in 1946.

Specifically, the Clinical Division offers the following services in support of Women's Health at HHS health clinics:

- Mammograms – FOH health centers often facilitate mobile mammogram screening at the worksite.
- Cervical Cancer screening - Pap smears are available as part of Periodic Health Exams.
- Lactation Program – FOH supports continued lactation for working mothers and offers lactation rooms at its health centers where space permits.
- Osteoporosis Screening – Like mammograms, many health centers coordinate/facilitate mobile bone density/osteoporosis screening by mobile vendors at the worksite.

In addition, many HHS sites do special events to promote women's health issues during awareness campaigns such as:

- Wear Red Day in February
- Breast Cancer Awareness events in October

FOH offers a Women's Health Seminar with a focus on osteoporosis, menopause, heart disease, bladder disorders, etc.

Clinical Services provided at the workplace offer many benefits to both employees and employers. Employees who participate in worksite-based health promotion programs reap the rewards of better health and lower health care premiums. Employers benefit from reduced costs as a result of decreased absenteeism, improved morale, and increased productivity. FOH provides a full range of occupational and preventive health services that keep federal employees at the worksite, with minimal time away from their workstation.

Clinical Health Center Services include:

- First Aid and Emergency Response
- Immunizations
 - Influenza

- Tetanus
 - Pneumonia
- Physician prescribed services
 - Allergy screening
 - Blood pressure
 - Glucose monitoring
 - Cervical cancer screening
- Health awareness programs
 - Smoking cessation
 - Stress management
 - Cancer risks
- Health screenings for:
 - High blood pressure
 - Diabetes
 - Cholesterol levels
 - Vision
 - TB testing
 - Hearing loss
 - Glaucoma
 - Cardiac risk profile
- Maintenance of employee health records
- Emergency response planning
- Healthy Focus4You, www.HF4Y.com an online program that offers personalized health promotion tools
- HIV education and screening
- Colon cancer screening
- Mammography and Osteoporosis services (available to employee for a fee)
- Lactation Services
- Educational lectures, such as:
 - Nutrition for a Healthy Heart
 - Women's Wellness
 - Men's Wellness
 - Podiatry

1.1.a) Relevant Statistics (October 2008 to March 2009):

As reflected in the table, FOH has provided 19,610 encounters for various clinical services. Over 25 percent of encounters were for blood pressure screenings.

Summary of Clinical Health Center Services to HHS Employees:

Services	Encounters
Blood Pressure Monitoring (by physician order)	2000
Blood Pressure Screening	5071
Glucose Monitoring (by physician order)	10
Glucose Screening	252
Health Education Program (Participants)	1000
Hearing Screening	154
Lipid panel screenings/Cholesterol	401
Mammogram Screening (employee or insurance pay)	38
Spirometry/Pulmonary Function Screening	8
Tuberculosis Screening	333
Vision Screening	57
Other Encounters (walk-in care, immunizations, etc.)	10,295

1.1.b) Evaluation/Feedback Mechanism (October 2008 to March 2009):

The Clinical Health Centers are successful and provide value added services to HHS in the form of enhanced morale and a healthier workforce. Client satisfaction surveys are typically above 97 percent. The Director of Clinical Services oversees all aspects of the program.

Overall Satisfaction Rates for Clinical Services, as well as those from HHS sites (Humphrey, Parklawn and CMS HQ) based on total of 20,550:

Satisfaction Areas	All surveys (%)	HHS surveys (%)
Flexibility in Scheduling	97	97.3
Prompt attention upon arrival	98	99
Courteousness of staff	98.8	99.8
Explanation of procedure	98	98.3
Thoroughness of service	98.2	99.3
Privacy/confidentiality of environment	97.2	97.6
Explanation of results/answer questions	98.2	99.4
Clarity on follow-up actions to take	98	99.7
Helpfulness of education/information	97.2	96.6
Overall helpfulness of our services	98.4	99.5

1.2 Program Description - Wellness-Fitness Services:

FOH provides onsite wellness/fitness centers, fitness education, fitness assessments, and personal training at various HHS agencies since the 1980's.

Through the operations of wellness-fitness services, FOH encourages regular physical activity. Benefits to federal employees include improved cardiovascular health and a reduction in risk factors for heart disease (high blood pressure, high cholesterol, increased body fat, and high glucose levels as well as diabetes). Regular exercise can help control, reduce, or eliminate each of these risk factors.

Wellness-Fitness Services include:

- Operation and management of on-site fitness centers
- One-on-one facility and equipment orientation
- Personalized exercise prescriptions
- Group Exercise classes
- Body composition analysis
- Flexibility measurements
- Muscular strength/endurance measurements
- Submaximal aerobic capacity testing
- Cardiovascular and strength training equipment
- Virtual fitness programs

1.2.a) Relevant Statistics (October 2008 to March 2009):

FOH provided wellness services to 1,808 HHS federal employees. Over 61 percent of HHS participants are women.

Wellness-Fitness Services to HHS Employees:

Total # Members (includes non-HHS employees)	# HHS Female Members	# HHS Male Members
683	35	17
406	207	199
261	208	53
43	29	14
305	189	113
160	55	49
605	367	238
220	22	13
2,683	1,112	696

1.2.b) Evaluation/Feedback Mechanism (October 2008 to March 2009):

The Wellness-Fitness Centers have strong client satisfaction scores above 4.7/5.0. Clients are satisfied with the level of fitness classes. The Director of Clinical Services oversees all aspects of the program.

1.3 Program Description - Employee Assistance Program:

The Employee Assistance Program (EAP) provided by FOH is a comprehensive program that helps HHS employees resolve personal problems that may adversely impact their work performance, conduct, health and well-being. FOH's EAP addresses problems in the quickest, least restrictive, and most convenient manner while minimizing cost and protecting client confidentiality. FOH manages the largest EAP in the country, covering more than 740,000 federal workers each year. At HHS, FOH provides EAP services to over 45,000 employees since the 1970's.

All the services of the EAP are available to both men and women. The services more highly utilized by women, are as follows:

- In-person, individual short-term assessment, referral and counseling services (e.g., related to relationship issues, family, depression, anxiety, stress) – 55.4% of the utilizers of FOH's EAP in-person counseling services are women; 44.6% men.
- Nationwide referral resources for childcare and eldercare providers – the large majority of primary caregivers are women, so these services are generally utilized by women.
- In-person health and wellness presentations, online trainings, online podcasts and webinars. Selected presentation topics of potentially special interest to women are:
 - Psychological issues – e.g., depression; stress management and building resiliency; beating job stress
 - Parenting/caregiving – e.g., the art of parenting; life with a child with autism; eldercare
 - Life issues – e.g., getting a better night's sleep; balancing work and personal life
 - Domestic Violence – e.g., presentations discuss increasing awareness, the complex factors that keep victims in abusive relationships, ways to address the problem
- In-depth written educational materials
 - Thousands of articles on our website, www.FOH4You.com, pertaining to physical and mental health, life management, resources, etc.
 - 145 in-depth articles alone related to women's health (e.g., cervical cancer screening, thyroid issues pertaining to women, depression in women, alcohol and women, women's health issues and weight)
 - Hundreds of articles related to children's issues, relationship issues, and families.

EAP Services include:

- Confidential counseling services by licensed counselors
- Assessment, referral, and face-to-face short term counseling

for a wide variety of emotional, substance abuse and work/life concerns

- Assistance with response to traumatic events
- Consultation with management regarding workplace issues impacting employee health and well-being
- Convenient Access
 - Call from anywhere in the United States via toll free telephone number
 - 24-hours/day, 365 days/year
- Financial and Legal Services
 - Free initial consultation with financial experts and licensed attorneys for:
 - Living will preparation
 - Health Care power of attorney
 - Housing or real estate matters
 - Education funding advice
 - Retirement planning
 - Investment strategies
- Website www.FOH4You.com
 - Educational resources
 - Self-assessment tools
- Education and Training for Employees and Supervisors
 - Lunch and Learn Sessions

1.3.a) Relevant Statistics (October 2008 to March 2009):

Summary of EAP Services to HHS Employees:

EAP Counseling Cases	Number	Percent
Female	276	70.4
Male	116	29.6
Total	392	

1.3.b) Evaluation/Feedback Mechanism (October 2008 to March 2009):

The EAP services are generally regarded as value added by employees. Overall satisfaction is strong with the majority of employees satisfied with services. Satisfaction with the 24/7 toll-free 800 line received lower satisfaction scores and steps are being taken to increase levels of satisfaction. The Director of EAP Services oversees all aspects of the program.

Overall Satisfaction Rates for EAP Services:

Questions	Percent
1. How satisfied were you with the help you received when you called the 800 number?	86
2. How satisfied were you with how easy it was to get the EAP services you needed?	98
3. How satisfied were you with your EAP counselor?	98
4. How satisfied were you with how the EAP services helped you resolve your problem?	92
5. How satisfied were you with the overall service you received?	96
6. Would you recommend the EAP to other employees?	100

1.4 Program Description – Work/Life Program:

FOH Work/Life Program is designed to help HHS employees and family members better manage daily responsibilities and life events, especially relating to caregiving. One of the biggest challenges facing employees today is balancing personal and work responsibilities. Employees are now dealing with issues ranging from child care to elder care to retirement planning. Finding ways to manage these issues is not always easy. FOH has designed a Work/Life Program for participating HHS employees, with a flexible range of options, which allows employees to manage their personal and professional lives since early 2001. The program offers information, referrals to qualified resources, and consultation services.

Specific services for caregivers include support groups that cover parenting teens, children with autism, and adult caregiving. There are currently four kits offered: a Prenatal Kit, a Child Safety Kit, an Eldercare Kit, and a College Kit.

Included on the FOH Website www.Worklife4You.com is a specific topic area entitled, Mothers at Work Program. FOH recognizes that as one of the fastest growing segments of the workforce, working women need support to balance their personal and professional lives, especially when they are facing major life events such as having a baby. Mothers at Work provides toll-free 24/7 personalized referrals to lactation consultants, parenting classes, child care providers, adoption agencies, and other parenting resources. FOH also connects working women with any applicable prenatal or well baby programs offered by the agency.

FOH provides access to specialists who offer customized research and referral services and guidance to employees and their family members in the following Work/Life Program areas:

- Adult care & aging
- Child care & parenting

- Education
- Financial & legal concerns
- Health & wellness
- Prenatal care and adoption
- Relocation and personal support for urgent everyday issues
- Professional Work/Life Consultants

**1.4.a) Relevant Statistics (October 2008 to March 2009):
Summary of Work/Life Services to HHS Employees:**

EAP Work/Life Cases	Number	Percent
Female	28	57.1
Male	21	42.9
Total	49	

1.4.b) Evaluation/Feedback Mechanism (October 2008 to March 2009):

The Work/Life satisfaction is conducted as a component of the EAP services. The results are the same as found in 1.3.b. The Director of EAP Services oversees the Work/Life Program.

2. Future Efforts:

None planned at this time.

HHS University

Overview

HHS University was established in 2003 with mission of fostering Department-wide continuous learning environment by providing cost-effective quality services, and competency-based learning and career development activities, using innovative training solutions aligned with the Department's strategic goals. Available courses include acquisition, administrative systems, business skills, career planning and retirement, communication and interpersonal skills, EEO and Diversity Academy, information technology, and leadership and management.

Programs That Improve the Lives of America's Women and Girls

Emerging Leaders Program (ELP) – A competitive, two-year, paid federal internship with HHS. Provides a unique opportunity to develop analytical and critical leadership skills in one of the largest federal agencies in the nation. Rotation opportunities to expand leadership competencies are available throughout the Department and across federal agencies. Candidates are recruited for GS-9 level positions in the following career tracks: Administrative, Social Sciences, Public Health, Human Resources, Scientific, and Information Technology. Recruits well-qualified, exceptional leaders with an interest in public policy and commitment to public service. Managed through HHS University.

HHS Mentoring Program – Provides a forum for employees and managers at all levels to "Partner for Excellence" in order to enhance their performance, achieve their professional goals, and fulfill the Department's mission. Mentoring relationship for one year with the following goals: 1) develop and retain a diverse, high-performing workforce, 2) preserve the knowledge and skills of employees nearing retirement age, and 3) help new employees transition into HHS. Two mentoring options: Senior-to-Junior - participants are paired with a mentor of senior career level; Peer-to-Peer (P2P) - participants are paired with a mentor of equivalent career level. Managed through HHS University.

Senior Executive Service (SES) Candidate Development Program – 18-month program that prepares high potential GS-15 employees for the SES ranks. Prepares participants for SES Certification by the Office of Personnel Management; establishes an HHS pool of qualified candidates for SES positions; and prepares future executives for collaborative leadership within and outside of the Department. Provides a broad range of developmental experiences and formal, practical training experiences including: mentoring from an SES member; leadership assessments and feedback; creation and execution of an Executive Development Plan; online and classroom instruction in executive level competencies; rotational assignments within and outside of the Department; and group project on high level Department issues. Managed through HHS University.

Presidential Management Fellows (PMF) – Two-year program to attract outstanding individuals from a variety of academic disciplines who have a clear interest in, and commitment to, excellence in leadership and management of public policies and programs. Program helps HHS meet its workforce and succession planning needs by attracting such individuals to federal service. Managed through HHS University.

Relevant Statistics:

- HHS has hired over 1,000 PMFs since the program was established in 1977
- HHS averages 60 PMF hires annually.

Leadership in Context Program - LinC will address critical skills needed for first-line supervisors or managers with two or less years of Federal supervisory experience. 12-day cohort program offered in four segments over a 4-month period.

Dimensions of Leadership (DoL) – Program for supervisors and managers with 5 or more years of management experience. Designed to meet career development needs of mid-level management employees

Federally Employed Women (FEW) Forum – FEW is a membership organization working for the elimination of sexual discrimination and the advancement of women in government. For 40 years FEW has been working for the advancement of women in government through its outstanding training. HHS hosts an agency forum for female HHS employees nearly every year during the annual FEW Forum. At this year's FEW Forum (July 20-24, 2009 in Orlando, FL), the HHS Forum will focus on the State of Women at HHS. Discussions will include employment, statistical and barrier analysis, raising the bar and moving beyond the barrier, Work-life balance and a Diversity Video. The Office of Diversity Management and EEO within the Office of the Assistant Secretary for Administration and Management serves as the point of contact for the HHS agency forum.

Relevant Statistics:

- Approximately 60 HHS employees will attend 2009 FEW Forum (NIH and FDA employees registered at this time)

Office of Small and Disadvantaged Business Utilization (OSDBU)

Programs That Improve the Lives of America's Women and Girls:

1) Program Description:

The Office of Small and Disadvantaged Business Utilization (OSDBU) trains and educates Women-Owned Small Businesses (WOSBs) on how to obtain contracts with the Department of Health and Human Services (HHS). OSDBU is located within the Office of the Secretary, the Director reports to the Deputy Secretary and receives administrative support from the Assistant Secretary for Administration and Management. The Department has a WOSB Representative housed within the Immediate Office of the Director. In addition, OSDBU has co-located staff within the Operating Divisions at HHS, who also support the WOSB Program.

a. Relevant Statistics:

The dollar percentage of awards to WOSBs is statutorily mandated at 5%. In FY 2008, HHS awarded 5.33% or \$702M dollars to WOSBs. Historically, HHS has been able to meet and/or exceed the WOSB goal of 5%.

Future Programs

We continue to participate in outreach events specifically designed for WOSBs. In FY 2010, HHS plans to host its own WOSB Outreach Event and the focus will be on companies that are new (five years or less) to the general marketplace and/or new to the Federal Government.

2) Program Description:

Grants to Women-Owned Small Businesses

a. Relevant Statistics:

In FY 2008, HHS provided \$6,155,588 in grants to women-owned small businesses.

Office of the Assistant Secretary for Planning and Evaluation (ASPE)

Office Overview

The Assistant Secretary for Planning and Evaluation (ASPE) is the principal advisor to the Secretary of the U.S. Department of Health and Human Services on policy development, and is responsible for major activities in policy coordination, legislation development, strategic planning, policy research, evaluation, and economic analysis.

Programs That Improve the Lives of America's Women and Girls

Financial Literacy

Program Description: Consumer Education Initiatives in Financial and Health Literacy

ASPE will soon begin a project that will assess the current state of HHS' consumer education efforts for low-income individuals and identify effective health literacy and financial literacy initiatives that can serve as models for future activity in this area. Lessons learned from the more-established health literacy field and the growing focus on financial literacy in human services programs can inform efforts in both areas to help the low-income population manage the broad array of interrelated and critical financial decisions they confront. We will examine the consumer education efforts being used across HHS programs to provide a more comprehensive understanding of the array of consumer education efforts being used in the Department, which approaches work best for different subgroups, and the interrelationships between health literacy and financial literacy skills. The study will involve: (1) a detailed scan and summary of agency- and program-specific consumer education efforts around financial and health literacy, (2) a synthesis of what is known about the effectiveness and success of these initiatives in general and for specific low-income subgroups of interest, (3) identification of promising components and design features of the various initiatives, and (4) an analysis of how specific kinds of approaches can inform efforts to improve and expand consumer education across HHS programs serving low-income populations.

Administration for Children and Families (ACF)

Agency Overview

- A. **Executive Summary:** The Administration for Children and Families (ACF), within the Department of Health and Human Services (HHS) is responsible for federal programs that promote the economic and social well-being of families, children, individuals, and communities. ACF programs aim to achieve the following:
- families and individuals empowered to increase their own economic independence and productivity;
 - strong, healthy, supportive communities that have a positive impact on the quality of life and the development of children;
 - partnerships with individuals, front-line service providers, communities, American Indian tribes, Native communities, States, and Congress that enable solutions which transcend traditional agency boundaries;
 - services planned, reformed, and integrated to improve needed access;
 - and a strong commitment to working with people with developmental disabilities, refugees, and migrants to address their needs, strengths, and abilities.

Programs That Improve the Lives of the Federal Workforce

ACF provides initiatives to help improve the lives of women and girls/families. ACF offers a Telework program that allows employees to work 2 days per week from an alternate duty station. In addition, ACF offers a Lactation Room for nursing mothers to have access to a private, comfortable and convenient space in the work place.

Telework Program

The Flexiplace/Telework Program permits employees to voluntarily work remotely from home or at other approved locations. The Flexiplace/Telework Program is expected to improve the quality of employee work life, increase employee productivity, and reduce workspace and related costs at the Official Duty Station (ODS). Our Flexiplace/Telework Program started July 9, 1996 for our Regional Offices and November 19, 1998 for Central Office.

In ACF's annual Telework Data Report submitted to the Department in February 2009, ACF reported that 329 employees participate in some form of Telework, of which 249 employees work at an alternative duty station one to two days per week. The number employees participating in the program continues to increase.

The number of employees who participate in Telework by grades are provided below:

- GS 7 – 3 employees
- GS 8 – 1 employee
- GS 9 – 4 employees

GS 11- 19 employees
GS12 – 134 employees
GS 13 – 118 employees
GS 14 – 50 employees
GS 15 – 10 employees

The Office of Management Resources, Office of Administration, oversees the Telework program. Administrative Officers, Office Directors and Regional Administrators work together to carry out the guidelines of the program.

ACF is tracking the two Bills in Congress that seek to expand Telework government-wide. ACF plans to implement all new requirements of the OPM Telework policy with guidance from the Department.

Lactation Room

ACF opened the new lactation room for mothers who are breast-feeding their babies on January 2, 2009. The Lactation Room is located on the 7th Floor of the Aerospace Building. The Office of Management Resources, Office of the Administration is responsible for oversight of the Room.

The Lactation Room is available to ACF employees and contractors to help balance the demands of work with family responsibilities. Most mothers generally return to work within one to three months of giving birth. Access to a private, comfortable and convenient space in the work place is critical in helping women who like to breast-feed. A well-designed lactation room can reduce some of the anxiety and stress that new mothers may have upon returning to work. ACF plans to increase its marketing and promotion of the Lactation room by use of email, computer pop ups and intranet postings. Within the next 2 years, ACF anticipates implementing a full Lactation program.

Programs That Improve the Lives of America's Women and Girls

ACF highlights the following programs providing services that improve the lives of America's women and girls:

- Family Violence Prevention and Service Programs
- Chafee Foster Care Independence Program
- Child Care and Development Block Grant
- Temporary Assistance for Needy Families
- Healthy Marriage/Responsible Fatherhood Initiative
- Office of Community Services
- Child Support Enforcement
- Head Start
- Native American Programs
- Disaster Case Management

The **Family Violence Prevention and Services Act (FVPSA)** provides the primary Federal funding stream dedicated to the support of emergency shelter and related assistance for victims of domestic violence and their dependents. FVPSA funding sustains core services that provide safety for victims of domestic violence when they are in crisis – the network of community-based shelters and non-residential services that offer safe housing, advocacy, legal assistance, counseling and support groups, safety planning, and crisis response. FVPSA-funded programs also take the next steps to stop violence before it starts and ensure children grow up safe and secure.

FVPSA provides formula funding for every State and Territory and over 200 Tribes, which subgrant funds to more than 1,200 community-based domestic violence shelters and 300 non-residential services programs, providing both a safe haven and an array of supportive services to intervene in and prevent abuse. FVPSA also provides funding for the National Domestic Violence Hotline, State Domestic Violence Coalitions, a network of National Resource Centers and Culturally Specific Institutes, and small discretionary grants.

Fiscal year 2009 appropriations were \$127.8 million for FVPSA formula grants and \$3.2 million for the National Domestic Violence Hotline.

Emergency Domestic Violence Programs (FVPSA Formula Grants to States, Territories and Tribes): FVPSA-funded programs focus on both intervention and prevention. In fiscal years (FYs) 2007 and 2008, FVPSA-funded programs served 593,600 victims and their children and responded to 4.7 million crisis calls. FVPSA-funded programs not only provide a wide range of protective and supportive services to victims and their children, they also work to enhance community awareness and response to domestic violence; in FY 2008, programs in 22 States provided 111,200 community education presentations. On September 17, 2008, 78% of identified domestic violence programs in the United States (or 1,553 out of 2,000 programs) participated in a 24-hour survey. In just one day, 60,799 victims were served, 20,658 hotline calls were answered, and 30,024 professionals and community volunteers were trained by these 1,553 programs.¹²

¹² *Domestic Violence Counts 08: A 24-hour census of domestic violence shelters and services across the United States.* The National Network to End Domestic Violence. (2009).

Shelter programs have been found to be among the most effective resources for victims with abusive partners.¹³ Staying at a shelter or working with a domestic violence advocate significantly reduces the likelihood that a victim will be abused again and improves the victim's quality of life.¹⁴ The Family and Youth Services Bureau (FYSB) through the FVPSA Program, has collaborated with the National Institute of Justice to support the first multi-state study of domestic violence shelter services, *Meeting Survivors' Needs: A Multi-State Study of Domestic Violence Shelter Experiences* (2008), which confirms the critical role that domestic violence shelters play in increasing the protections and supports available to victims and their children. According to the study, shelter stays led to:

- *Access to Safety*: more ways to plan for safety (91%), options and choices (91%), and community resources (85%);
- *Increasing survivor confidence*: will achieve goals (93%), hopeful about future (92%);
- *Improvements for children*: feel more supported (84%), understand what is happening (78%), able to express feelings without violence (77%);

These outcomes are associated with longer-term improved safety (less violence) and well-being in experimental, longitudinal studies.¹⁵

¹³ See: Bennett, L., Riger, S., Schewe, P., Howard, A., & Wasco, S. (2004). Effectiveness of hotline, advocacy, counseling and shelter services for victims of domestic violence: A statewide evaluation. *Journal of Interpersonal Violence*, 19(7), 815-829; Bowker, L.H., & Maurer, L. (1985). The importance of sheltering in the lives of battered women. *Response to the Victimization of Women and Children*, 8, 2-8; Gordon, J.S. (1996). "Community services for abused women: A review of perceived usefulness and efficacy." *Journal of Family Violence* 11(4): 315-329; Sedlak, A.J. (1988). Prevention of wife abuse. In V.B. Van Hasselt, R.L. Morrison, A.S. Bellack, & M. Hersen (Eds.), *Handbook of Family Violence* (pp. 319-358). NY: Plenum Press; Straus, M.A., Gelles, R.J., & Steinmetz, S.K. (1980). *Behind closed doors: Violence in the American family*. NY: Anchor Press; Tutty, L.M., Weaver, G., & Rothery, M. (1999). Residents' views of the efficacy of shelter services for assaulted women. *Violence Against Women*, 5(8), 898-925.

¹⁴ See: Berk, R.A., Newton, P.J., & Berk, S.F. (1986). What a difference a day makes: An empirical study of the impact of shelters for battered women. *Journal of Marriage and the Family*, 48, 481-490; Bybee, D.I., & Sullivan, C.M. (2002). The process through which a strengths-based intervention resulted in positive change for battered women over time. *American Journal of Community Psychology*, 30(1), 103-132;

Constantino, R., Kim, Y., & Crane, P.A. (2005). Effects of a social support intervention on health outcomes in residents of a domestic violence shelter: A pilot study. *Issues in Mental Health Nursing*, 26, 575-590;

Goodkind, J., Sullivan, C.M., & Bybee, D.I. (2004). A contextual analysis of battered women's safety planning. *Violence Against Women*, 10(5), 514-533;

Sullivan, C.M. (2000). A model for effectively advocating for women with abusive partners. In J.P. Vincent & E.N. Jouriles (Eds.), *Domestic violence: Guidelines for research-informed practice* (pp. 126-143). London: Jessica Kingsley Publishers;

Sullivan, C.M., & Bybee, D.I. (1999). Reducing violence using community-based advocacy for women with abusive partners. *Journal of Consulting and Clinical Psychology*, 67(1), 43-53.

¹⁵ Bybee, D. I., & Sullivan, C. M. (2002). The process through which a strengths-based intervention resulted in positive change for battered women over time. *American Journal of Community Psychology*, 30(1), 103-132.

National Domestic Violence Hotline: Since opening in 1996, the National Domestic Violence Hotline (Hotline) has received over 2 million calls and now averages 20,800 calls a month. More than 60% of callers report that this is their first call for help. The Hotline provides a live and immediate response to thousands of victims of domestic violence and their families. The Hotline directly connects the caller to a seamless referral system of over 5,000 community programs in response to the needs of the women, men, youth and children on the line. The Hotline operates 24 hours a day, 7 days a week and is available in 170 languages. Current growth rates project the Hotline will receive its 3 millionth call in 2011, which is less than half the amount of time it took to reach the first million.

Not only have total Hotline calls increased, but also calls have become more complex. The average length of calls increased 24 percent between FYs 2007 and 2008 – from 6.79 minutes to 8.4 minutes. The number of calls requiring use of translation services provided through the AT&T Language Line also increased 20 percent over FY 2007. Additionally, the Hotline reported call spikes experienced when the Hotline was featured on nationally syndicated television shows, such as the Oprah Winfrey Show and Spanish-language television. For example, on two days on which the Hotline number was aired on Oprah and on Despierta America¹⁶ call volume increased over 130 percent.

(a) Relevant Statistics: The safety and security of women and girls in America is a primary concern. However, as the following statistics demonstrate, violence in the home or at the hands of an intimate partner places women and girls at risk every day:

- Approximately 2.3 million people each year in the United States are physically assaulted and/or raped by a current or former spouse, boyfriend or girlfriend.¹⁷
- One in every four women has experienced domestic violence during their lifetimes.¹⁸
- Female victims of domestic violence were physically assaulted an average 6.9 times per year by the same partner.¹⁹
- Approximately 15.5 million children are exposed to domestic violence every year.²⁰
- Domestic violence is the second leading cause of death for pregnant women.²¹ Some 25 to 50 percent of adolescent mothers experience partner violence before, during or just after their pregnancy.²²

¹⁶ Despierta America is a popular Spanish-language morning show.

¹⁷ Tjaden, Patricia & Thoennes, Nancy. National Institute of Justice and the Centers for Disease Control and Prevention, “Extent, Nature and Consequences of Intimate Partner Violence: Findings from the National Violence Against Women Survey.” July 2000.

¹⁸ Tjaden, Patricia & Thoennes, Nancy. National Institute of Justice and the Centers for Disease Control and Prevention, “Extent, Nature and Consequences of Intimate Partner Violence: Findings from the National Violence Against Women Survey.” July 2000.

¹⁹ Tjaden, Patricia & Thoennes, Nancy. National Institute of Justice and the Centers for Disease Control and Prevention, “Extent, Nature and Consequences of Intimate Partner Violence: Findings from the National Violence Against Women Survey.” July 2000.

²⁰ McDonald, R., et al. (2006). “Estimating the Number of American Children Living in Partner-Violence Families.” *Journal of Family Psychology*, 30(1), 137-142.

- One in three high school girls who has been abused by a boyfriend has become pregnant. Being physically and sexually abused leaves teenaged girls up to 6 times more likely to become pregnant.²³
- The health-related costs of intimate partner violence in the United States exceed \$5.8 billion each year; \$4.1 billion for direct medical and mental health services alone.²⁴ These are the costs borne by victims; the costs to the health care system as a whole are projected to be much greater. The predicted incremental cost to the health care system ranges between \$462 billion and \$620 billion annually, or 23% to 31% of the total health care dollar.²⁵

The **Chafee Foster Care Independence Program (CFCIP)** offers assistance to States to provide independent living services to help current and former foster care youth (both male and female) achieve self-sufficiency. States and local agencies are encouraged to assist youth in a wide variety of areas designed to support a successful transition to adulthood. Activities and programs provide help with education, employment, financial management, housing, emotional support and assured connection to caring adults for older youth in foster care, as well as to youth ages 18-21 who have emancipated or “aged out” of the foster care system. The Education and Training Vouchers Program (ETV) for Youths Aging out of Foster Care was added to the CFCIP in 2002. ETV makes available vouchers of up to \$5,000 per year per youth for postsecondary education and training for eligible youth. The basic CFCIP grant is funded at \$140 million per year. The ETV program is funded at \$45.4 million in fiscal year (FY) 2009.

²¹ Chang, J., Berg, C.J., Saltzman, L.E., Herndon, J. “Homicide: a leading cause of injury deaths among pregnant and postpartum women in the United States, 1991-1999.” *Am J Public Health*. 2005 Mar; 95(3):471-7;

Krulwich CJ, Pierre-Louis ML, de Leon-Gomez R, Guy R, Green R. “Hidden From View: Violent Deaths Among Pregnant Women in the District of Columbia, 1988–1996.” *Journal of Midwifery and Women’s Health*. 2001;46:4–10;

Frye V. “Examining Homicide’s Contribution to Pregnancy-Associated Deaths.” *JAMA*. 2001;285(11):1510–1511.

²² Leiderman, S. and Almo, C. 2001. *Interpersonal violence and adolescent pregnancy: Prevalence and implications for practice and policy*. Center for Assessment and Policy Development and the National Organization on Adolescent Pregnancy, Parenting and Prevention.

²³ Silverman JG, Raj A, Clements K. Dating violence and associated sexual risk and pregnancy among U.S. adolescent girls. *Pediatrics* 2004;114(2):e220-225.

Silverman JG, Raj A, Mucci LA, Hathaway JE. Dating violence against adolescent girls and associated substance use, unhealthy weight control, sexual risk behavior, pregnancy, and suicidality. *Journal of the American Medical Association (JAMA)* 2001; 286:572-9.

²⁴ *Costs of Intimate Partner Violence Against Women in the United States*. 2003. Centers for Disease Control and Prevention, National Center for Injury Prevention and Control. Atlanta, GA.

²⁵ Dolezal, T., McCollum, D., Callahan, M., Eden Prairie, MN: Academy on Violence and Abuse; 2009.

While the program at the Federal level is not designed to be gender specific, each State uses CFCIP funds in a way that would promote independence for youth. Therefore, the program may be designed to address the specific needs of girls and young women in foster care or transitioning from foster care. States are encouraged to partner with other State agencies and community-based organizations to provide life skills and other services to young people; this could include skills and services to meet the needs of women and girls.

Services for youth in foster care and who have aged out of foster care differ among States, placement types, and youth. For youth placed in a pre-adoptive placement, independent living services may be provided in a home-based environment, while for youth in foster care in a group home, independent living services might include classes or field trips into the community to build skills.

The majority of States require that services are based on an assessment of the skills of the youth. Many States use assessments that are youth-driven in order to provide the youth the opportunity to help decide what skills are critical to their self-sufficiency. These assessments also build on skills and strengths of the youth. Furthermore, the needs of individual youth and young adults are different based on their permanency and personal goals. The assessment of skills and needs of individual youth enables States to tailor services to address the unique needs of women and girls. In some cases, Chafee and ETV can be used in combination to support the efforts to youth to transition to self-sufficiency. Additionally, some States offer college tuition waivers that allow former foster youth to attend colleges or universities in their State without charge.

Future programs: A new data collection initiative for these programs, the National Youth in Transition Database, is currently under development. States will begin submitting data in FY 2011. States will report data on the independent living services and supports they pay for or provide in eleven broad categories: independent living needs assessment; academic support; post-secondary educational support; career preparation; employment programs or vocational training; budget and financial management; housing education and home management training; health education and risk prevention; family support and healthy marriage education; mentoring; and supervised independent living. States will also report financial assistance they provide, including assistance for education, room and board, and other aid. In addition, States will survey youth regarding six outcomes: financial self-sufficiency, experience with homelessness, educational attainment, positive connections with adults, high-risk behavior, and access to health insurance. Youth who turn 17 in foster care will be surveyed within 45 days of their 17th birthday and then will be surveyed again at ages 19 and 21.

The **Child Care and Development Fund (CCDF)** supports working families by providing them with child care financial assistance and by promoting children's learning through high-quality early care and education and afterschool programs. Many of the families served are headed by single mothers.

Child care assistance for low-income families supports working women and promotes parental choice of providers. Through the Child Care and Development Fund, ACF provides \$5 billion in Federal block grants to States, Territories and Tribes to improve the affordability, accessibility and quality of child care in a variety of settings. On average, the program serves an estimated 1.7 million children per month with child care subsidies. This enables parents from approximately 1 million low-income families to work and gain economic self-sufficiency or attend training and/or education activities designed to upgrade their skills and provide opportunities for employment. We know that more than 85 % of these families are single-parent households, the vast majority headed by women. Low-income women frequently work irregular hours in low-wage jobs. About eighty percent of the child care assistance is provided through vouchers, which can be used at child care centers, family child care homes, and a wide variety of afterschool programs. CCDF empowers low-income women to make their own child care choices to meet their families' needs.

Child care services employ millions of women and provide entrepreneurial opportunities to start women-owned businesses. The child care workforce is largely comprised of women. Some estimates put the paid child care workforce as high as 2 million workers, 90% of whom are women according to the Bureau of Labor Statistics.²⁶ The Child Care and Development Fund includes set-asides to improve child care quality. Quality improvement initiatives not only improve the quality of care, they also improve the career opportunities for the child care workforce. Examples include scholarship programs for professional development and other incentives to move up a career ladder, increased salaries, and tiered reimbursement payment systems that pay more for higher quality care.

About 35 percent of child care workers are self-employed,¹⁵ and most of these provide child care in their homes. These predominantly women-operated child care businesses can receive payments for services to CCDF-eligible families. Women who operate child care businesses can receive provider payments for services given to families eligible to receive CCDF. Using CCDF's quality improvement funds, many States and Tribes provide start-up grants and financial assistance for health and safety improvements, materials and equipment, and for reaching accreditation or other high quality benchmarks. Between 2006 and 2016, the need for child care workers is estimated to grow 18 percent, a difficult prospect with the high turnover that characterizes the field.

²⁶ Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook, 2008-09 Edition*, Child Care Workers, on the Internet at <http://www.bls.gov/oco/ocos170.htm> (visited June 30, 2009).

Child care consumer education helps all parents make informed choices for the care of their children while they work. ACF and State and Tribal grantees offer services to help parents make better informed child care choices through Child Care Aware, a national toll-free hotline (1-800-424-2246) and website (www.childcareaware.org). The website includes a wealth of materials for parents, including: printed checklists of questions to ask prospective child care providers, short videos to help parents learn how to evaluate potential child care settings, and a link to the child care resource and referral agency in the parent's local area. The national hotline connects to a network of local resource and referral agencies, many of which are funded by States' Child Care and Development Fund grants, which include targeted funds for this purpose. Local agencies maintain databases of providers, including key information about the ages served, hours of services, and whether they meet particular quality benchmarks. They directly assist families in locating care over the phone or, increasingly, through interactive websites.

CCDF Programs Provide Support for Teen Mothers. The CCDF requires grantees to give priority to children with special needs and to children from very low-income families. Grantees also have the option of classifying teen mothers as a priority for receipt of CCDF services. For FY 2008-2009, a total of 14 States and Territories established additional priority rules to ensure access to child care services for targeted populations, including teen parents and other vulnerable sub-groups. Therefore, in several States teen parents are in a high priority group for CCDF.

(a) Relevant Statistics:

- During FY 2007, on average, 991,500 families in US States and Territories received child care subsidies each month.
- During FY 2007, on average, 1,706,600 children in US States and Territories received child care services each month.
- During FY 2007, 665,529 child care providers received some CCDF funds.²⁷
- From March 1975 to March 2000, the labor force participation rate of mothers with children under age 18 rose from 47 percent to a peak of 73 percent. (These data were collected in the March CPS.) By 2004, the rate for these mothers had receded to 71 percent, where it remained through 2007. In general, mothers with older children (6 to 17 years of age, none younger) are more likely to participate in the labor force than mothers with younger children (under 6 years of age), and unmarried mothers have higher participation rates than married mothers. In 2007, 76 percent of unmarried mothers were in the labor force, compared with 69 percent of married mothers.²⁸

²⁷ Source: FFY2007 ACF-801 and ACF-800 data

²⁸ Source: Women in the Labor Force: A Databook; US Dept of Labor; US Bureau of Labor Statistics; December 2008; Report 1011

- The United States child care workforce is female-dominated, with more than 90 percent of the child care workforce being represented by women. While in family child care settings the average provider is in her mid-forties, teachers and assistant teachers in child development centers are younger, with one-third of teachers being 29 years or younger, and 15 percent being older than 50 years. Of the assistant teachers, 49 percent are 29 years or younger, and only 9 percent are older than 50 years.¹⁵
- Approximately 35 percent of child care workers are self-employed, with the majority of these workers serving as family child care providers. In 2006, the U.S. Department of Labor estimated that child care workers held about 1.4 million jobs. Additionally, in 2006 there were an estimated 437,000 preschool teachers.¹⁵

The **Temporary Assistance for Needy Families (TANF)** program is a block grant program to help needy families with children transition from welfare to self-sufficiency. Under the welfare reform legislation of 1996, TANF replaced the old welfare programs known as the Aid to Families with Dependent Children (AFDC) program, the Job Opportunities and Basic Skills Training (JOBS) program, and the Emergency Assistance (EA) program. The law ended Federal entitlement to assistance and instead created TANF as a block grant that provides States, Territories, and Tribes Federal funds each year. These funds cover benefits and services targeted to needy families. The assistance is time-limited and promotes work and personal responsibility. It provides funds for benefits, administrative expenses, and other supportive services. Citizens apply for TANF at the respective agency administering the program in their community.

The Deficit Reduction Act of 2005 reauthorized the TANF program through fiscal year 2010. On February 17, 2009, President Obama signed the American Recovery and Reinvestment Act of 2009 (Recovery Act). In addition to other changes to the TANF program, the Recovery Act established the Emergency Contingency Fund for State TANF Programs (Emergency Fund). It provides up to \$5 billion to help States, Territories, and Tribes in FY 2009 and FY 2010 that have an increase in assistance caseloads and basic assistance expenditures, or in expenditures related to short-term benefits or subsidized employment.

The four purposes of TANF are:

- assisting needy families so that children can be cared for in their own homes;
- reducing the dependency of needy parents by promoting job preparation, work and marriage;
- preventing out-of-wedlock pregnancies; and
- encouraging the formation and maintenance of two-parent families.

Work Activities: In assisting families to move to work, the TANF program provides 10 work activities. Many of the TANF families are headed by single parents; some have limited or no work experience. Some have not completed high school; some are still high school age, but have dropped out of school. TANF provides a variety of opportunities for parents to obtain the education, training, job skills, job readiness or job search assistance they need to move to work. The work activities are:

- unsubsidized or subsidized employment
- work experience
- on-the-job training
- job search and job readiness assistance – not to exceed 6 weeks in a 12-month period and no more than 4 consecutive weeks (but up to 12 weeks if a State meets certain conditions)
- community service
- vocational educational training – not to exceed 12 months
- job skills training related to work
- education directly related to employment
- satisfactory secondary school attendance
- providing child care services to individuals who are participating in community service.

Personal Employability Plans: States must make an initial assessment of a recipient's skills. States may develop personal responsibility plans for each recipient to identify the education, training, and job placement services needed to move into the workforce.

Teen Parent Live-at-Home and Stay-in-School Requirement: Recognizing the importance of this time, unmarried minor parents must participate in educational and training activities and live with a responsible adult or in an adult-supervised setting. For teens who can not live at home, States are responsible for assisting in locating adult-supervised settings.

TANF funds may also be used to pay for child care, transportation, and other supportive services.

Tribal Programs: Federally recognized Indian Tribes may apply directly to the Department of Health and Human Services to operate a TANF block grant program. Like States, Tribes may use their TANF funding in any manner reasonably calculated to accomplish the purposes of TANF. The Federal government approves tribal plans.

Native Employment Works Program: The former tribal JOBS program has been replaced with the Native Employment Works (NEW) Program. NEW provides funding to tribes and inter-tribal consortia to design and administer tribal work activities, while allowing tribes and States to provide other TANF services.

(a) Relevant statistics: Over 90 percent of adult TANF recipients are female, with more than 50 percent of these females being between 20 and 29 years of age. The average number of children in each TANF family is two, and approximately one third of families are African American. Almost all TANF families receive medical assistance, and more than 80 percent receive Supplemental Nutrition Assistance as well. One in 10 families receive child support, and over 80 percent of adult recipients report being single or separated. The \$17 billion TANF program includes Tribal TANF and the Native Employment Works programs. There are 54 State TANF programs (including DC and 3 Territories), 298 Tribes served by 63 Tribal TANF plans and 78 Native Employment Works (NEW) programs.

The **Healthy Marriage/Responsible Fatherhood** program provides \$150 million in grants each year. Key requirements of the authorizing legislation specify that funds may be used for competitive research and demonstration projects to test promising approaches to encourage healthy marriages and promote involved, committed, and responsible fatherhood by public and private entities and also for providing technical assistance to States and Tribes.

- Applicants for funds must commit to consult with experts in domestic violence; applications must describe how programs will address issues of domestic violence and ensure that participation is voluntary.
- Healthy marriage promotion awards must be used for eight specified activities, including marriage education, marriage skills training, public advertising campaigns, high school education on the value of marriage and marriage mentoring programs.

Office of Community Services programs: The Office of Community Services (OCS) works in partnership with states, tribes, territories, communities, and other agencies to provide a range of human and economic development services and activities which address the causes and characteristics of poverty and otherwise assist persons in need. The aim of these services and activities is to increase the capacity of individuals and families to become self-sufficient, to revitalize communities, and to build the stability and capacity of children, youth, and families so that they become able to create their own opportunities. OCS programs are not gender-specific.

Major Goals:

- Provide employment and entrepreneurial opportunities through industrial, business, physical or commercial development;
- Promote individual self-sufficiency through the creation of new, full-time, permanent jobs;
- Assist community development corporations and community action agencies in leveraging existing Federal, State and local resources for neighborhood revitalization activities;
- Provide financial and technical resources to State, local, public and private agencies for economic development and related social service support activities;
- Provide energy assistance to low-income households;
- Provide financial literacy and family budgeting training and access to Individual Development Accounts (matched savings accounts) to enable low-income families to accumulate savings for purchasing a first home, capitalizing a business, and pursuing higher education; and
- Provide training, technical assistance and financial assistance to help faith-based and community organizations increase their effectiveness and enhance their ability to provide social services to those most in need in their communities.

With a budget of approximately \$8 billion, OCS disburses block and discretionary grants to states, tribes, territories and a network of community-based and faith-based organizations. OCS is comprised of three programmatic divisions – the Divisions of State Assistance, Community Discretionary Programs, and Energy Assistance – as well as the Assets for Independence Program and the Compassion Capital Fund.

Division of State Assistance

- ***Community Services Block Grant Program.*** This is a mandatory formula grant to 50 States, the District of Columbia, six territories, and 66 Native American tribes. Grant recipients work to ameliorate the causes of poverty by assisting low-income individuals with employment, education, and adequate housing. Grant recipients assist low-income individuals to make better use of their income, solve problems that are blocking the achievement of self-sufficiency, and obtain emergency health services, food, housing, and employment-related assistance. This program was funded at \$654 billion in regular fiscal year 2009 funds. The program received an additional \$1 billion in the American Recovery and Reinvestment Act (ARRA).
- ***Social Services Block Grant Program.*** This block grant provides funds to 50 States, the District of Columbia, and five territories and insular areas for the provision of social services directed towards achieving economic self-sufficiency, preventing or correcting neglect, abuse, or the exploitation of children and adults, preventing or reducing inappropriate institutionalization, and securing referrals for institutional care. Funded at \$1.7 billion in fiscal year 2009 in regular block grant funds, each State has the flexibility to determine what services will be provided and then either provides services directly or purchases them from qualified providers. States also received a supplemental amount of \$600 million in fiscal year 2009 to provide social services to individuals affected by Presidentially-declared natural disasters, and \$550 million in supplemental FY 2005 funds to address the 2005 Gulf Coast hurricanes.
- ***Empowerment Zones / Enterprise Communities.*** This block grant program provides flexible grants for comprehensive community renewal projects in urban neighborhoods and rural areas designated as Empowerment Zones or Enterprise Communities. The local-level renewal organizations provide the grant funds to neighborhood based service providers for a wide variety of activities, including job training and placement; business assistance and economic development; childcare, after-school care and youth development; substance abuse treatment; health care services; and other supports for working families. While \$1 billion was originally disbursed in 1994, some \$200 million still remain available for use at the State level.

Division of Community Discretionary Programs

- ***Community Economic Development Program.*** Community Economic Development (CED) discretionary grants are awarded to nonprofit community development corporations in disinvested communities for purposes of creating new jobs for low-income individuals, including Temporary Assistance for Needy Families (TANF) recipients. These grants serve as catalysts for attracting additional private and public dollars; for every CED dollar awarded, three-to-five dollars is leveraged. The Community Economic Development grant funds projects such as: business incubators, shopping centers, manufacturing businesses, and agriculture initiatives. \$31.5 million was appropriated in fiscal year 2009.

- ***Job Opportunities for Low-Income Individuals Program.*** Job Opportunities for Low-Income Individuals (JOLI) discretionary grants are awarded to nonprofit organizations to implement a range of job creation strategies. This is a small, highly competitive program. Approximately 10 grants are awarded each year. Job creation strategies for the JOLI program are through self-employment, micro-enterprise, new business ventures and business expansion. \$5.3 million was appropriated in fiscal year 2009.

Division of Energy Assistance

- ***Low Income Home Energy Assistance Program.*** The Low Income Home Energy Assistance Program (LIHEAP) is a block grant program administered by States, territories and Tribes through a network of local community-based organizations. The purpose of LIHEAP is to assist low-income households meet their home energy costs. \$5.1 billion was appropriated in fiscal year 2009. 50 States, the District of Columbia, five territories, and approximately 140 Tribes and Tribal organizations receive LIHEAP grants each year. State and Federally recognized Tribes (including Alaska native villages) may apply for direct LIHEAP funding. A supplemental amount of \$590 million in fiscal year 2009 was awarded to States to address unforeseen energy crises due to emergencies.
- ***Leveraging Incentive Program.*** The law authorizes supplemental Low Income Home Energy Assistance Program (LIHEAP) funding for grantees that acquired non-Federal leveraged resources for their LIHEAP programs in the preceding fiscal year.
- ***Residential Energy Assistance Challenge Option (REACH) Program.*** The law authorizes supplemental LIHEAP funding for grantees to receive competitive grants for implementation through local community-based agencies of innovative plans to help LIHEAP eligible households reduce their energy vulnerability.

Assets for Independence

- The ***Assets for Independence*** (AFI) program is demonstrating and testing the effectiveness of Individual Development Accounts (IDAs) as a tool for enabling low-income individuals and families to become economically self-sufficient. Participating individuals attend financial literacy classes to learn money management, and they save earned income and receive matching funds in their IDA with the goal of acquiring any of three assets: a first home, a business, or post-secondary education. AFI awards grants and provides training and technical assistance to community-based nonprofits and State, local and Tribal government agencies that implement IDA projects. Congress appropriated \$24.5 million for the program in fiscal year 2009. OCS currently administers grants for more than 400 AFI projects throughout the nation. The program has an active portfolio of upwards of \$100 million in grant funding.

Compassion Capital Fund

- The ***Compassion Capital Fund*** (CCF), which was created in 2002, helps faith-based and community organizations increase their effectiveness and enhance their ability to provide social services in their communities. In fiscal year 2009, \$42.7 million was appropriated to CCF, which distributes funds through three competitive grant programs:
 - The CCF Demonstration Program works through intermediary organizations that serve as a bridge between the Federal government and the faith-based and community organizations on which the program focuses; these intermediaries provide technical assistance and financial sub-awards to local organizations to help increase their capacity.
 - The CCF Targeted Capacity Building Program makes one-time 12-month capacity-building grants of \$50,000 each directly to faith-based and community organizations to build the capacity of their own organizations.
 - The CCF Communities Empowering Youth (CEY) program is designed to increase the capacity of community coalitions working to combat gang activity and youth violence.

Strengthening Communities Fund

- The ***Strengthening Communities Fund*** (SCF), which was created in the 2009 Recovery Act, helps faith-based and community organizations increase their effectiveness and enhance their ability to provide social services to address broad recovery issues present in communities. \$50 million was appropriated to SCF, which distributes competitive grants through two programs: economic recovery issues present in communities. \$50 million was appropriated
 - **Nonprofit Capacity-Building Program** – Makes awards of up to \$1 million to lead organizations to provide nonprofit project partners with capacity building training, technical assistance and competitive financial assistance.
 - **State, Local and Tribal Government Capacity Building Program** – Provides awards up to \$250,000 to State, local or tribal government offices responsible for community and faith-based efforts, including to support start-up efforts, to build the capacity of nonprofit organizations.

Office of Refugee Resettlement (ORR)

The ORR Preferred Communities Program supports the resettlement of newly arrived refugees in preferred communities where they have ample opportunities for early employment and sustained economic independence and, to address special populations who need intensive case management, culturally and linguistically appropriate linkages and coordination with other service providers to improve their access to services. As part of the ORR Preferred Communities Program, Lutheran Immigration Resettlement Services (LIRS) administers the Women's Empowerment Program. The primary focus of the program is to provide support to refugee and asylee women to enhance their ability to successfully integrate into U.S. society. The Women's Empowerment Program builds on the strengths of refugee women, such as the ability to adapt to new and difficult situations, a strong sense of community and family, the ability to learn quickly, and eagerness to work. This program provides women an opportunity to learn new skills, facilitate opportunities to connect with women in both the mainstream and refugee communities, and improve their ability to secure gainful employment. This program includes English as a Second Language and literacy classes, informational workshops, mentors, individualized skill building and employment services.

ORR's Ethnic Community Self-Help Program builds bridges between newcomer refugee communities and community resources by assisting refugee community based organizations and other groups that support the integration of newly arriving refugees (and other refugees that maybe in need of such assistance regardless of their resettlement date). Funded services include, but are not limited to: organizing newly arriving refugees for self-help and mutual assistance, organizational and leadership development, civic participation; inspiring self-determination; job readiness and employment assistance; vocational skills for women, linking technical assistance and resources for local ethnic communities; orientation on the background and potential of refugees to the larger community, including establishing and strengthening links with institutions such as schools, crime prevention and law enforcement entities, promoting mediation and constructive conflict resolution, promoting health and mental health services and augmenting agency linkages via internet connections; facilitating information dissemination on ethnic-specific issues; or convening of national or regional meetings and/or conference calls.

ORR's Supplemental Services for Recently Arrived Refugees Program provides services to arriving refugees or sudden and unexpected large secondary migration of refugees where communities are not sufficiently prepared in terms of linguistic or culturally appropriate services. As an example, the International Rescue Committee Burundian Adjustment Program located in Phoenix, Arizona administers a program to promote self-reliance, specifically among women and young children. During the 17 month project period the program will assist more than 200 Burundian refugees, including adjustment assessments for 60 Burundian households and in-home hygiene classes for at least 40 families, including monthly life skills workshops for 100 adults, an education program for 40 mothers of pre-school-aged children, and development-focused activities for 40 preschool-aged children.

Under the Microenterprise Development (MED) and Individual Development Account (IDA) programs, ORR provides Financial Literacy training. Clients are provided training in budgeting, savings, credit scores, etc. as a condition for meeting the larger goals of starting a business (MED) or saving for a particular asset goal in IDA: house, education, small business, or car necessary for employment. In the MED program, 50% of the clients are women. Under the IDA program, the asset goal is identified initially and clients establish a bank account and begin saving toward their goal. A shadow account is established with matching federal funds. Once the savings goal has been met, the asset is purchased using the funds from both accounts.

A number of financial literacy training materials are available to the refugee network from our technical assistance providers and the ORR website. The successful integration of refugee women is key to the success of their children and the U.S. communities where they are resettled.

Below is an example of an ORR grantee that focuses specifically on services to women: The **Refugee Women's Network, Inc. (RWN)**, is located in Atlanta, Georgia. It was created in 1995 as a national non-profit organization created by women, for women, that focuses on enhancing refugee and immigrant women's strength, skills, and courage through leadership training, education and advocacy to promote independence, self-sufficiency, and networking among its participants.

Refugee Women's Network is governed and staffed by refugee and immigrant women from Africa, Asia, Europe, the Middle East, and the Americas.

Currently, RWN focuses its activities on the following four major programs:

- **Microenterprise** – helps women in Atlanta area to start, expand, or strengthen their businesses and attain economic self-sufficiency.
- **Leadership Training** – gives women across the U.S. the skills they need to help their communities develop their own solutions.
- **Health Promoters** – trains women to be health educators and liaisons between their communities and healthcare providers.
- **Advocacy** – promotes increased participation by refugee and immigrant women in decision making processes.

The **Child Support Enforcement Program (CSE)** is a Federal/State/Tribal/local partnership to help families by increasing family income and promoting child well-being. Along with Earned Income Tax Credits and food assistance, child support has become one of the most substantial income supports for low-income single parent families. All States and territories run a child support enforcement program, usually in the human services department, department of revenue, or the State Attorney General's office, often with the help of prosecuting attorneys and courts. Currently, 35 Tribes operate a comprehensive child support program authorized under Title IV-D of the Social Security Act and 9 Tribes operate start-up programs. Services are available to all children living apart from one of their parents, including automatic services for eligible children receiving assistance under the Temporary Assistance for Needy Families (TANF), Medicaid, and certain Foster Care programs. Other families seeking government child support services must apply directly through their State, local, or Tribal agency.

(a) Relevant Statistics: Over 80 percent of poor single parent families eligible for child support participate in the child support program. Most of these families are headed by mothers. In 2004, child support lifted 1 million people out of poverty. In FY 2008, the program collected and distributed \$26.6 billion in child support payments; a 6.8-percent increase over 2007. Paternities established or acknowledged totaled 1.78 million; a 3.1-percent increase over the previous year. Support orders established totaled 1.19 million; a 1.3-percent increase.

OCSE Future Programs: OCSE continues to provide technical assistance and training to State and Tribal CSE agencies to improve outreach and services to both parents, as well as other customers, including ongoing collaborative initiatives such as: the Child Support/Child Welfare Workgroup; the Hispanic Workgroup; Judicial/Child Support Enforcement Task Force; Employer Outreach; and Urban, Interstate, and Interagency, and Tribal initiatives. OCSE funds grants related to family strengthening, expanding health care coverage to children through child support orders, and addressing the impact of the economic downturn on families.

OCSE will continue working with States to improve services to parents and their children and collaborative relationships with a variety of Federal, State, Tribal and local partners. OCSE also will be working on regulations, policies, and projects aimed at strengthening low-income families by fostering economic stability and cooperative parenting skills among low-income parents, increasing the number of children with health care coverage, collaborating with other programs to provide safe and effective services to domestic violence survivors, and providing incentives to non-custodial parents to fulfill financial and emotional support responsibilities.

The **Head Start** program provides funding to local agencies that enroll nearly one million age and income eligible children nationwide. The program's purpose is to promote the school readiness of low income children by enhancing their cognitive, social and emotional development. This is accomplished through the provision of a learning environment that supports children's growth in language, literacy, mathematics, science, social and emotional, physical and creative development and approaches to learning. Children also receive health, mental health and nutrition services and parents are supported with social services as needed. The inclusion of parents in the governance of local programs is one of its most unique attributes. At least half of the children enrolled are girls and many are members of single female headed households. The majority of the local program staff are women.

There are approximately 840,000 three to five year old children and 61,000 pregnant women, infants and toddlers enrolled each year. There are 2,200 grantee and delegate agencies operating 20,000 centers and 50,000 classrooms.

Early Head Start: Early Head Start (EHS) programs not only serve pregnant women, these programs also prioritize enrollment for outreach, recruitment, enrollment of teen parents with an emphasis on staying in school. Some EHS programs are co-located in high schools. Early Head Start has been found to have significant effects for some subgroups on reducing maternal depression and increasing monthly wages of women after enrolling in the program.

In 2008, Early Head Start programs provided services to 10,114 pregnant women. Services include prenatal and postpartum healthcare, mental health interventions, prenatal education on prenatal development, and information on the benefits of breastfeeding, and dental services and exams for expectant women.

Early Head Start programs provide services to pregnant women and their families and during the child's first three years of life in order to impact:

- healthy pregnancies and positive childbirth outcomes;
- supportive postpartum care for the parent(s) and child;
- fully involving fathers in the lives of their very young children; and
- nurturing and responsive care during infancy.

It is expected that pregnant women and their families who receive EHS services will enroll their child in EHS following birth. One goal of serving pregnant women and their families in EHS is ultimately to provide EHS services to their children in the appropriate child development Program Option (Center Based, Home Based, or Combination Option). Planning for the transition to the appropriate child development Program Option should begin at the time the pregnant woman is enrolled in the EHS program.

The Head Start Program Performance Standards describe the services the EHS grantee must provide to pregnant women, and those services that they must **assist** pregnant women to obtain. EHS programs must provide prenatal education on:

- fetal development, including the risks from smoking and alcohol;
- labor and delivery;
- postpartum recovery, including information on maternal depression; and
- The benefits of breastfeeding.

(a) Relevant Statistics

Single Parent Families: Forty-three percent (419,999) of the 978,000 families that are served by Head Start (HS) and Early Head Start (EHS) are two parent families and fifty-seven percent (557,943) of the families are single parent families. Many of these single parents are female headed households. In 2006, 47.9% of the children were living in households with their biological or adoptive mother only (data from Family and Child Experiences Survey (FACES)). Parents with children enrolled in HS and EHS have opportunities to engage in partnerships with staff around family support and goal setting, parent education, adult education/family literacy, leadership development, and professional and career building opportunities.

Homeless Families: In 2007, Head Start Act amendments established homeless children and families as categorically eligible for Head Start and Early Head Start programs. Approximately twenty-six thousand homeless families were served in these programs in 2008. Research indicates that the fastest growing segment of the homeless population is young mothers with children, so we anticipate expanded enrollment of these parents.

Grandparents Raising Grandchildren: The Office of Head Start has funded 13 Early Head Start and Head Start programs around the country to provide specialized services to grandparents raising their grandchildren. Many of these grandparent headed households are female, single grandparents. Community-based Head Start Programs are providing specially tailored support groups, individual case management services, and parent education services to these grandparents.

Females in the Head Start Work Force: From its inception, the Head Start workforce has been predominately female, especially in the positions working most directly with children: teachers, teacher assistants, home visitors, health coordinators, family service workers and others. Many were former Head Start parents who worked their way up from volunteering while their children were in Head Start, moving into aide positions, completing educational and training programs and moving into teaching and coordinator positions. In 2008, 26% of all EHS/HS staff in 2008 were former EHS/HS parents.

Degrees for Female Head Start Teaching Staff: Since 1997, the Office of Head Start has funded institutions of higher education to assist Head Start teaching staff in obtaining two-year and four-year degrees in early childhood education. The personnel who enroll in these degree programs are primarily females from local Head Start.

Math and Science Instruction: Over the past two years, the Office of Head Start has been creating and broadcasting a national series of early childhood math and science webcasts focused on increasing teacher knowledge and skills in the areas of math and science, and in turn increasing early opportunities to learn and pursue math and science. All photos, video clips, and experiences are purposely focused on making the involvement of Head Start girls more prominent and more participatory in math and science experiences in the early years, and to avoid any stereotypic representations, inclusions, actions, or statements by teachers featured in this programming. This series featured six episodes on math and a four-part series on science. The webcasts are accompanied by written guides. This focus on intentional teaching of math and science in early childhood will lay a foundation for continued interest and learning.

Head Start Healthy Marriage Grants: The Office of Head Start currently funds 24 Healthy Marriage grants in local communities. These grantees offer a wide variety of services and interventions. Among the programming offered are relationship education and classes focused on parenting, financial literacy, and women's survival skills. In addition, some grantees host specific events for single women and single female parents. These Head Start agencies also have partnerships with agencies focused on domestic violence prevention and assistance.

Daisy Girl Scouting: Since 1990, Head Start and the Girl Scouts of the United States of America have shared an interagency agreement supporting local opportunities for female graduates of Head Start to join the Daisy Girl Scouts, with orientation to this program happening in the transition from Head Start to kindergarten. Programs voluntarily participate so not all Head Start communities are active with Girl Scouting. Daisy Girl Scouts are welcomed into the Girl Scout family after a year-long program designed especially for girls who are entering kindergarten. The focus of Daisy Girl Scouts is on self-esteem and helping girls strive to succeed in school. Literacy enhancement and leadership training are also offered to their parents. Girl Scouting has also seen an increased participation of young girls of Asian, Hispanic, American Indian, and African American heritage. Parents can continue the Head Start emphasis on parent involvement. Adults who become Daisy Girl Scout leaders receive the benefit of Girl Scout training and program support, further enhancing their ability to nurture their child's growth while increasing their own leadership and job skills. In the "Daisy Girl Scouts-A Head Start on Literacy: Playing in the World of Words" project, female Head Start graduates explore the overall Girl Scout program. With an emphasis on getting "a head start on literacy," age-appropriate activities encourage pre-literacy skill. The Daisy Girl Scouts literacy project is designed with particular sensitivity to the needs and interests of girls from low-income families. Recognizing that low income populations include disproportionate numbers of minorities and single-parent, female heads of households, as well as high rates of illiteracy, limited English proficiency, transience, and unemployment, project services are being designed with (not just "for") participants. Support is bilingual and individualized as needed.

Native American Programs provide discretionary competitive funds to eligible Tribes and Native American non-profit organizations for community-based and community-designed projects focused on social and economic development, language and cultural preservation, and environmental regulatory enhancement.

Project funding is driven by the needs and demands of the communities. While women and girls often benefit from Administration for Native Americans (ANA) project funding they are not specifically targeted, unless the projects select women and girls as their target beneficiaries or participants. Below are descriptions of projects that improve the lives of America's women and girls in education and/or careers in science, financial literacy and work/life balance.

(a) Relevant Statistics: To further build community capacity, ANA provides free training and technical assistance to prospective applicants and to ANA grantees implementing projects. These services are provided through contractors in each ANA geographic region; two of the three T/TA provider companies are minority, women-owned small businesses. These contracts total approximately \$5 million.

Native American Management Services, Inc. (NAMS) is an American Indian, woman-owned, small business providing management support services to the federal government, tribal governments and the private sector. Patricia Parker (Choctaw) and Tonya Parker (Choctaw) founded NAMS in 1992 in the Washington, DC area, after successful careers in both tribal and federal governments. The Parker sisters used their professional expertise, grounded with cultural traditions, to create a company uniquely suited to deliver quality services with excellent leadership and teamwork.

Alaska Summit Enterprise, Inc. (ASE) is a Native woman-owned, Alaska small business corporation. ASE provides management support, coordination, consulting and evaluation services on behalf of federal, state, and local governmental agencies, private sector organizations, and federally recognized tribes and native-owned businesses throughout Alaska, the lower 48 states and the Pacific Basin. ASE was established by current ASE principal Ms. PJ Wilkins-Bell in the 1980s as Alaska Safety Education.

Ongoing/Future Programs:

Education and/or Careers in Science

- **The Educational Excellence Project** (hosted by the Mashkisibi Boys and Girls Club): This two-year project focuses on reinforcing the importance of the commitment to school and academic success. Utilizing elders, teachers, parents, community advisors and community partners, the Education Excellence Project will develop a high yield learning curriculum. The focus areas are discussions with knowledgeable adults, leisure reading, writing activities, homework help and study, community service, and games that sharpen cognitive skills. Five participating teen

members will also receive training as Peer Leaders to help facilitation of learning activities. To date, 33 girls have participated in the Educational Excellence Project.

- **Ike No’eau Native Hawaiian Math and Science Curriculum and Culture Project** (hosted by Partners in Development): Partners in Development is working with the Ka Pa’alana Traveling Preschool and Homeless Outreach to create a culturally sensitive curriculum to improve the math and science skills of pre-school aged Native children living with families below the poverty line. So far, 148 children and 98 caregivers (primarily women) have been recipients of this curriculum.
- **Tribal Leaders Youth Camp** (hosted by the Native Village of Georgetown): These training programs (camps) will introduce youth to career and economic opportunities along the Kuskokwim River - the original territory of the Native Village. One-third of the youth participants are girls.

Financial Literacy

- **The Native Economic Self-Sufficiency Training (NEST) Project** (hosted by Native American Community Services of Erie & Niagara Counties, Inc.): The NEST project will improve the economic stability of urban Native community members by focusing on decreasing debt levels while increasing savings. Through a series of training workshops, attendees will learn to identify and change monetary spending. So far, 32 women have participated in the NEST project to improve their financial literacy.
- **Kukuli I Na Hale ‘Ohana Makepono: Building Family Homes Affordably** (hosted by Nanakuli Housing Corporation): The Nanakuli Housing Corporation is designing affordable and environmentally-friendly modular housing for homestead residents to address the housing needs of Native Hawaiians. The organization focuses its efforts on a comprehensive home repair program; helping people repair credit, walking them through the home loan process, helping them secure down payment assistance, and training families to maintain homes and make minor repairs.

In a recent evaluation visit, ANA staff met two families participating in the project. They are currently working with Nanakuli staff to improve their credit scores and possibly receive loans for new houses. Both families were led by single mothers; one mother had lost her job and the other was a grandmother with a low income who was helping to raise her grandchildren. Both families were thrilled about the prospect of owning a new home and spoke glowingly about the project.

- **Life Skills Development & Economic Security Project for Native Americans** (hosted by the Native American Youth and Family Center): This is a three-year project to provide low income and unskilled American Indian and Alaska Native youth and adults with opportunities to build assets to reduce poverty, prepare for lifelong learning, establish financial security and improve the economy of the region. Out of the 28 current participants, 17 are women. Currently, 11 of the women are eligible for the Individual Development Accounts program for education and micro enterprises, and six more could be eligible as the project continues.

Work/Life Balance

- **East Star Family Center** (hosted by Cumberland County Association for Indian People, Inc.): Cumberland County Association for Indian People, Inc. (CCAIP) has identified the lack of adequate, affordable childcare and housing as specific needs among Lumbee tribal members and other Native Americans in the community. While some community members are employed, rising costs of childcare and rent make it difficult to stay employed. The community and the CCAIP Board of Directors were also concerned about the number of school dropouts and the number of Indian teens involved in anti-social behavior caused by drug and alcohol abuse, crimes to support drug habits, and the number of teen girls becoming pregnant and resulting early marriages and related problems.

This ANA-funded project aims to create a community-based approach to developing and implementing the programs necessary to make the East Star Family Center fully operational. The family center will offer a number of programs to assist families, teen and single mothers, and young girls, achieve success in work and life. The daycare center will open in September 2009.

- **The “Voices of Tomorrow”** (hosted by American Indian Recruitment Programs): The objective of this program is to increase economic and self-expressive opportunities for youth through a specifically targeted, culturally sensitive after-school program. “Voices of Tomorrow” incorporates workshops to promote higher education, decrease dropout rates and gain exposure to employment opportunities. The grantee reports that 95 girls and young women have participated in the program.
- **Winyan Ki Igluonihanipi - Women Reclaiming Sacredness** (hosted by Cangleska, Inc.): This project created a healing center to support Lakota women, their partners, and kinship networks in the reclamation of a healthy and a balanced lifestyle. The project established a facility that provides tangible mental health services and treatment that serves to improve the lives of individuals, families, kinship networks, and the tribal community.
- **Healthy Relationship Skills for Youth** (hosted by the National Indian Women’s Health Resource Center): This project was a partnership with the American Indian Young Women’s Sorority, Gamma Delta Pi (University of Oklahoma), the Chickasaw Nation, and the United Keetowah Band of Cherokees, to develop and implement a Healthy Relationship Skills curriculum and training for youth/young adults ages 11-23.

Disaster Case Management (DCM) is the process of organizing and providing a timely coordinated approach to assess disaster-related needs as well as existing healthcare, mental health and human services needs that may adversely impact an individual's recovery if not addressed. DCM facilitates the delivery of appropriate resources and services, works with a client to implement a recovery plan and advocates for the client's needs to assist him or her in returning to a pre-disaster status while respecting human dignity. The ACF model is based upon the principles of self-determination, self-sufficiency, federalism, flexibility and speed, as well as support to states. Individuals and families focusing on their own needs, resources, and interests are far more likely to reach favorable results for themselves and for the broader community. The purpose of disaster case management is to create a coordinated system that enables an individual or family who has survived a disaster to provide information about their situation to one organization that will help them achieve pre-disaster levels of functioning and equilibrium. The number of women and children that require and receive DCM services is generally high.

Emergency or disaster shelters are set up during disasters to meet the immediate feeding and sheltering needs of an impacted community. Women and children needs are often assessed in these shelters through various entities. Access to key services in disaster shelters, such as childcare and temporary housing, can assist families and particularly women with children to efficiently return to their work/life balance. Services provided in disaster shelters allows mothers to have adequate child supervision while they seek enrollment to social services, new employment opportunities or new housing.

(a) Relevant Statistics: ACF Disaster Case Management Pilot Program

Affected Populations – Client Households:

- 75% of cases are female heads of households
- 39% of individuals are children under 18 years of age
- 22% of cases report the head of household as a single female parent
- 31% of individuals reported a disability
- 48% of registered households report an annual income between \$15k and \$30k yearly
- 7% of registered households report an annual income over 30k yearly
- 25% of registered households not reporting an income

Ethnicities:

- Asian - .01%
- Hispanic - .01%
- African American - 67%
- White - 19%
- American Indian - 1%
- Other - 1%
- Not reporting - 12%

Administration on Aging (AoA)

Programs That Improve the Lives of America's Women and Girls

The Administration on Aging

Our vision for older people is embodied in the Older Americans Act (OAA) and is based on the American value that dignity is inherent to all individuals in our democratic society, and the belief that older people should have the opportunity to fully participate in all aspects of society and community life, be able to maintain their health and independence, and remain in their own homes and communities for as long as possible.

Relevant statistics concerning older women in the United States²⁹:

- Older women outnumber older men at 21.9 million older women to 16.0 million older men.
- Older men were much more likely to be married than older women--73% of men vs. 42% of women. Forty-two percent (42%) of older women in 2007 were widows.
- About 30 percent (10.9 million) of non-institutionalized older persons live alone (7.9 million women, 2.9 million men).
- Half of older women (49%) age 75+ live alone.
- The median income of older persons in 2007 was \$24,323 for males and \$14,021 for females.

Women's Health and Wellness and the Older Americans Act

The Older Americans Act (OAA) provides valuable services for older adults (defined as age 60 years or older). These services and supports are critically important to many older women but also to younger women as women are the predominate caregivers in the United States. Because men have a shorter life expectancy than women, older populations are disproportionately female. Compared to the U.S. elderly population, clients of OAA services are much more likely to be female.

AoA Supportive Services and Nutrition Services Programs

AoA's Supportive Services and Nutrition Services Programs provide formula grants to states primarily based on their share of the national population aged 60 and over. The services provided by these programs include, but are not limited to:

- Access services such as transportation, case management, and information and assistance;
- In-home services such as personal care, chore, and homemaker assistance;
- Community services such as legal services, mental health services, and adult day care;

²⁹ Principal sources of data are the U.S. Bureau of the Census, the National Center on Health Statistics, and the Bureau of Labor Statistics.

- Congregate nutrition services in a variety of settings, including senior centers; and,
- Home-delivered nutrition services for individuals who are homebound due to illness, disability, or geographic isolation

Seventy-one percent of clients receiving home-delivered meals were female, corresponding to a female-to-male ratio of 244 women to every 100 men. Eighty-four percent of clients receiving transportation services were female (a female-to-male ratio of 506 to 100) and 76 percent of caregivers were female (a sex ratio of 312 females to 100 males). Females served by OAA programs were more likely to live alone than males; 38 to 50 percent of male program clients of home-delivered meals or transportation services reported living alone, compared to about two thirds (65 to 70 percent) of female clients. Slightly more care recipients were female (61 percent), which is likely to reflect the fact that women more often live longer than men and therefore need the assistance of a caregiver.

AoA Health, Prevention and Wellness Program

Older Americans are disproportionately affected by chronic diseases and conditions, which include arthritis, diabetes and heart disease, as well as by disabilities that result from injuries such as falls. Complicating this picture is the presence of multiple chronic conditions. Adults ages 65 years and over have more chronic conditions – especially 2 or more chronic conditions, than any other age cohort. More than one-third of adults 65 or older fall each year. Twenty-one percent of the population age 60 and older – 10.3 million people – have diabetes. Seven of every 10 Americans who die each year, or more than 1.7 million people, die of a chronic disease. Chronic disease not only kills, but it may also negatively affect one’s quality of life, as well as threaten the ability of older adults to remain independent within their own homes and communities.

To address the challenges that older Americans and the health and long-term care systems face, the Administration on Aging (AoA) created the Evidence-Based Disease and Disability Prevention (EBDDP) Program using its discretionary grants authority under the Older Americans Act in 2003. This program awards competitive grants designed to empower older adults of all races and ethnicities to take more control over their own health through behavior and lifestyle changes that have proven effective in reducing the risk of disease, disability, and utilization of health care services, such as emergency room visits, among the elderly population. This effort is consistent with the President’s and HHS’ emphasis to help Americans of all ages and their health care providers manage chronic diseases while using health care services as effectively and efficiently as possible.

The centerpiece of AoA's EBDDP program is the Chronic Disease Self-Management Program, which 27 states are currently delivering at hundreds of local sites. Developed at Stanford University's Patient Education Research Center by Dr. Kate Lorig with support from the Agency for Healthcare Research and Quality (AHRQ), this program is a six-week workshop designed to empower individuals of all ages with various chronic diseases to take control of their health by encouraging the adoption of self-efficacious positive behaviors, ranging from healthy eating and exercising, to learning skills that enable more effective communication between an individual and his or her medical provider. This program has been shown to significantly improve participant health status while reducing the use of hospital care and physician services. Participant EBDDP program data from 2003-2008 indicates that over 75% of the approximate 17,000 participants were women, most of whom were 70 years and older.

AoA National Family Caregiver Support Program

The National Family Caregiver Support Program (NFCSP), established in 2000, provides formula grants to States and Territories to fund a range of supports that assist family and informal caregivers to care for their loved ones at home for as long as possible. Families are the major provider of long-term care, but research has shown that caregiving exacts a heavy emotional, physical and financial toll. Many caregivers who work and provide care experience conflicts between these responsibilities. Twenty two percent of caregivers are assisting two individuals, while eight percent are caring for three or more. Almost half of all caregivers are over age 50, making them more vulnerable to a decline in their own health, and one-third describe their own health as fair to poor.

The NFCSP offers a range of services to support family caregivers, including:

- information to caregivers about available services,
- assistance to caregivers in gaining access to the services,
- individual counseling, organization of support groups, and caregiver training,
- respite care, and
- supplemental services, on a limited basis

Caregivers of frail older individuals are usually family members or friends who informally take on the role of providing care to an ailing loved one; indeed, 41 percent of people receiving OAA-funded caregiver support services were spouses of the care recipient. Among those caring for their spouse, it was more likely that a wife was caring for her husband, as 66 percent of spouse caregivers were female. Almost the same fraction of caregivers was a daughter or daughter-in-law (40 percent). Almost four times as many caregivers were daughters (or daughters-in-law) than sons (or sons-in-law), reflecting the tendency for women than for men to be the more likely caretaker of parents.

Almost half (47 percent) of all caregivers served by AoA programs in 2005 were retired. About one in five (18 percent) were not working at all, and 12 percent were working part-time. The fraction of caregivers who reported being retired varied by gender; 66 percent of men said they were retired compared to only 41 percent of women. Twenty-three percent of female caregivers—but only 6 percent of male caregivers—said they were not currently working (as opposed to retired). Female caregivers were twice as likely as men to be working part-time while caregiving (13 percent versus 6 percent). Females were more likely than males to have their participation in the labor force interrupted by the responsibilities of caregiving. Of the two-thirds of caregivers who said they were either not working or retired, 27 percent said they quit their job because of caregiving responsibilities (not shown). This effect was about twice as high among women than men; 30 percent of women—but only 17 percent of men—reported that they had to quit work in order to keep up with their caregiving responsibilities.³⁰

AoA Alzheimer's Disease Supportive Services Program

The Alzheimer's Disease Supportive Services Program (ADSSP) provides competitive awards to states to expand the availability of community-level supportive services for persons with Alzheimer's Disease and related disorders (ADRD) and their caregivers. In collaboration with the Aging Network and a variety of state and community-level partners, the ADSSP supports efforts to create and maintain responsive, integrated, and sustainable service delivery systems for persons and families impacted by dementias across the United States. Through the ADSSP, AoA and its partners utilize a multi-pronged, collaborative approach to achieve several goals including:

- Deliver supportive services and facilitate informal support for family caregivers of persons impacted by dementia.
- Translate evidence-based research into practice and advance state initiatives toward coordinated systems of home and community-based care.
- Provide individualized and accessible information, education, and referrals about diagnostic treatment and related services; sources of assistance for services; and legal rights of people affected by dementia.
- Link public and nonprofit agencies that develop and operate community-based supportive, educational, and diagnostic services within the states for individuals and families seeking services.

Though women are only slightly more likely to develop Alzheimer's than men, its prevalence among women is roughly twice as high simply because women live longer. It has been estimated that one in six women are at risk for developing Alzheimer's disease (AD) in their lifetime, while the risk for men is one in ten. It is also estimated that half of all women over 85 in the U.S. will eventually develop Alzheimer's disease.

³⁰ Results from the Administration on Aging's Third National Survey of Older Americans Act Program Participants *Final Report March 12, 2008*.

AoA Women and Retirement Planning Program

The National Education and Resource Center on Women and Retirement Planning was established through a cooperative agreement between the Administration on Aging (AoA) and the Women's Institute for a Secure Retirement (WISER). The goal of the Center is to provide women with access to a one-stop gateway that integrates financial information and resources on retirement, health, and planning for long-term care into ongoing programs such as Older Americans Act Nutrition and Supportive Services Programs.

WISER is making user friendly financial education and retirement planning tools available to traditionally hard-to-reach women, including average and low income women, women of color and women with limited English speaking proficiency, rural and other "under served" women. WISER's strategy for reaching these women and their families is to enlist the assistance of strategic public-private coalitions as volunteers and trainers. WISER's "Aging Network Advisory Council," which is composed of representatives of 15 organizations from across the country promotes nationwide outreach on financial education and retirement planning through the formation of strategic partnerships. Coalition memberships include national and local women's organizations, local government agencies, representatives of the business and financial sectors and the National Network on Aging.

Through these diverse coalitions, the Center is providing women with needed access to financial expertise. Information is offered through financial and retirement planning programs such as model programs, and workshops tailored to meet their special needs, and publications in hard copy and Web based formats. Materials include booklets such as "Financial Steps for Caregivers," and fact sheets such as "How to Start Saving" available in English, Spanish and Korean. This one stop gateway is helping women nationwide to access comprehensive, culturally competent financial and retirement planning information. Ultimately, the efforts of WISER and AoA are enabling women to attain information that can lead to secure retirements.

Key Statistics that highlight the importance of retirement planning for women:

- 60 % of women over age 14 participate in the workforce
- Two thirds of working women earn less than \$30,000 per year
- Over the next two decades, nearly 40 million women will reach retirement age
- Women have less retirement income than men, largely because of lower earnings
- Women's median Social Security income is 70% of men's income
- Many older women rely on Social Security as their only income source in retirement; they have no retirement plan and little savings.

The Center has provided financial and retirement planning information through the following:

- **Workshops:** Over the course of its operation, the Center has conducted more than 20,000 workshops on strategies to access financial and retirement planning information for women. In the past three months alone, WISER has presented 150 workshops that reached approximately 3,000 women nationwide.
- **Newsletter:** During the same period, through their newsletter, WISER disseminated over 10,000 pieces of financial and retirement planning information tailored to the specific needs of hard-to-reach women.
- **Web Site:** The WISER Web site contains information of importance to women in categories ranging from money basics, investments, pensions and social security to health, caregiving and long-term care.
- **Publications:** Several publications including a monthly newsletter, 72 fact sheets, materials available in Spanish, Portuguese, Korean and Vietnamese, present concise, easy-to-understand information on important financial topics.

Future Programs and Overarching Recommendations

Older women outnumber older men at 21.9 million older women to 16.0 million older men. According to the 1998 National Elder Abuse Incidence Study, women make up 71 percent of the victims of domestic elder abuse. It is not clear, however, what proportion of these women are victims of elder abuse, or victims of late life domestic violence. Elder abuse, broadly defined, includes physical, sexual and emotional abuse, financial exploitation, neglect and self-neglect, and abandonment. The distinctive context of domestic abuse in later life is the abusive use of power and control by a spouse/partner or other person known to the victim. Unfortunately, when a woman who has been a victim of domestic violence turns 60, she is often left without the supports she has relied on, as most domestic violence programs are not prepared, trained, or understand how the needs of older women may differ from those of younger victims.

Although AoA has an array of programs that support women's health and well-being, including the Elder Abuse Prevention Program and the National Center on Elder Abuse, more could be done throughout HHS to specifically consider and address the needs of older women victims of late life domestic violence. It is recommended the following be considered in future programming targeting women:

- Reports and studies conducted by or for HHS, such as on domestic and interpersonal violence, should include specific questions designed to target older women victims. To date, many reports or studies cite elder abuse statistics generally. Secondary sources of information do not accurately capture those victims of late life domestic violence.³¹ Many times what is classified as elder abuse is, in reality, intimate partner violence. Such misidentification results in older victims not receiving effective interventions.

³¹ Example: "Addressing Interpersonal Violence in the Wake of Disaster: Opportunities for Action in Disaster Preparedness and Response". Report prepared for the U.S. Department of Health and Human Services' (HHS) Health Resources and Services Administration (HRSA), Office of Women's Health

- AoA is unaware of any federal efforts targeting the education of health care providers about late life domestic violence, although research demonstrates older victims of even modest forms of abuse have dramatically (300%) higher morbidity and mortality rates than non-abused older people, all other factors being equal.³² While 75% of hospital emergency departments have protocols for dealing with child abuse, only 27% have elder abuse protocols.³³ In addition, despite mandatory reporting laws in most states, physicians report only 2% of all reported cases of elder abuse, including late life domestic violence.³⁴

(OWH), and the Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Mental Health Services (CMHS) by Nina Kammerer, Ph.D., under contract to Policy Research Associates, Inc. (2007).

³² Lachs, M.S., Williams, C.S., O'Brien, S., Pillemer, K.A., & Charlson, M.E. (1998). "The Mortality of Elder Mistreatment." *JAMA*. 280: 428-432.

³³ McNamara R.M., Rousseau E., Sanders A.B. (1992) "Geriatric emergency medicine: a survey of practicing emergency physicians." *Annals of Emergency Medicine*. 21:796-801.

³⁴ Rosenblatt D.E., Cho K., Durance P.W. (1996). "Reporting mistreatment of older adults: the role of physicians." *Journal of the American Geriatric Society*. 44: 65-70.

Agency for Healthcare Research and Quality (AHRQ)

Agency Overview

The mission of the Agency for Healthcare Research and Quality (AHRQ) is to improve the quality, safety, efficiency and effectiveness of health care through health services research. AHRQ supports research on all aspects of health care provided to women. This includes enhancing the response of the health care system to women's needs; understanding differences between the health care needs of women and men; understanding and eliminating disparities in health care; and empowering women to make better health care decisions. AHRQ's Senior Advisor for Women's Health and Gender Research coordinates agency activities pertaining to research on women's health, and is an active member of the Department of Health and Human Services (DHHS) Coordinating Committee for Women's Health.

Programs That Improve the Lives of the Federal Workforce

Current AHRQ Wellness/Life balance program includes the following activities for all employees:

Physical Activities

- a. Yoga
- b. Pilates
- c. Boot Camp
- d. Dance
- e. Access to a Wellness Center at a low cost to Agency and employees

Nutrition

- f. Weight Watchers

Lactation Room

- g. Available for all nursing mothers.
- h. Includes a door that locks, a comfortable chair, a mini-fridge, and storage for breast pumps

Automated External Defibrillator

- i. Available on each floor now.
- j. Staff members on each floor will be trained in using the tool.

Communications related to health and healthcare:

- k. AHRQ Intranet – Wellness program has posted information
- l. Wellness Program Charter and Statement of Work were developed and approved in 2008. The documents are on the AHRQ Intranet.
- m. Email – program activities are communicated regularly via email

Environment

- n. Wellness Room which offers a dedicated wellness space where employees can relax
- o. Stairwells were improved to encourage staff to use the stairs more

Alternative Work Schedules

- p. Alternative work schedules are made available to all employees. Women comprise 71% of those who have chosen to telework.

Evaluations

- q. Formal
 - i. Two formal surveys have been done since the inception of the wellness program. The most recent was completed in November 2008.
 - ii. Class participation is tracked regularly using sign up sheets. Average class participation is 5 people per class. Many classes have had more participants lately. This may be due to the improved space in which the classes are held.
- r. Informal
 - i. Information is collected on a regular basis via email
 - ii. Programs and specific activities have been implemented based on the feedback received.

Programs That Improve the Lives of America's Women and Girls

1. Program Description:

Health services research pertaining to women is supported through all AHRQ portfolios and centers, and all AHRQ program announcements address the importance of including both women and men in AHRQ-supported research studies. Over the years AHRQ has also collaborated with other DHHS agencies/components (e.g., CDC and ASPE) on research on women's health.

AHRQ's approach to the improvement of gender-sensitive and women-specific healthcare services is based on research; the synthesis, dissemination, and implementation of research; as well as the development and dissemination of practical tools for implementation in actual healthcare practice settings.

- a) **Relevant Statistics:** A cross-section of AHRQ-supported extra/intramural and interagency health services research includes women-specific/sensitive approaches and outcomes to healthcare services. AHRQ has produced outcomes on a variety of research topics.

- The program brief titled “Women’s Health Highlights: Recent Findings” (<http://www.ahrq.gov/research/womenh1.htm> - AHRQ Pub No. 05-P020, April 2009) provides a summary of findings from a variety of research projects on women’s health supported by AHRQ and published between Jan 2005-Dec 2008. This document addresses cardiovascular disease; cancer screening and treatment; reproductive health; chronic illnesses and their care; health impact of violence against women; health care costs; access to care; health care quality and safety; medications; and data sources for gender research.
- AHRQ-supported investigators seek ways to narrow the gap between white and minority women’s health services, to ensure that women of all races and cultural backgrounds receive high-quality health care. The program brief titled “Health Care for Minority Women” (AHRQ Pub No. 09-PB003, April 2009) provides recent research findings pertaining to minority women’s health. This brief addresses topics such as cancer screening and treatment; cardiovascular disease; cancer screening and treatment; impact of violence on health; reproductive health; data sources; health care projects that address minority women; chronic illnesses; mental health issues; health care access and costs; health care quality and safety; management of healthcare; etc.
- AHRQ-supported Centers for Education and Research on Therapeutics (CERTs) conduct research and provide education that are intended for advancing the best use of therapeutics (i.e., drugs, medical devices, and biological products). This program seeks to increase awareness of the benefits and risks of new, existing, and combined uses of therapeutics, thereby improving the effectiveness and safety of their use. The program brief titled “CERTs Research: Women’s Health” (in press) offers knowledge compiled from work conducted in the last five years, to be used by providers, women patients, and policymakers, to improve the use of therapeutics for women.
- AHRQ supports vigorous research focused on breast, cervical, ovarian and other cancers that impact women. This research addresses women’s access to accurate diagnoses, appropriate referrals for procedures, and optimal use of proven therapeutics for cancer. The program brief titled “Cancer Screening and Treatment in Women: Recent Findings” (AHRQ Pub No. 09-PB004, April 2009) provides the outcome findings of studies that were conducted in the last five years.

- AHRQ supports the career development of health services researchers through three types of grant programs: 1) National Research Service Award (NRSA) Program, which supports the pre-doctoral and post-doctoral training of clinical and non-clinical research scientists through institutional grants; 2) Dissertation Program, which supports the dissertation part of doctoral work; and 3) Career Development Program, which supports mentored and non-mentored career development support.
- Participation in the NIH-initiated BIRCWH Program allows AHRQ to support the mentored research career development of junior faculty members who have recently completed clinical training or postdoctoral fellowships, and who will be engaged in research relevant to women's health and/or sex/gender factors. The goal of this initiative is to increase the number and skills of investigators through a mentored research and career development experience, leading to an independent scientific career that will benefit the health of women. Currently AHRQ is co-sponsoring three BIRCWH grants, which focus on health services research relevant to women.
- An ongoing AHRQ technical assistance program for prospective grantees includes information and training related to the development of applications with credible financial plans, which are designed within certain budgetary restrictions and offer accurate/acceptable cost.

2. Future Programs:

- **Evaluation of Women's Health and Gender-sensitive Research at AHRQ.** The purpose of this evaluation study is to: 1) conduct content analysis on past and on-going AHRQ-funded research, knowledge synthesis, dissemination, and implementation activities/products that focus on gender-sensitive and women-specific healthcare issues; 2) identify important gaps and emerging areas for gender-sensitive and women-specific health services research not addressed by AHRQ or other organizations in the field; and 3) develop a set of gender-sensitive and women-specific health services research objectives through an AHRQ-supported agenda for women's health and gender research for the next decade.

- **Target Populations:** The target population for the content analysis component of this evaluation will be all women and girls included in AHRQ research studies to date. However, if the gap analysis component of this evaluation identifies emerging health services issues pertaining to particular subpopulations of women and girls, then appropriate research addressing the needs of those subpopulations will be recommended for inclusion in AHRQ's research agenda.
- **Benchmarks:** This evaluation study will be completed in the next 12-18 months, and will ideally lead to a set of gender-sensitive and women-specific health services research objectives, to be incorporated in the agendas of AHRQ research portfolios.
- **Virtual Laboratory for Women's Health Services Research.** In order to best study women of all backgrounds and needs within each state, access to multiple databases representing different geographical areas, healthcare systems, and racial/ethnic/socioeconomic groups is necessary. Currently, accessing data from multiple databases is difficult, as each data repository has specific legal, proprietary, and human subject protection concerns. AHRQ is in the process of setting up a virtual laboratory for the development of a data warehouse prototype, which can be adopted and adapted by all states across the country. California has been selected for the development of the prototype due to its geographic and demographic diversity, as well as the availability of multiple state and academic databases. The initiative will include the creation of a coalition of governmental, academic, and private entities within the State of California, to collaboratively provide public access to the databases of their institutions, in order to answer research questions relating to the health and healthcare of women and minorities. This project will result in a data warehouse containing public use de-identified data files, with documentation that can be accessed using an easy to use interface, and that is available for a wide range of investigations by a broad segment of the research community. Once developed, this data warehouse prototype will be available for adoption and adaptation by all states of the USA.
 - **Target Populations:** Women living in the boundaries of any state.
 - **Benchmarks:** The prototype for state-based data warehouse will be available for adoption and adaptation by all states of the USA within the next 12-18 months.

Overarching Recommendations

- In spite of advancements in women's health services research through the efforts of AHRQ and other organizations, there is need for more focused attention to gender-sensitive and women-specific health services research. We are beginning to recognize many differences in men and women pertaining to disease manifestation and the process of care variables, which may explain some of the male-female differences in treatment outcomes. The evaluation study described above will be instrumental in identifying important and emerging gender-sensitive and women-specific health services research objectives to be adopted by AHRQ. However, the adoption of such evaluation-based recommendations for research would depend on the availability of appropriate funds, without which AHRQ and the field will miss an invaluable opportunity for addressing emerging healthcare issues for women through innovative healthcare approaches. Therefore, funding support for the implementation of the recommended research will be necessary.
- Leveraging of existing data is a cost-efficient way to perform research on women's issues. Once the prototype for state-based data warehouses (described above) has been developed, states would need financial assistance in the adoption, adaptation and institutionalization of state-specific data warehouses.

Centers for Disease Control and Prevention (CDC)

Programs That Improve the Lives of the Federal Workforce

CDC Lactation Support Program

Implemented in September 1996 as a component of the CDC WorkLife Programs for staff, the nationwide *Lactation Support Program* is designed to help educate expectant parents and provide a supportive environment for nursing mothers. The program includes a breastfeeding class, unlimited phone consultation with a certified lactation consultant, worksite lactation rooms with a hospital-grade Medela pump, return to work consultation, and breastfeeding discussion groups called "Baby Talk." The program goals include: 1) providing education for parents-to-be on the importance of breastfeeding; 2) providing support to new mothers after delivery with unlimited phone counseling with a lactation consultant; and 3) meeting the needs of mothers returning to work by providing a return-to-work consultation and an equipped lactation room at the worksite that will allow mothers to continue supplying the important nutritional benefits of breast milk.

CDC started the program with one lactation room at the Atlanta Clifton Road facility and approximately 52 participants. Today there are 28 lactation rooms at various CDC facilities including seven locations outside Atlanta. Over 200 mothers are currently enrolled in the program. In 2007, 77 percent of the mothers continued to breastfeed at one year, which far exceeds the Healthy People 2010 goal of 25 percent at one year. In addition, CDC has a Breastfeeding Listserv, which is a voluntary electronic community of parents of infants, and young children who are interested in breastfeeding or supporting breastfeeding women. The listserv provides the opportunity to share personal thoughts and recommendations about breastfeeding. Due to increased registrations for the breastfeeding classes, the program expanded this year to include additional classes and monthly breastfeeding discussion groups in order to provide mothers with multiple opportunities to attend.

Future program plans include increasing the number of lactation rooms with the goal of a lactation room in every CDC building, requesting dual-station lactation rooms in large buildings to accommodate two users at a time, and promoting focused programs for staff in field locations and in lower graded positions.

(Atlanta Human Resources Center, Workforce Relations Division; and Program Support Center, HHS)

<http://www.cdc.gov/breastfeeding/index.htm>

CDC/ATSDR Women's-Network-Listserv

The CDC/ATSDR Women's-Network-Listserv is envisioned as a voluntary electronic community of people who desire happy and healthy lives. Work on the listserv began in spring 2009. The planned CDC/ATSDR Women's-Network-Listserv will help CDC employees interested in learning how to be healthy women, spouses, partners, sisters, daughters, and moms, giving their best to families, friends, co-workers and the global community. The CDC/ATSDR Women's-Network-Listserv will welcome women and their friends of all shapes and sizes who are interested in addressing issues and concerns of women. Plans are to launch the CDC/ATSDR Women's-Network-Listserv by the end of 2009.

(Centers for Disease Control and Prevention, National Center for Preparedness, Detection & Control of Infectious Diseases, Office of Minority and Women's Health)

Telework

In November 1991, CDC began participation in a one-year pilot of the Federal Flexible Workplace Program sponsored by the President's Council on Management Improvement. Twenty-eight employees throughout the agency participated in the pilot. Participants were required to work a minimum of two days a week at the official duty station. The pilot was successful and expanded to include 36 participants.

In April 1995, the Public Health Service developed the Flexible Workplace Arrangements Program, commonly referred to as Flexiplace, to allow civil service employees and Commissioned Corps officers to work from home or another alternate duty station. In mid-1995, CDC began drafting a policy for a permanent program. CDC implemented the agency policy in February 1996, then known as the Flexible Workplace Arrangements Program.

In November 2006, a second pilot program began with 125 participants. CDC provided telework training for employees and supervisors, and distributed encrypted laptops to replace the office desktop and included a multifunction printer/scanner/fax. The employee agreed to share office space, if required, and was responsible for providing the high-speed internet connection with partial agency reimbursement. In 2008, the telework policy was revised as a result of the pilot program and now requires teleworkers to provide the internet connection with the agency providing the required computer equipment. To assist supervisors in determining eligibility for telework, we developed a Telework Determination form to analyze the job functions and employee characteristics. This has served as an effective tool in assessing the number of positions that meet the telework criteria. Of 9386 civil service positions, 7210 have been determined telework eligible.

With the growth of telework over the years, we now have 1926 core teleworkers with a participation rate of 26.7%.

Future program plans include:

- *Developing agency specific telework training for employees and managers
- *Creating a Telework Management Officer position for program administration

*Developing an electronic telework registration and tracking system for reporting

Programs That Improve the Lives of America's Women and Girls

Program Descriptions

National Breast and Cervical Cancer Early Detection Program (NBCCEDP): The NBCCEDP provides clinical breast examinations, mammograms, pelvic examinations, and Pap tests, as well as diagnostic follow-up for women with abnormal screening results. Eligible women diagnosed with cancer are referred to treatment by the state Medicaid program. Within its 68 funded programs, the NBCCEDP provides free or low-cost breast and cervical cancer screening and diagnosis to low-income, uninsured, and underinsured women, with special attention to women 50-64 years of age, women who have not been screened within the last five years or more, and certain racial and ethnic minority groups.

In FY 2008, CDC funded 50 states, the District of Columbia, 5 U.S. territories, and 12 American Indian/Alaska Native tribes or tribal organizations, to provide clinical screening and diagnostic services to medically underserved women.

Sixty percent of the state funds are used for clinical services including case management and the remaining 40 percent for public health infrastructure to support an effective screening program. This includes public awareness and education; outreach and recruitment; professional development; quality assurance and quality improvement; tracking, surveillance, and evaluation; and, program management.

CDC and its 68 grantees collaborate with an array of partners, including the American Cancer Society, Avon Foundation, and Susan G. Komen for the Cure, to increase cancer awareness and access to breast and cervical cancer early detection and treatment services.

- a) In 2008, the NBCCEDP: 1) Screened 301,209 women for breast cancers;
- 2) Detected 3,792 breast cancers;
- 3) Screened 321,298 women for cervical cancer using the Pap test; and,
- 4) Found 11,703 pre-malignant cervical lesions and invasive cervical lesions. CDC estimates that the NBCCEDP serves approximately 15 percent of women aged 40-64 years who are eligible for mammography screening and approximately 8.7 percent of women aged 18-64 years who are eligible for Pap test screening (cervical cancer screening).

Ovarian Cancer: Since 2000, CDC has developed public health activities aimed at reducing ovarian cancer morbidity and mortality. CDC currently supports seven cancer projects in California, Florida, Michigan, New York, Pennsylvania, Texas, and West Virginia through the National Comprehensive Cancer Control (NCCC) Program and Ovarian Cancer funds. These projects represent the coordinated efforts of the NCCC Programs and their key partners to increase awareness and understanding of ovarian cancer among the public, health care professionals and other decision makers.

CDC supports specific ovarian cancer research activities at CDC's Prevention Research Centers. The primary objective of these studies is to identify factors that distinguish women diagnosed with ovarian cancer at stages one and two from those diagnosed at a later stage. Another objective is to examine the barriers to ovarian cancer diagnosis and treatment.

CDC has initiated a number of projects, including studies of ways in which women decide to seek medical care for nonspecific symptoms, risk perception and use of ovarian cancer screening among women at different levels of risk, clinical practice in the follow-up of ovarian masses, and ovarian cancer treatment patterns and outcomes. Additionally, CDC funds education programs in Alabama, Colorado, and West Virginia.

CDC's National Program of Cancer Registries (NPCR) collects surveillance data for all cancers, including ovarian and other gynecologic cancers. Data collected through the NPCR often are used by states to create burden assessments that guide program planning, outreach, and education efforts.

- a) All women are at risk for ovarian cancer, but older women are more likely to get the disease than younger women.³⁵ About 90 percent of women who get ovarian cancer are older than 40 years of age, with the greatest number being aged 55 years or older. In 2005, 19,842 women in the United States were told that they have ovarian cancer, making it the second most common gynecologic cancer, after uterine. Ovarian cancer causes more deaths than any other gynecologic cancer in the U.S., but it accounts for only about 3 percent of all cancers in women.

Gynecologic Cancer: Inside Knowledge: Get the Facts About Gynecologic Cancer is an initiative that supports the Gynecologic Cancer Education and Awareness Act of 2005, or Johanna's Law. In FY 2006, CDC received funding to develop a national gynecologic cancer campaign to raise awareness of consumers, providers, and program planners about health issues and concerns related to gynecologic cancers. CDC, in collaboration with the Department of Health and Human Services' Office on Women's Health, developed the *Inside Knowledge* campaign to:

- Raise awareness of the five main types of gynecologic cancer: cervical, ovarian, uterine, vaginal, and vulvar (a sixth type of gynecologic cancer is the very rare fallopian tube cancer)
- Develop materials that convey the messages that many cancers are curable if detected early and treated appropriately; and
- Educate women and health care professionals about the signs and symptoms of specific gynecologic cancers, screening tests (if available), risk factors and prevention strategies.

³⁵ Ovarian Cancer. Available at <http://www.cdc.gov/cancer/ovarian/index.htm>.

CDC developed messages intended for women between the ages of 40 to 60. CDC developed consumer-oriented materials that include the following:

- Campaign identity and logo that provides the opportunity for the tailoring and adaptation for each of the individual gynecologic cancers.
- Gynecologic Cancer section on CDC's website.
- Consumer/patient fact sheets on ovarian, cervical, uterine, and vaginal and vulvar cancers which are also posted on CDC's website.

Racial and Ethnic Approaches to Community Health across the United States (REACH U.S.): The REACH program supports community coalitions that design, implement, evaluate, and disseminate community-driven strategies to eliminate health disparities among racial and ethnic populations. Racial and ethnic groups targeted include African American/Black, American Indian/Alaska Native, Asian, Native Hawaiian/Other Pacific Islander, and Hispanic/Latino. Although, REACH U.S. targets 6 health priority areas; the two that impact women are breast and cervical cancer and infant mortality. The REACH U.S. program continues to demonstrate that health disparities can be reduced and the health status of groups most affected by health inequities can be improved. This program has developed innovative approaches that focus on racial and ethnic groups and is improving people's health in communities, health care settings, schools, and work sites. Other Agencies Involved: National Center on Minority Health and Health Disparities/National Institutes of Health.

a) Although breast cancer is diagnosed 10% less frequently in African American women than in white women, African American women are 34% more likely to die of the disease. American Indian women are 1.7 times more likely to die of cervical cancer than white women. Infant mortality rates among American Indians/Alaska Natives are 1.4 higher than among non-Hispanic whites. Rates of cervical cancer among Vietnamese/American women are higher than rates among any other ethnic group in the United States—5 times higher than non-Hispanic white women. In 2004, Hispanic women were twice as likely as non-Hispanic white women to be diagnosed with cervical cancer.³⁶

WISEWOMAN: The WISEWOMAN program provides low-income, under insured or uninsured women aged 40–64 years with chronic disease risk factor screening, lifestyle intervention, and referral services in an effort to prevent cardiovascular disease. CDC funds 21 WISEWOMAN programs, which operate on the local level in states and tribal organizations. WISEWOMAN programs provide standard preventive services including blood pressure and cholesterol testing. WISEWOMAN programs also offer testing for diabetes. Women are not just tested and referred, but can also take advantage of lifestyle programs that target poor nutrition, physical inactivity, and smoking, such as healthy cooking classes, fitness competitions, or quit-smoking classes. The interventions are designed to promote lasting, healthy lifestyle changes.

³⁶ Racial and Ethnic Approaches to Community Health (REACH U.S.) Finding Solutions to Health Disparities At A Glance 2009. Available at <http://www.cdc.gov/nccdphp/publications/aag/reach.htm>.

a) From 2000 to mid-2008, WISEWOMAN reached over 84,000 low-income women across America and identified 7,674 new cases of previously undiagnosed hypertension, 7,928 new cases of undiagnosed high cholesterol, and 1,140 new cases of undiagnosed diabetes.³⁷ These women would have been unaware of their risk factors if not for this program. WISEWOMAN has also provided more than 210,000 lifestyle interventions during that time. Due to its success in reducing risk for chronic diseases, WISEWOMAN was found very cost-effective in a study conducted in 2006. In the study, WISEWOMAN extended women's lives at a cost of \$4,400 per estimated year of life saved, as opposed to a much higher bypass surgery expense of \$26,000 per estimated year of life saved.

Public Health Initiative on Diabetes and Women's Health (DWHI): The DWHI which is co-sponsored by CDC, the American Diabetes Association, the American Association of Diabetes Educators, the American Public Health Association, and the Association of State and Territorial Health Officials, provides a national public health action plan to address the specific impact of diabetes and its complications on girls and women across the life span. The action plan includes national objectives, which focus on gaps that currently exist for women with diabetes in the following areas: community health, education and community outreach, quality care, research and surveillance.

a) The DWHI collaborated with the Agency for Healthcare Research and Quality (AHRQ) to develop a report, *Women with Diabetes: Quality of Care, 2004-2005*. This report assessed data from three nationally representative surveys and describes the quality of care that women with diagnosed diabetes receive in the United States. The report includes measures of access to healthcare, general health and well-being, diabetes-specific preventive care, immunization, and other complications. By stratifying data by sex, this report revealed specific subpopulations of women with diagnosed diabetes that may be vulnerable to receiving low levels of preventive care services.

Advocates for Youth (AFY): CDC funds Advocates for Youth (AFY) to provide Capacity-Building Assistance for Preventing HIV Infections in Organizations that Serve African American and Latina Females. AFY is dedicated to creating programs and advocating for policies that help young people make informed and responsible decisions about their reproductive health.

AIDS Alliance for Children, Youth, and Families (AIDS Alliance): CDC funds AIDS Alliance for Children, Youth, and Families (AIDS Alliance) to provide Capacity-Building Assistance for Preventing HIV Infections in Organizations that Serve African American and Latina Females. AIDS Alliance was established in 1994 to give voice to the needs of women, children, youth, and families living with and affected by HIV and AIDS.

³⁷ WISEWOMAN: Capitalizing on Opportunities to Improve the Health of Women. Available at http://www.cdc.gov/wisewoman/about_us.htm.

Girls Inc.: CDC funds Girls Inc. to provide Capacity-Building Assistance for Preventing HIV Infections in Organizations that Serve African American and Latina Females. Girls Inc. provides educational programs to millions of American girls, particularly those in high-risk, underserved areas; the organization is dedicated to inspiring all girls to be strong, smart, and bold.

Talking Parents, Healthy Teens: The CDC Prevention Research Center at the University of California, Los Angeles developed the Talking Parents, Healthy Teens program to help parents improve their communication skills, so they can promote healthy sexual development in their children and reduce their kids' risky sexual behaviors.

a) Reported communication improved substantially by the first follow-up survey and continued through the last survey. Between baseline and the first follow-up, parents participating in Talking Parents, Healthy Teens reported discussing more new topics with their adolescents than parents who were not part of the program (mean 4.0 vs 0.8, $P < 0.001$). This difference persisted at the three- and nine-month follow-ups.

Reports from the adolescents showed a similar pattern.

Planet Health: Researchers at Harvard University's CDC Prevention Research Center developed an interdisciplinary curriculum called Planet Health for public middle schools, in collaboration with teachers and school principals. The curriculum was designed to fit easily into existing language, math, science, social studies, and physical education classes; to foster basic educational competencies required by the state of Massachusetts; and to provide materials easy for teachers to use. Other agencies and departments involved: STEPS to a Healthier U.S., Boston Public Health Commission, U.S.

Department of Education, National Institutes of Health.

a) 76% to 100% of BPS teachers found the curriculum highly acceptable and 78% to 100% planned to continue using it. More than 90% found the curriculum effective and believed that it made a positive contribution to their classes. Planet Health is being implemented in more than 120 schools in Massachusetts, and in the past two years, more than 1,000 teachers have been trained to use it. In addition, 2,000 copies of the curriculum have been purchased by interested parties in 48 states and 20 countries. Researchers found that the prevalence of obesity among girls who participated in Planet Health decreased by over 24% after a two year period. Based on an independent economic analysis of Planet Health, the program was projected to save money via avoided medical costs and productivity losses later in life. For every dollar spent on the program in middle school, \$1.20 in medical costs and lost wages would be saved when the children reach middle age.

Health and Safety of Home Care Workers: A Priority of Women's Health: A cross cutting initiative to decrease health disparities due to occupational exposures, has funded a model 5-year community intervention program to decrease the work-related risks for home care workers. The project, currently in its fourth year of funding, is developing community-based resources, educational materials and policy initiatives to improve safety for home care workers in one county of California which employs 15,000 home care workers. The project is working collaboratively with the local Agency on Aging, the labor union representing the home care workers and with a variety of other governmental and non-governmental stakeholder groups within California. The final year of the project will include a rigorous evaluation of the intervention using a randomized control design. The effectiveness of the intervention will examine improvements both from the perspectives of worker as well as client satisfaction.

a) The in-home paraprofessional workforce is disproportionately female, minority, poor and uninsured: 90% of home care workers are women, 22.5% are African American, 18.8% are Hispanic, and 6.2% are Asian and average hourly wage rates are between \$8 and \$10. One study based on data from the Current Population Survey found that almost 40% of home care aides lived below 150% of the poverty level and only half had some form of health insurance.³⁸

Study: Risk for Adverse Reproductive Outcomes among Nurses: Female nurses may be at increased risk of adverse reproductive outcomes through exposure to a variety of reproductive hazards. This project seeks to understand the impact of chemical and physical exposures on reproductive health. The study population is the ongoing Harvard Nurses' Health Study.

Birth Defects and Parental Occupational Exposures Study: The purpose of this study is to provide detailed exposure assessment data for the National Birth Defects Prevention Study that will allow for examination of the link between occupational exposures and birth defects. The study is a collaboration between CDC and the eight state-based centers that form the National Birth Defects Prevention Study.

Preventing Violence: CDC's website contains research information as well as links to external research programs, statistical reports, and public and private initiatives to address the problems of workplace violence.

Ascertainment of Exposure to Mainstream Smoke, Environmental Tobacco Smoke and Smokeless Tobacco During Pregnancy and its Impact on Pregnancy Outcome Study: The Division of Laboratory Sciences (DLS) in the National Center for Environmental Health has collaborated with Columbia University, Texas Woman's University and the California Department of Health Services on a series of studies aimed at understanding the impact of exposure to environmental tobacco smoke (ETS) on the outcomes of pregnancy.

³⁸ Recruiting and Retaining A Quality Paraprofessional Long-Term Care Workforce: Building Collaboratives with the Nation's Workforce Investment System May 2004. Available at <http://aspe.hhs.gov/daltcp/Reports/natwis.pdf>.

a) DLS has analyzed clinical samples for biomarkers of exposure to tobacco smoke. These studies have found associations between prenatal ETS exposure and birth weight, newborn heart rate and head circumference.

Pregnant Women and Perchlorate Exposure Study: Ammonium perchlorate is widely used as a solid oxidant in products ranging from automotive airbags to rocket motors. Perchlorate salts are known to effect thyroid function via inhibition of iodide uptake and thus have been used to treat hyperthyroid conditions. Widespread perchlorate contamination of water in the US has led to substantial concerns about human exposure and potential health effects, especially in vulnerable populations such as pregnant women and neonates.

a) The Division of Laboratory Sciences (DLS) in the National Center for Environmental

Health has collaborated with Sótero del Río Hospital in Santiago, Chile to determine that perchlorate in the drinking water of pregnant women was not associated with neonatal thyroid function or fetal growth retardation. By analysis of data from the National Health and Nutrition Examination Survey, DLS has determined that, depending on urinary iodine levels, urinary perchlorate concentrations in women is associated with thyroid stimulating hormone and total thyroxine.

Prevention of HIV transmission in High Risk Population of Women Study: The Division of Laboratory Sciences (DLS) in the National Center for Environmental Health - participated in macaque monkey trials with the Division of HIV/AIDS Prevention (NCHHSTP) to demonstrate the chemoprophylactic potential of FDA-approved antiretroviral drugs for prevention of sexual HIV transmission. DLS developed and implemented methods that allowed the measurement of internal dose levels of drug metabolites in the macaque subjects. These measurements are crucial for accurately assessing drug persistence and determining effective minimal doses as well as windows of protection in humans.

a) The results of the macaque studies are already influencing ongoing epidemiology

studies and drug trials conducted among high-risk populations of women around the globe.

Measuring Acrylamide Exposure in Women Study: Collaborated with researchers from the Harvard School of Public Health to examine environmental exposure to acrylamide in women. Acrylamide is a chemical that can form in some foods during high-temperature cooking processes, such as frying, roasting, and baking. Acrylamide in food forms from sugars and an amino acid that are naturally present in food; it does not come from food packaging or the environment. Acrylamide is produced industrially for use in products such as plastics, grouts, water treatment products, and cosmetics. In addition, it can be found in cigarette smoke.

a) DLS researchers measured acrylamide exposure in women in samples obtained from the Nurses Health Study 2. Researchers determined that women are exposed to acrylamide and that exposure mainly originates from food containing this chemical. As a result of these findings, a follow-up study is planned to examine the association of acrylamide exposure and breast cancer in this same study cohort.

Breast Cancer Awareness For Women with Physical Disabilities: CDC launched the ***Right to Know*** campaign promoting breast cancer screening for women with physical disabilities. The campaign materials are available free of charge via the *Right To Know* website located at www.cdc.gov/righttoknow.

Women with bleeding disorders: According to a CDC study, it took an average of 16 years from the onset of bleeding symptoms until a diagnosis; in order to close that gap, CDC must focus its efforts towards early identification and management among adolescents. There have not been questions to target female bleeding history, reproductive history, and types of treatment. CDC has designed a female-specific surveillance instrument to better characterize women with blood disorders.

a) For 10 years, CDC has supported a surveillance system, the Universal Data Collection (UDC), within the network of 135 HTC's in order to monitor the safety of the blood supply among patients with blood disorders. Increasingly, more women with blood disorders have been seeking care at these HTC's and participating in UDC; currently we have over 4,000 women participating in UDC.

Blood disorders contribution to maternal mortality: Study: Blood disorders also have a significant contribution to maternal mortality rates. Pulmonary Embolism (blood clots that dislodge and travel to the lungs) is a leading cause of maternal mortality in the U.S. and second leading cause of maternal mortality internationally (behind post-partum hemorrhage). CDC has recently partnered with University of Pittsburgh – Magee Women’s Hospital to determine the prevalence of blood disorders among women with post-partum hemorrhage (PPH); identify symptoms, risk factors, and co-morbidities associated with a blood disorder; and to assess adverse pregnancy outcomes associated with a blood disorder.

Preconception Health Report: In April 2006, CDC published “Recommendations to Improve Preconception Health and Health Care --United States” which described 10 recommendations to promote the value of good preconception health awareness and behavior. These recommendations focused on advocating changes in consumer knowledge, clinical practice, public health programs, health-care financing, data requirements and research activities to promote and understand preconception care (PCC). Each recommendation was accompanied by specific action steps that when implemented would advance research and practice on PCC. CDC’s Prevention Research Branch is currently conducting formative research among women and men of childbearing age and healthcare providers to explore their knowledge, attitudes, beliefs (KABs), barriers to and facilitators of reproductive health. Findings from this research will help to inform the development of audience centered messages, strategies for optimizing communication with key audience segments as well as dissemination activities. CDC’s formative research activities around preconception health will result in a reservoir of applied tools and findings from which partner organizations and other national groups can draw when developing their preconception health campaigns. As a result of these activities, the national call to increase consumer awareness of preconception health is underway.

Preventing Infections in Pregnancy: CDC works to promote healthy pregnancy among women by helping them avoid infections that may harm themselves or their unborn child. Cytomegalovirus (CMV) is the most common virus transmitted to a fetus during pregnancy, and untreated infection can result in permanent disabilities for the child, such as hearing loss, vision loss, or intellectual disabilities. However, awareness among women about CMV and other types of infections is low. In partnership with American College of Obstetricians and Gynecologists (ACOG), CDC researchers have conducted published studies, reviews, and commentaries on the effects of, screening for, and prevention of congenital CMV and other infections during pregnancy.

Data briefs that focus on women:

- Changing Patterns of Nonmarital Childbearing in the United States
<http://www.cdc.gov/nchs/data/databriefs/db18.htm>
- Marital Status is Associated With Health Insurance Coverage for Working-age Women at all Income Levels, 2007
<http://www.cdc.gov/nchs/data/databriefs/db11.htm>

Data Requests: In response to a data request from the Office on Health Reform, NCHS provided tabulated data on reduced access to medical care due to cost for women and men 18-64 years of age.

Women's Health and Diabetes Activities Report: Collaborated with the Agency for Healthcare Research and Quality (AHRQ) to develop a report, *Women with Diabetes: Quality of Care, 2004-2005*. This report assessed data from three nationally-representative surveys and describes the quality of care that women with diagnosed diabetes receive in the United States. The report includes measures of access to healthcare, general health and well-being, diabetes-specific preventive care, immunization, and other complications. This collaboration with AHRQ is ongoing, as CDC and AHRQ are currently analyzing additional data to assess quality of care for women at risk for diabetes.

Gestational Diabetes (GDM) Study: CDC has funded the National Association of Chronic Disease Directors to conduct a gestational diabetes validation project to: 1) establish a 5-state collaboration to identify, catalogue, and validate routinely collected data about GDM; 2) identify gaps in quality of GDM prevalence data; 3) develop recommendations for improving data quality; and 4) to determine implications for care.

a) Gestational diabetes (GDM) affects approximately 3-8% of all pregnancies in the United States. Up to one-third of affected women will have impaired glucose metabolism at postpartum screening and it is estimated that up to 50% will develop type 2 diabetes in the future. The findings from Phase I of this validation project reveal that there is a lack of consistent GDM diagnosis and documentation when various data sources were compared, such as PRAMS, medical records, and discharge data. As a result of this, such data sources may underestimate the prevalence of GDM. This project will continue with Phase II exploring opportunities to increase knowledge and change behavior among health care providers and women with GDM and make recommendations to improve data collection system.³⁹

Contributions to Preventing and Controlling Malaria During Pregnancy in Sub-Saharan Africa: In collaboration with many partners—other government agencies, international organizations, and African ministries of health—CDC has worked to: 1) Quantify the burden of adverse effects caused by malaria infection during pregnancy; 2) Evaluate the efficacy of novel strategies to prevent malaria during pregnancy; 3) Formulate strategies to deliver effective interventions to reduce malaria's ill effects on the health of pregnant women and their children; 4) Work with partners to scale up interventions to prevent and control malaria during pregnancy. CDC specific contributions are as follows:

- *Reduction of low birth weight:* Determined the risk of malaria-associated low birth weight and shown how this risk could be reduced through the delivery of efficacious antimalarial drugs as part of routine antenatal care.

³⁹ DIABETES Successes and Opportunities for Population-Based Prevention and Control: At A Glance 2009. Available at <http://www.cdc.gov/nccdphp/publications/aag/ddt.htm#aag>.

- *Estimates of malaria burden:* Updated estimates of the burden of anemia, low birth weight (due both preterm delivery and intrauterine growth retardation), and infant mortality associated with malaria infection during pregnancy. With partners, have generated estimates of the burden of malaria during pregnancy in areas with limited data, including West Africa, areas of sub-Saharan Africa with low malaria transmission, and South/ South East Asia. Most recently, conducted a comprehensive review of the epidemiology and burden of malaria in pregnancy to identify gaps in knowledge.
- *Rapid assessment methodology:* Developed a methodology to estimate the burden of malaria during pregnancy and assess how best to incorporate antimalarial interventions into the existing antenatal care system. To date, CDC has provided training for this methodology in Asia, Africa, and the Americas.
- *Intermittent preventive treatment in pregnancy (IPTp):* With partners, developed the strategy of IPTp, and demonstrated that this intervention was effective in reducing maternal anemia and delivery of low birth-weight babies in different settings in sub-Saharan Africa.
- *Interaction of Malaria and HIV:* Demonstrated both the higher burden of malaria in HIV-seropositive (compared to HIV-seronegative) pregnant women and their impaired response to antimalarial treatment.
- *Insecticide-treated nets (ITNs):* Demonstrated that the use of ITNs by pregnant women can reduce severe malarial anemia during pregnancy and reduce delivery of low birth-weight infants.
- *Folic acid and SP:* Demonstrated that a high dose, but not the recommended low dose, of folic acid supplementation in pregnant women reduces the efficacy of sulfadoxine-pyrimethamine (SP), the drug currently used for intermittent preventive treatment for pregnant women (IPTp).
- *Monitoring and evaluation:* In conjunction with WHO and other international partners, CDC has developed a standardized system for monitoring the uptake of strategies to prevent malaria during pregnancy, as well as demonstrate the impact on preventing anemia and low birth weight.

Preventing Toxoplasmosis: Production of health education materials for prevention of toxoplasmosis (which can cause severe birth defects) during pregnancy

Managing Lymphatic filariasis: Work with partners in India, Togo, and Haiti on programs for lymphedema management, a condition that affects the most impoverished peoples, and disproportionately affects women.

Reducing incidence of Chagas disease: Work with partners in Peru and Bolivia to study the epidemiology of Chagas disease and to design improved testing algorithms to test pregnant women and infants to prevent congenital Chagas diseases.

Treating Visceral leishmaniasis: An innovative approach to this issue could include integration of visceral leishmaniasis surveillance and referral for treatment with community nutritional interventions.

a) This disease causes disproportionate morbidity and mortality in women of childbearing age, with case-fatality rates 3 times higher in women than in men in our data from Bangladesh. These effects appear to be connected to poor micronutrient (vitamin A, zinc, iron) nutrition in women of childbearing age.

Various parasitic diseases: Working with the American College of Obstetrics and Gynecology to assess US clinicians' knowledge of various parasitic diseases, including toxoplasmosis, Chagas disease, cryptosporidiosis, and giardiasis. Results are used to design medical educational materials for disease prevention.

Choose Respect: A national initiative designed to prevent dating violence and encourage persons aged 11-14 years to have healthy, respectful relationships.

a) Findings from the 2007 Youth Risk Behavior Survey indicated that approximately one in 10 high school students reported being victims of physical dating violence during the 12 months preceding the survey.⁴⁰

DELTA (Domestic Violence Prevention Enhancement and Leadership through Alliances): CDC funds 14 state domestic violence coalitions to develop and implement prevention activities that can integrate into Coordinated Community Responses (CCR) or similar community-based collaborations. Building on the successes of the DELTA Program, CDC, in collaboration with the CDC Foundation and the Robert Wood Johnson Foundation, has developed the DELTA-PREP Program to provide training, technical assistance and funding to non-DELTA state domestic violence coalitions that are ready to build their capacity to prevent intimate partner violence.

Rape Prevention and Education (RPE) Grant Program: Program provides support rape prevention activities in all 50 states and 7 territories, including the District of Columbia. RPE programs use funding to increase awareness about sexual violence through educational seminars (for professionals, the public, schools, colleges, and universities), hotline operations, and development of informational materials.

a) Early evaluation efforts have demonstrated that this approach helps create social environments that promote positive male behaviors that contribute to reducing and preventing sexual violence.

Prevention of Teen Dating Violence: Undertaking the development, implementation, and evaluation of a comprehensive approach to promote respectful, nonviolent dating relationships in high-risk urban communities that builds on current evidence-based practice and experience.

a) Teen dating violence is a serious public health problem and the prevalence is higher in communities with higher poverty and fewer resources.

⁴⁰ Youth Risk Behavior Surveillance —United States, 2007. Available at http://www.cdc.gov/healthyouth/yrbs/pdf/yrbss07_mmwr.pdf.

Global Activities: In collaboration with Swaziland's United Nations Children's Fund (UNICEF), conducted a national survey on violence against children (with a special focus on sexual violence against girls). Based on the success in Swaziland, additional national surveys have been requested and are being planned for Kenya and Tanzania. CDC just received a request to also assist in a national survey in Papua New Guinea and to explore potential work throughout Asia.

a) Data from the survey have been used to inform legislative action on child protection and domestic violence and are being used by stakeholders to guide the development and implementation of prevention strategies and programs. In response to concern about the alarming rates of violence against children documented in the 2007 national study, Swaziland has established its first Sexual Offenses Unit for children and young people.

National Intimate Partner and Sexual Violence Surveillance System (NISVSS):

Developed in collaboration with the National Institute of Justice and the U.S. Department of Defense. Beginning in 2010, NISVSS will provide national and state-level data, producing frequent, consistent, and reliable information on the magnitude and nature of intimate partner violence, sexual violence and stalking.

a) Using consistent definitions and survey methods over time, NISVSS will provide improved prevalence lifetime and 12-month estimates to monitor trends and to guide and evaluate intervention and prevention efforts.

The SISTA (Sisters Informing Sisters about Topics on AIDS) project: Is a social-skills training intervention for African American women. It is aimed at reducing HIV sexual risk behavior. It is comprised of five 2-hour sessions, delivered by peer facilitators in a community-based setting. The sessions are gender specific and culturally relevant and include behavioral skills practice, group discussion, lectures, role-playing, prevention video viewing, and take-home exercises. In 2008, CDC made competitive awards to five CBOs that were funded to deliver the evidence-based program model, SISTA to participate in an outcome-monitoring project that will assess changes in clients' self-reported HIV risk behaviors. The five CBOs are located in Southern rural cities that have high rates of HIV: Atlanta, GA; Jackson, MS; New Orleans, LA; Panama City, FL.

a) The original research revealed that women who participated in the SISTA intervention demonstrated increased condom use than women who did not participate in the intervention group. Data from the outcome-monitoring project of SISTA will assess whether behavior changes among participants are similar to the original research.

Studies on Women's Issues using the National Biomonitoring Program (NBP):

- *Ascertainment of Exposure to Mainstream Smoke, Environmental Tobacco Smoke and Smokeless Tobacco During Pregnancy and its Impact on Pregnancy Outcome*
 - a) These studies have found associations between prenatal ETS exposure and birth weight, newborn heart rate and head circumference.

- *Measuring Folate Levels in People:* Knowing folate levels is important because women of childbearing age with low folate levels are at risk of giving birth to a baby with birth defects of the brain or spine.
 - a) The laboratory found that serum folate levels have nearly tripled in the U.S. population since 1998.

Safe Motherhood: Maternal and Infant Health Program: Promotes the health of women before, during, and after pregnancy to include the physical, mental, cultural, and socioeconomic aspects that move beyond absence of disease to the well-being of the childbearing woman and her family. Other Agencies/Departments involved: The Health Resources and Services Administration (HRSA), U.S. Agency for International Development (USAID), The World Health Organization (WHO), The National Institute of Health (NIH), The Indian Health Service (IHS), The Department of Justice (DOJ), The Food and Drug Administration (FDA).

- a)
 - Each year in the U.S. approximately 6 million women become pregnant.
 - In 2005, for every 100,000 deliveries in the United States, approximately 15 women die from pregnancy or its complications.
 - African American women experience more than three times greater risk of dying due to pregnancy and its complications than white women
 - Women 35 years and over are more than three and a half times as likely to experience a pregnancy related death in comparison to women 20-24 years of age.
 - About one in four women, or one million per year, will have serious complications during labor, delivery, or the postpartum period.
 - Preterm births rates have increased 28 percent over the past 20 years.
 - In 2006, 12.8 percent of all liveborn infants were born preterm, translating to more than 545,000 preterm births each year.
 - Analysis of cause of death data indicates that more than 36 percent of infant deaths are due to preterm-related causes.
 - Preterm delivery contributed to nearly half of all deaths among African American infants in 2005 compared to 34 percent of the deaths of Hispanic infants and 32 percent of non-Hispanic white infants.
 - Each year in the U.S., approximately 4,600 infants die suddenly of no immediately obvious cause.
 - Approximately half of these sudden unexpected infant deaths (SUID) are attributed to SIDS, the leading cause of SUID and of all deaths among infants aged 1-12 months.
 - SIDS is the third leading cause of all infant mortality and the leading cause of post-neonatal mortality.
 - About one-third of girls in the U.S. get pregnant before the age of 20.
 - In 2006, 435,427 infants were born to mothers aged 15-19 years, a birth rate of 41.9 live births per 1,000 women in this age group but the rate was; 83/1,000 among Hispanics; 63.7/1,000 among non-Hispanic blacks; 54.7/1,000 among American Indian or Alaska Natives, and 26.6/1,000 among non-Hispanic whites. More than 80% of these births were unintended.

- Pregnancy and birth rates among girls aged 15-19 increased for the first time since 1991 from (40.5/1,000 women in 2005 to 41.9/1,000 in 2006.
- In 2002, of the approximately 62 million women of reproductive age, about 1.2 million or 2 % had an infertility-related medical appointment within the previous year.
- Of married couples in which the woman was of reproductive age, 2.1 million couples reported they had not used contraception for 12 months and the woman had not become pregnant.
- Over half a million women die each year from complications of pregnancy and delivery with 99 percent of these deaths occur in the developing world.

Major initiatives under Safe Motherhood include:

The Pregnancy Risk Assessment Monitoring System (PRAMS): is a surveillance project of the CDC which in concert with state health departments focus on women's behaviors during pregnancy and during children's early infancy collecting state-specific, population-based data on maternal attitudes and experiences before, during and shortly after pregnancy. PRAMS participants number 37 states and NY City and represents approximately 75% of the live births in the United States.

Maternal and Child Health Epidemiology (MCH EPI) Program: is a collaborative effort between CDC, The Health Resources and Services Administration (HRSA) and external partners focused on improving the health of women, children and families by building capacity at the state, local and tribal levels to effectively use and apply epidemiologic research and scientific information to inform public health action.

Research on Preterm Birth: is a program with a comprehensive research agenda to identify women at risk for preterm delivery and opportunities for prevention. Work is implemented through a broad coalition of partnerships. This initiative focuses on surveillance, research, and programs that target identifying social, clinical, and biological factors that cause preterm birth; identifying women at risk early in their pregnancy; translating new research discoveries to public health prevention; and associated racial disparities.

Assisted Reproductive Technology (ART): DRH's Assisted Reproductive Health Technology surveillance activity was instituted in response to the Fertility Clinic Success Rate and Certification Act (FCSRCA) of 1992 which mandated that clinics that perform ART provide data annually on all procedures performed to CDC. The primary objective of the ART surveillance activity is to evaluate the efficacy and safety of ART by providing surveillance, research, training, technical assistance, consultation and collaboration with partners and to publish success rates annually for each clinic.

Sudden Unexpected Infant Death Initiative (SUIDI): This initiative undertakes both research and program activities to better understand and prevent SIDS and SUIDs in the U.S. CDC and its partners have implemented activities aimed at improving the accuracy and consistency of reporting and classification of SUID deaths. CDC has begun development of a SUID Case Registry (SUID-CR) which establishes a surveillance system that links death certificates to child death review data, death scene investigation and pathology data.

Unintended and Teen Pregnancy Prevention Program: CDC's Adolescent Reproductive Health (ARH) team works with community coalitions to help them mobilize and organize resources in support of comprehensive, effective and sustainable programs to prevent adolescent pregnancy. The initiative, Promoting Science Based Approaches (PSBA) to Teen Pregnancy Prevention, uses science-based principles to design and implement adolescent reproductive health programs, including comprehensive pregnancy prevention and HIV/STD prevention. Since 2005 CDC has funded a five-year cooperative agreement with three national organizations, four Title X (OPA) regional training organizations and nine state teen pregnancy prevention coalitions.

Global Health: CDC/DRH has a long history of involvement in international activities in a variety of areas of reproductive health. The DRH global health initiative has identified 4 focus areas: 1) reducing maternal morbidity and mortality; 2) reducing infant morbidity and mortality; 3) reducing the incidence of unintended pregnancy, including improved child spacing and 4) improving women's health, particularly in regards to HIV/AIDS. DRH staff including epidemiologists, physicians, demographers, social scientists, statisticians, public health advisors, and many others provide technical assistance across the developing world, principally in Africa, Latin America, and the former Soviet Union.

The Women's Reproductive Health Study: Evaluates the effects of occupational exposures on pregnancy outcomes, birth defects in offspring, and infertility. Within this program we study a variety of occupational working conditions that are suspected of being reproductive toxicants, such as exposure to solvents and pesticides, ionizing and cosmic radiation, hazardous drugs, long working hours and shift work, and physical factors, such as heavy lifting or prolonged standing. Our studies include women who work in all job sectors, including manufacturing jobs, health care workers, cleaning staff, flight crew and agricultural workers. The program is run by senior epidemiologists in the Industry wide Studies Branch of DSHEFS / NIOSH, and involves collaborations with the National Center on Birth Defects and Developmental Disabilities (CDC), the Centers for Birth Defects Research and Prevention, and other external partners.

a) The percent of children born to working mothers has risen steadily from 31% in 1976 to 59% in 1998, and approximately 65% of employed women and men are of reproductive age, thus providing an increased probability of occupational reproductive exposures. A discrepancy exists between the number of chemicals in commerce (over 80,000) and the number that have been evaluated in laboratory animals for reproductive toxicity potential (4,000); fewer than 100 chemicals have been evaluated in epidemiologic studies. It is estimated that 10–20% of recognized pregnancies end in spontaneous abortion or stillbirth, in addition to those that are lost before recognition of pregnancy. In addition, 10–15% of couples are unable to conceive after 1 year of unprotected intercourse. Approximately 3% of all live births have major malformations and it is estimated that 3% of these major malformations are strictly due to toxicant exposure, 28% can be attributed to genetic causes, and approximately 23% are attributable to multifactorial causes, which are complex interactions between genes and environmental factors. The cause is unknown in more than 40%. What is known, however, is that identifying the causative agents, mechanisms by which they act, and any potential target populations will present the opportunity to intervene and better protect the reproductive health of the public.

Global AIDS Program (GAP): The HHS/CDC Global AIDS Program (GAP) is an implementing partner of the President's Emergency Plan for AIDS Relief (PEPFAR) currently providing technical leadership and assistance to 80 resource-constrained countries to strengthen laboratory, epidemiology, surveillance, public health evaluation and workforce capacity. CDC/GAP staff works hand-in-hand with Ministries of Health (MOHs) building indigenous capacity to manage HIV prevention, care and treatment service delivery and the establishment of information and program monitoring systems for data-driven programming. CDC/GAP also works closely with other US Government agencies implementing PEPFAR, including Department of State: USAID, Embassies; Department of Health and Human Services: NIH, HRSA, FDA, SAMHSA; and Departments of Defense, Labor, and Commerce; and Peace Corps.

a) PEPFAR results in 15 countries from 2004 - 2008:

- 15,901,499 pregnant women received PMTCT testing and counseling services
- 1,238,934 HIV+ pregnant women received ARV prophylaxis for PMTCT
- 6,522,997 women received HIV related palliative care services
- 3,624,123 orphan and vulnerable female children (0-17) received care and support services

PEPFAR results in 15 countries from 2006 - 2008:

- 128,794 female children (0-14) were receiving ART
- 1,715,815 women (15+) were receiving ART

The 2008 PEPFAR Annual Progress Report (APR) reported that at least 6 countries have achieved $\geq 80\%$ PMTCT counseling and testing among women attending antenatal clinic (ANC).

Preventing Congenital Syphilis (Summary of CDC's contributions/activities):

- *Surveillance and strategic information system:* CDC clinicians, medical epidemiologists and laboratory scientists are members of the WHO working group on HIV/STI/TB Surveillance and provide input into WHO's surveillance and strategic information systems.
- *Laboratory systems and networks:* CDC laboratory scientists form the WHO Collaborating Center supporting the STI Diagnostics Initiative, evaluating new rapid point-of-care tests (particularly new syphilis treponemal tests).
- *Public health workforce capacity building:* CDC funding has supported WHO in conducting a series of Regional Meetings to adopt a roadmap for CSE in moderate and high burden countries, integrating the program into the existing MNCH health systems delivery.
- *Translation of research into policy and practice:* CDC has supported WHO in the development of documents and strategies to support the global congenital syphilis elimination (CSE) effort and overall STI control. Recent outputs include:
- *Monitoring and evaluation:* With scientists in the WHO Geneva and Regional Offices, CDC personnel have supported a process of identifying and implementing of common indicators to measure local, national and global program progress and impact of the CSE effort.

Publications

- Eliminating Congenital Syphilis: A Global Health Priority (2006)
- The Use of Rapid Syphilis Testing (2006)
- The Global Elimination of Congenital Syphilis: Rationale and Strategy for Action (2007)
- Global Strategy for the Prevention & Control of STIs: 2006-2015 (2007)
- Sexually Transmitted Diseases and other Reproductive Tract Infections: A Guide for Essential Practice (2005)
- Guidelines for the Management and Treatment of STIs (currently under revision)
- Training Modules for Syndromic Management of STIs (2007)
- Guidelines for Sexually Transmitted Diseases Surveillance (currently under revision)
- Consultations on STI Interventions for Prevention of HIV: What is the Evidence (2000 and 2006)
 - a) (International) WHO currently estimates that each year between 715,000 and 1,575,000 pregnant women are infected with syphilis and most of these will suffer a serious adverse pregnancy outcome. Untreated syphilis results in fetal loss or stillbirth, preterm delivery, early neonatal death or an infant with congenital syphilis in up to 70% of cases. Globally, the annual perinatal mortality associated with syphilis is estimated at 327,000 cases, exceeding the perinatal mortality of HIV, malaria or tetanus. Untreated maternal syphilis is the most common infection causing stillbirth, and in settings with > 5% maternal prevalence, maternal syphilis can be the most common cause of stillbirth overall. Syphilis screening early in pregnancy (e.g., 1st antenatal visit) with prompt treatment of positives can prevent most perinatal deaths and disability.

(Domestic) After 14 years of decline in the United States, the rate of congenital syphilis increased 15.4% between 2006 and 2007 (from 9.1 to 10.5 cases per 100,000 live births). In 2007, 430 cases were reported, an increase from 373 in 2006. This increase in the rate of congenital syphilis may relate to the increase in the rate of P&S syphilis among women that has occurred in recent years. In 2007, the rate of congenital syphilis (based on the mother's race/ethnicity) was 32.3 cases per 100,000 live births among blacks and 15.3 cases per 100,000 live births among Hispanics; rates that are approximately 14 and 7 times higher than among whites respectively. While most cases of congenital syphilis occur among infants whose mothers have had some prenatal care, late or limited prenatal care has been associated with congenital syphilis. Failure of health care providers to adhere to maternal syphilis screening recommendations also contributes to the occurrence of congenital syphilis.

Infertility Prevention Project: in collaboration with the Office of Population Affairs (OPA) of the Department of Health and Human Services (HHS), supports a national Infertility Prevention Program (IPP) that funds chlamydia and gonorrhea screening and treatment services for sexually active women, and their partners, attending family planning (both Title X and non-title X), STD, and other women's healthcare clinics. Key IPP partners include the Indian Health Service's national STD prevention program, state and local STD prevention programs (64 grantees) and family planning programs (grantees and delegate agencies), 10 family planning regional training centers [IPP Infrastructure] and state public health laboratories.

a) This program has shown that routine screening of women can reduce chlamydia prevalence and pelvic inflammatory disease (PID) incidence in women.

Human Papillomavirus Vaccine Monitoring (summary of CDC's contributions/activities): Based on formative research, CDC developed HPV print and web materials targeted to the general public, patients, and health care providers. New materials published in 2008 include: adapted informational HPV brochures for American Indian and Alaska Native women and a patient brochure for women receiving Pap and/or HPV test results (*Making Sense of Your Pap & HPV Test Results*). CDC also update existing materials, including the HPV fact sheet, HPV Vaccine Information for Young Women (English and Spanish); HPV Vaccine Information for Clinicians (English and Spanish); and HPV Vaccine Safety.

- Collected, analyzed and published data on HPV prevalence and abnormal Pap tests among a diverse group of women in the U.S. cervical screening population from six cities (*Annals of Internal Medicine* 2008; 148: 7). Subanalyses are ongoing.
- Collected and analyzed HPV prevalence and surveillance information for the U.S. population using NHANES. Results for 2003-2004 were published in *JAMA* (2007; 297:813-819). Results for 2005-2006 will be available soon.

- Developed and evaluated standardized HPV serology assays and continues to use these assays to assess specimens collected as part of CDC's HPV sentinel surveillance programs, NHANES, and studies of HPV in adolescents and persons with AIDS.
- Collaborated with the National Cancer Institute's (NCI) Early Detection Research Network to identify and validate molecular markers of incipient cervical cancer that can be used to improve sensitivity and specificity of screening. As part of this collaboration, CDC has established a biorepository of research specimens linked to clinical and epidemiologic data.
- Collaborated with NCI and the World Health Organization (WHO) to provide technical expertise concerning HPV vaccination strategies and policy. Serve as Global Reference Laboratory in WHO HPV Laboratory Network.
- Initiated a pilot project to evaluate the feasibility and acceptability of HPV DNA testing to increase cervical cancer screening intervals in the National Breast and Cervical Cancer Early Detection Program.
- Initiated *HPV Typing of Cancers* project (HPV TOC) to examine the feasibility of collecting data on type-specific distribution of HPV-associated cancers.
- Initiated monitoring of cervical cancer precursors (CIN 2/3) and associated HPV types through collaboration with Emerging Infection Program (EIP) and Vaccine Safety Datalink (VSD) projects and the National Program of Cancer Registries (NPCR).
- Began a study on immunogenicity of the HPV vaccine through the Arctic Investigation Program (AIP), CDC.
- Analyzing administrative claims data from a national HMO database to measure frequency of HPV related sequelae-abnormal Pap tests, cervical precancers and cancers, and genital warts.
- Initiated genital wart surveillance through a sentinel network of STD clinics and using data from administrative datasets.
- Evaluated vaccine uptake and attitudes to HPV vaccination among parents and providers in areas with high rates of cervical cancer and conducted national surveys of provider attitudes and practices regarding HPV vaccines..
- Provided training to health care providers on HPV through its website (webcast and online training courses), treatment guidelines, and clinical training through its network of 10 STD Prevention Training Centers.
- Led a collaborative effort to produce a 22-article supplement in the journal *Cancer* entitled "Assessing the Burden of Human Papillomavirus (HPV)-Associated Cancers (ABHACUS)."
- Administered two grant programs that allow grantees to make HPV vaccine available to some recommended populations in their jurisdictions. The Vaccines for Children (VFC) program is an entitlement program that provides free routinely recommended vaccines to individuals 0 through 18 years of age who are: Medicaid-eligible, have no insurance, American Indian/Alaska Native, or underinsured with respect to vaccination and receiving their vaccines through either a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC).

a) As of August 31, 2008, there were 10,326 reports of adverse events after Gardasil vaccination, of which 6% were considered serious. Based on the ongoing assessments of vaccine safety information, CDC and FDA continue to find that Gardasil is a safe and effective vaccine. Preliminary data from a large U.S. controlled study of the Vaccine Safety Datalink do not find Gardasil to be associated with seizures or other serious neurologic conditions.

Project Connect: STD Prevention among Youth: Health Research Association (Peter Kerndt, PI) in collaboration with the LA Unified School District, the LA County STD Program, the University of California at Los Angeles, and the Rand Corporation, has been funded by the Centers for Disease Control and Prevention (Patricia Dittus, Division of STD Prevention, Project Officer) to develop, implement and evaluate an integrated multi-level intervention to reduce sexually transmitted diseases, including HIV, and teen pregnancy.

a) *Parent Intervention program:* Among intervention school girls in the cross-sectional sample, reports of having initiated sexual intercourse decreased significantly from baseline to Time 3 (47.4% vs. 40.9%), a drop which did not occur among comparison school girls (44.8% vs 43.9%).

Provider Intervention program: Increases in reports of STD testing were particularly strong for intervention school girls (29.2% vs. 42.0%), as compared to comparison school girls (27.4% vs. 31.9%).

School Intervention program: Among sexually experienced students, there was a significant increase among intervention school students in the percent who went to the school nurse for condoms but not for comparison school students.

Expedited Partner Therapy: CDC funded and participated in several randomized, controlled trials and observational studies on the practice and effectiveness of arranging for the treatment of partner of persons with selected STD without prior referral for examination, a process known most widely as *expedited partner therapy* (EPT). EPT is typically accomplished by *patient-delivered partner therapy* (PDPT), whereby the index case receives medication (or prescriptions) for his or her partner. Summary of CDC Program Activities:

- CDC published permissive guidance for EPT use as a clinical option for heterosexual men and women with uncomplicated gonorrhea or chlamydial infection in early 2006. Because state differ in their laws governing the practice of medicine, providers are advised to verify the legality of this practice in their jurisdiction.
- CDC has provided, on request, technical assistance, consultation and comment to jurisdictions taking up EPT, as well as organizations endorsing the practice.
- CDC has provided and maintained an overview of the legal landscape by state and selected other jurisdictions, first developed December 2006 and updated regularly.
- Paper on legal landscape in press at AJPH

a) *U.S. Practice Patterns*: Observational studies were based on a 2000 nationwide sample of 4133 physicians in five specialties (internal medicine, obstetrics/gynecology, emergency medicine, pediatrics, general/family practice). Half or more had used PDPT: 50% for gonorrhea, 56% for Chlamydia.

EPT Efficacy: Three trials compared EPT to referral of sex partners for care through patients notifying partners for gonorrhea or chlamydia.

All found reduced rates of reinfection of similar magnitude among index patients and equivalent or statistically superior notification and treatment rates.

- ~20% for chlamydia; 50% or better for gonorrhea

A composite estimate based on trial data found statistically significant reductions in reinfection for GC and CT (Trelle et al. 2007).

Trials also yielded fewer risky sexual behaviors among those receiving EPT, some of which was due to increased treatment efficacy

Trials included a high standard of counseling/educational messages in control and EPT arms

Perinatal HIV Prevention: Provides funding for state and local health departments to work with health-care providers to promote routine, universal HIV screening of all pregnant women. In addition, CDC grantees work with organizations involved in prenatal and postnatal care for HIV-infected women to ensure that appropriate HIV prevention counseling, testing, and therapies are provided to reduce the risk of perinatal transmission.

a) Between 120,000 to 160,000 women in the United States are infected with HIV, the virus that causes AIDS. Nearly one out of four of these women don't know they have HIV. This puts them at high risk of passing the virus to their babies.

Diffusion of Effective Behavioral Interventions for HIV Prevention: The Diffusion of Effective Behavioral Interventions project (DEBI) is a national-level strategy to provide high quality training and on-going technical assistance on selected evidence-based HIV/STD/Viral Hepatitis prevention interventions to state and community HIV/STD program staff. The following interventions use strategies that target women and adolescent girls:

CLEAR: Choosing Life: Empowerment! Action! Results!

Focus on Youth (FOY)

Healthy Relationships

Real AIDS Prevention Project

SIHLE: Sisters Informing, Healing, Living, and Empowering

Disease Detective Camp: The CDC Disease Detective Camp is an academic public health day camp held at CDC's headquarters in Atlanta, GA.

The James A. Ferguson Emerging Infectious Diseases Fellowship Program: Provides educational and experiential opportunities for underrepresented graduate students in medical, dental, pharmacy, veterinary medicine, and public health schools in a broad array of public health research activities.

Fellowships and Student Programs:

- *Epidemic Intelligence Service (EIS)*: Two-year program of training and service in applied epidemiology, largely for persons holding doctoral degrees (MD, DVM, PhD, DDS, also RN/MPH, PharmD/MPH)
 - a) Approximately 75-80 EIS officers per year, of whom, approximately 25-30% are assigned to state or large local health departments.
- *Preventive Medicine Residency/Fellowship (PMR/F)*: One-year program focusing on leadership, management, policy development, and program evaluation, largely for EIS graduates (MD or DVM)
 - a) Approximately 10-14 residents per year, assigned to either field or headquarters positions.
- *Public Health Prevention Service (PHPS)*: Three-year training and service program focusing on public health program management, for persons holding master's degree(s) and with work experience
 - a) Approximately 25 Prevention Specialists per year.
- *Prevention Effectiveness Fellowship*: Two-year postdoctoral fellowship for economists, health services researchers, decision scientists, operations researchers, and other quantitative policy analysts
 - a) Approximately 5-10 fellows enter each year.
- *Emerging Leaders Program (ELP)*: 2-year fellowship for individuals with a minimum of a bachelor's degree (with qualifying work experience) or a graduate degree, with focus on leadership and management
 - a) Approximately 10-20 fellows each year.
- *Presidential Management Fellows (PMF) Program*: 2-year fellowship for individuals with a masters, law or doctoral-level degree, with focus on leadership and management of public policy and programs
 - a) Approximately 5-10 fellows each year.
- *The CDC Experience Applied Epidemiology Fellowship*: One-year fellowships in applied epidemiology and public health for 3rd-or 4th-year medical students
 - a) Eight competitively selected students selected.
- *Epidemiology Elective for Medical and Veterinary Students*: Six- to eight-week rotation in applied epidemiology and public health for 4th-year medical or veterinary students
 - a) Approximately 50 students placed each year.
- *O.C. Hubert Student Fellowship in Global Health*: Six- to twelve-week rotation in public health for 4th-year medical or veterinary students, placed overseas with CDC staff
 - a) Approximately 6-12 students placed each year.

Career Paths to Public Health:

- *Science Ambassador Program:* Invites middle- and high-school science teachers nationwide to compete for the chance to collaborate with CDC scientists on epidemiology-based lesson plans
- *Science Olympiad:* A series of local, state, and national tournaments in which middle- and high-school students apply concepts in scientific fields, emphasizes problem solving and teamwork, and promotes students' interest in public health. The CDC-sponsored Disease Detectives event of Science Olympiad asks participants to apply epidemiology principles while addressing public health outbreak scenarios

CDC Lactation Support Program: Designed to help educate expectant parents and provide a supportive environment for nursing mothers.

- a) 28 lactation rooms at various CDC facilities including seven locations outside Atlanta. Over 200 mothers currently enrolled in the program. In 2007, 77% of the mothers continued to breastfeed at one year, which far exceeds the Healthy People 2010 goal of 25% at one year.

Publications

Intimate Partner Violence Compendium - CDC developed and disseminated the *Measuring Intimate Partner Violence Victimization and Perpetration: A Compendium of Assessment Tools* to measure victimization and perpetration of IPV, including physical violence, sexual violence, psychological abuse, and stalking.

- a) The compendium provides researchers and prevention specialists with a set of assessment tools with demonstrated reliability and validity for measuring the self-reported incidence and prevalence of IPV victimization and perpetration.

IPV Costs Report - Recognizing the need to better measure the scope of the problem of intimate partner violence and the resulting economic costs, CDC conducted a study to obtain national estimates of the occurrence of IPV-related injuries, to estimate their costs to the health care system, and to recommend strategies to prevent IPV and its consequences.

- a) The resulting report, *Costs of Intimate Partner Violence Against Women in the United States*, describes the development of the study; presents findings for the estimated incidence, prevalence, and costs of nonfatal and fatal IPV; identifies future research needs; and highlights CDC's research priorities for IPV prevention.

IPV Demonstration Projects - Recognizing the need for programs that address prevention in minority populations, the CDC funded 10 demonstration projects in 2000 to develop, implement, and evaluate culturally competent IPV/SV prevention strategies targeted for specific racial/ethnic minority groups.

a) *Preventing Intimate Partner Violence and Sexual Violence in Racial/Ethnic Minority Communities: CDC's Demonstration Projects* summarizes the work of the funded projects. The purpose of the document is to describe the approaches projects developed and highlight challenges and lessons learned in the development, implementation, and evaluation of IPV/SV prevention programs for racial/ethnic minority populations.

Sexual Violence Report - In 2009, CDC updated and republished *Sexual Violence Surveillance: Uniform Definitions and Recommended Data Elements*. This report is intended for individuals and organizations interested in gathering surveillance data on sexual violence. The document is intended to promote and improve consistency of sexual violence surveillance. If the recommended data elements are uniformly recorded and the data made available to numerous users, then better estimates of the incidence and prevalence of sexual violence can be obtained.

IPV Surveillance Report - CDC published *Intimate Partner Violence Surveillance: Uniform Definitions and Recommended Data Elements*. This report is intended for individuals and organizations interested in gathering surveillance data on IPV. The document is intended to promote and improve consistency of IPV surveillance. If the recommended data elements are uniformly recorded and the data made available to numerous users, then better estimates of the incidence and prevalence of IPV can be obtained.

IPV/SV Compilation - CDC published *Intimate Partner Violence and Sexual Violence Victimization Assessment Instruments for Use in Health Care Settings*. The purpose of this compilation is to provide practitioners and clinicians with the most current inventory of assessment tools for determining intimate partner violence and/or sexual violence victimization and to inform decisions about which instruments are most appropriate for use with a given population.

Evaluation Guide - CDC has developed an evaluation guide for violence against women programs to provide practitioners with information about how to conduct evaluations based on strong scientific methods. The guide will assist programs in identifying measurable objectives and goals and in linking these objectives and goals with services and evaluation plans. Information about data collection methodology and measures, data analyses, presentation of results, and selection of an external evaluator are included.

Ongoing Women Focused Research: This is a listing from the Financial Management Office of funded woman-focused research, containing institution funded and title of project

- FAMILY PLANNING COUNCIL , INC., Family Planning & Preconception HIV testing
- EMORY UNIVERSITY, Elimination of Health Disparities through Translation Research
- PENNSYLVANIA STATE UNIVERSITY-UNIV PARK, Employing Narrative Forms of Communication for Cervical Cancer Prevention Message

- MICHIGAN STATE UNIVERSITY, Physical Activity during Pregnancy, Fetal Growth, and Toddler Body Size
- HARVARD UNIVERSITY (SCH OF PUBLIC HLTH), Population Disparities in Breastfeeding in the United States
- UNIVERSITY OF NORTH CAROLINA CHAPEL HILL, Residential Segregation, Neighborhood Social Environment, and Preterm Birth among
- JOHNS HOPKINS UNIVERSITY, The Natural History of Bacterial Vaginosis and Modes of Transmission Among Women
- UNIVERSITY OF NORTH CAROLINA CHAPEL HILL, Genetic Susceptibility to Mother-To-Child Transmission of HIV
- UNIVERSITY OF FLORIDA, Neighborhood and Mammography: A multilevel approach to cancer screening behavior
- UNIVERSITY OF COLORADO DENVER, My Baby, My Move: A Perinatal Physical Activity Intervention
- JOHNS HOPKINS UNIVERSITY, Developing a Strategic Approach to Management of Adolescents with PID
- TULANE UNIVERSITY OF LOUISIANA, Translating efficacy into effectiveness of insecticide-treated nets (ITNs)
- UNIV OF MASSACHUSETTS MED SCH WORCESTER, Implementation of a Mammography Reminder System in a Healthcare Network
- FRED HUTCHINSON CANCER RESEARCH CENTER, Prevention of Ovarian Cancer in Women Participating in Mammography
- WOMEN AND INFANTS HOSPITAL-RHODE ISLAND, A Model Statewide Trial to Detect and Treat Maternal Hypothyroidism in Pregnancy
- UNIVERSITY OF MIAMI SCHOOL OF MEDICINE, Translating Effective Health Behavior Strategies Into Practice for HIV+ Women

Future Programs

Expand the number of states participating in the Pregnancy Risk Monitoring System (PRAMS)/ addresses:

- a) Pregnant women/Infants
- b) No data provided
- c) To provide data that program planners and policy makers for all states that participate in PRAMS to use in improving the health of mothers and infants. To become the premier public health surveillance system of perinatal health indicators among women who recently delivered a live infant.

CDC/ATSDR Women's-Network-Listserv

- a) CDC employees
- b) No data provided
- c) Plans are to launch the CDC/ATSDR Women's-Network-Listserv by the end of 2009

Preventing and Controlling Malaria During Pregnancy:

Evaluation of new and existing antimalarial drugs for pregnancy

- a) Pregnant women
- b) No data provided
- c) In collaboration with international partners, CDC is working to evaluate the safety and efficacy of new and existing antimalarial drugs and drug combinations for the treatment and prevention of malaria during pregnancy.

Pharmacokinetics and safety of antimalarials in pregnancy

- a) Pregnant women
- b) No data provided
- c) In collaboration with international partners, CDC is accumulating pharmacokinetic and safety data on the use of some artemisinin-based combination therapies (ACTs) in pregnancy. This effort will help ensure that pregnant women are not being underdosed with antimalarials (which may result in lower treatment efficacy in this vulnerable population and higher drug resistance) and will contribute to the currently small body of data on the safety of artemisinins in pregnancy.

Prevention of malaria in HIV-positive pregnant women

- a) HIV-positive pregnant women
- b) No data provided
- c) CDC is working to measure the effectiveness of daily cotrimoxazole (CTX) received for prevention of opportunistic infections, on the prevention of malaria in pregnancy in HIV-positive women. As part of a multicenter and multinational randomized controlled trial, CDC is also assessing the safety and efficacy of mefloquine for IPTp in HIV-positive women on CTX.

Estimating the burden of malaria in pregnancy

- a) Pregnant women
- b) No data provided
- c) In collaboration with national and international partners, CDC is helping to assess the burden of malaria during pregnancy in three countries in Latin America.

Influenza and Pregnancy:

Follow-up of pregnancy outcomes among women with confirmed novel influenza A (H1N1) infection.

- a) Pregnant women and newborns
- b) Pregnancy and newborn outcome on most identified cases of pandemic H1N1 infection in pregnant women
- c) As of May 18, 2009, 13 states have reported a total of 34 cases, with 11 women (32%) hospitalized. Additional cases have been identified after this initial reporting period, and several deaths have been reported. The severity of disease, vaccination status, and treatment with antivirals was documented at time of the outbreak. Pregnancy outcomes for most women are not known. We propose to compile a case series (n= 40 to 50 pregnant women) to assess pregnancy outcomes, maternal health and newborn health. This program will provide the initial data on the impact of novel influenza A (H1N1) infection and treatment on pregnant women and newborns.

Follow up of pregnancy outcomes and infant health among women with probable or confirmed influenza illness during influenza season 2009-10.

- a) Pregnant women
- b) An understanding of influenza infection in a large cohort (300) of pregnant women will provide sufficient statistical power to describe infection pathology in pregnant women and newborns and to generate hypotheses for future research.
- c) Pregnant women are at high risk for complications from seasonal influenza infection yet seasonal influenza vaccine immunization rates among this vulnerable population are less than 15%. Little is known about the adverse outcomes for pregnant women or newborns related to influenza infection during pregnancy or the protective effect of influenza vaccine given during pregnancy. Likewise, little is known about the impact of antiviral medications on pregnancy outcome or newborn health.

We propose to fund a single state health department to follow a cohort of at least 300 pregnant women with confirmed influenza illness during the 2009-10 influenza season to document the outcome of their pregnancies, health status of the mother and newborn, and health status of the infant at 3 months of age. Patient specimens (cord blood, placental/fetal tissue, and breast milk) will be sent for testing by CDC lab to identify possible vertical transmission of novel influenza A (H1N1) virus from mother to infant.

Education initiatives for pregnant women and their health care providers on pandemic H1N1 virus in pregnancy:

- a) Pregnant women
- b) Development and dissemination of communications materials, such as guidelines, communications toolkits for health care providers, and vaccination campaign materials.
- c) Early identification and treatment of pandemic H1N1 infection in pregnant women is critical. Preliminary data suggest that severity of illness is associated with delay to treatment. Mitigation strategies hinge largely on behavior changes at the individual level. In addition, compliance with seasonal influenza vaccination has been low. Vaccine use for pandemic H1N1 might also be low among pregnant women despite their high risk status. We anticipate that many women and health care providers might be reluctant to comply with public health recommendations for antiviral treatment and chemoprophylaxis because of concerns regarding potential effects on the fetus.

The cornerstone of prevention activities is promotion of seasonal and novel vaccine use among pregnant women. Given that healthcare providers are trusted sources of information for pregnant women, it is important that health care providers actively promote and provide vaccination to pregnant women. Education on fever recognition and early identification of infection can also help mitigate adverse pregnancy outcomes. We propose developing and disseminating education materials for health care providers and pregnant women on importance of vaccination, early recognition and treatment of infection and fever, and other public health mitigation strategies.

Future Cancer Research/Surveillance:

- a) Women diagnosed with breast cancer less than 40 years of age
 - b) This literature review will explore a variety of psychosocial, treatment, functional, and information concerns of young breast cancer survivors. Information gleaned from his review will be used to inform the development of future projects designed to promote long-term cancer-free survival and quality of life of young women diagnosed with breast cancer.
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- a) Cancer Survivorship Module for the Behavioral Risk Factor Surveillance System to support implementation of the recently developed cancer survivorship questions on the 2010 BRFSS survey.
 - b) These questions will provide quantitative data to describe the health state of cancer survivors. Data collected will allow DCPC and Comprehensive Cancer Control programs to assess cancer screening behavior among survivors and evaluate progress toward improving survivorship care for cancer patients.

AMIGAS:

- a) Mexican-American women 21 years of age or older who have not been screened for cervical cancer.
- b) Six months after implementing AMIGAS, members of the project team will ask women in all four groups if they have had cervical cancer screening and use participants' medical records to validate responses. The researchers will compare screening rates among the four groups to see if the AMIGAS program, with and without its various components, significantly affected screening rates. If AMIGAS is shown to be effective, researchers will report on the characteristics, settings, and delivery processes that facilitate adoption, implementation, and maintenance of the program.
- c) AMIGAS was recently revised and expanded by scientific collaborators at CDC in conjunction with a community health advisory group, *promotoras* (lay health educators recruited from the local community), and researchers from the University of Texas.

Preventing Teen Pregnancy among Latina Girls:

- a) Latina girls ages 13 – 17 at high risk for teen pregnancy
- b) Reduction in number of sexual partners, improvements in contraceptive use, increase in levels of school support and belonging, improved academic performance, among other outcomes
- c) Researchers at the CDC Prevention Research Center at University of Minnesota are developing and testing a multi-component, culturally relevant program designed to reduce sexual risk behaviors among Latina girls ages 13 – 17 at high risk for teen pregnancy.

Using Social Networks and Technology to Promote Healthy Sexuality:

- a) Young African-American adults age 18-24 recruited at public clinics that test for and treat sexually transmitted disease
- b) Increased knowledge about sexuality, changed perceptions of social norms, empowerment to make healthier choices regarding sexuality, increased use of condoms and HIV testing, and lower rates of sexually transmitted infections.
- c) Researchers at the CDC Prevention Research Center at the University of Michigan are using evidence-based peer education programs to teach 18-24 year olds about preventing sexually transmitted infections, including HIV.

Expansion of Health and Safety of Home Care Workers:

- a) NIOSH would like to expand on the pilot project to implement a larger intervention program targeting home care and home health care aides across the country. The population as described above currently includes about 1.5 million low wage women workers but is likely to increase over time. The target population also includes the expanding elderly population who will require caregiver assistance to remain living in their homes; one estimate projects that the number of elderly with activity limitations will reach 28 million by 2030. The elderly population, especially those over 80 who are most likely to need paid caregiver assistance at home, is also disproportionately female. Thus improved job safety and decreased job turnover are likely to improve the health of both the paid caregivers as well as care recipients, two large and growing underserved female populations.
- b) Benchmarks for success of such an initiative would be measured both through decreased injury and illness rates as well as decreased turnover rates for caregivers. A recent analysis using BLS data from 2005 and 2006 showed that almost half (48%) of home care aides had left that occupation within the year.

Expansion of The Women’s Reproductive Health Study:

- a) Our program focuses on women with occupational exposures that are suspected or known reproductive toxicants. Sector occupational groups include (but are not limited to) manufacturing, health care workers, cleaning staff, flight crew, and agricultural workers.
- b) Research to practice (R2P) components are part of all of our projects and include workshops, surveys, interventions, awareness campaigns, and other communication materials, in collaboration with our partners and labor organizations. Benchmarks include OSHA or other occupational regulations that protect women's reproductive health as a result of our research and better information on Material Safety Data Sheets in plain language. The overall goal is to reduce adverse reproductive outcomes associated with occupational exposures.

Global AIDS Program (GAP):

- a) In accordance with mandates from the 2008 PEPFAR reauthorizing legislation, efforts will intensify in building upon evidence-based interventions for women and children’s health and on program integration with other maternal and child health programs. In addition to child bearing women and children, women engaged in sex work will also be targeted as one of the subpopulations classified as Most at Risk Populations (MARPS). Future emphasis on integrating PMTCT programming within broader Maternal, Newborn and Child Health (MNCH) services and pediatric HIV services will increase program sustainability, strengthen health systems, and improve maternal, newborn, and child health outcomes overall.
- b) PEPFAR 10-year goals (by 2013): 1) Treatment for at least 3 million; 2) Prevention of 12 million new infections; 3) Care for 12 million, including 5 million orphans and vulnerable children; 4) Training for 140,000 health care workers; 5) 80% of those in need will be reached with PMTCT services.
- c) The Institute of Medicine (IOM), in its 2007 legislatively mandated, public evaluation of PEPFAR notes that, “In the transition from emergency response to sustainability...the U.S. Global AIDS Initiative will need to keep gender issues at the core of its efforts. The U.S. Global AIDS Initiative should continue to increase its focus on the factors that put women at greater risk of HIV/AIDS and to support improvements in the legal, economic, educational, and social status of women and girls.”

STD Prevention Programs:

- a) American Indian and Alaskan Native populations
- b) State and local STD programs are required to report twice-annually on a set of STD program performance measures. Four measures evaluate basic program activities thought to ultimately affect community prevalence and morbidity levels:
 - 1. Proportion of “priority” gonorrhea cases interviewed within 7, 14, and 30 days from the date of specimen collection. Priority populations are determined locally, and should be based on local epidemiology (e.g., pregnant women, women aged 15-19 years, women of childbearing age, resistant gonorrhea, MSM, etc).

2. Among clients of prevalence monitoring family planning clinics, the proportion of women with positive CT or GC tests that are treated within 14 and 30 days of the date of specimen collection.
3. Among clients of STD clinics, the proportion of women with positive CT or GC tests that are treated within 14 and 30 days of the date of specimen collection.
4. Proportion of female admittees to large juvenile detention facilities who were tested for chlamydia.

In addition, the 10 regional family planning training centers report annually on the following two regional performance measures:

1. Among clients attending title X family planning clinics, the proportion of sexually-active women screened for Chlamydia at least once during a calendar year, stratified by age group (OPA- Family Planning Annual Report)
2. Among clients attending IPP prevalence monitoring clinics, the number of women screened for chlamydia, stratified by age.

Overarching Recommendations

Increase the Prevalence, Quality, and Coordination of Employee Health Programs: To date, much of the focus on support for breastfeeding in employment settings has focused on improving support for breastfeeding mothers who return to work outside the home. There is a particular need for examining how to eliminate the barrier of returning to work, which factors into many mothers not breastfeeding at all. The majority of insight about lactation support programs and related characteristics has been gained on issues such as the size and contents of a room for mothers to use to express milk, where to store milk at the work site, how many breaks a mother needs, whether or not to provide a pump as part of a program, and how the program relates to other workplace wellness benefits. However, this narrow scope does not include considerations to reduce the amount of time mothers and infants are separated in the first year of life. Such considerations include co-locating child care at mothers' work location, improving flexibility in a mother's work schedule so that her time away from the baby is divided into small sections of time, telecommuting from home, accommodating infants at work locations, and providing paid maternity leave.

Work-Life/Flexibility: Women are entering the workforce at increasing rates, and couples are working longer hours. Due to these circumstances and recent trends in family planning (e.g., couples having children later in life when care of elderly family members may also become necessary), workers are increasingly finding themselves “sandwiched” between work and domestic responsibilities. The links between work-life conflict and employees’ well-being and functioning (both at work and home) have become a growing concern for both employers and workers. Further study is needed to examine the risks posed by work-life conflict and especially the design and benefits of work-life programs to restore work-life balance.

Evidenced Based Prevention Support: Recommend support to all 50 states and U.S. territories in the delivery and monitoring of evidence based prevention approaches within communities, with a particular emphasis on priority and risk groups. In addition, each state will receive assistance in developing the necessary on-going data collection systems needed to monitor the problem, track program progress, and evaluate the implementation of prevention programs.

Women’s Health and Diabetes: 1) Data from national surveys should be stratified by sex to identify gaps in addressing specific needs for women with diabetes across the lifestages. 2) Reports should be developed across the US (by all states and territories) to assess national gaps in quality of care for women with diabetes. 3) Programs should be developed based on findings from the data to reduce barriers to optimal care for women with diagnosed diabetes. In this regard, particular attention should be paid to the finding that women younger than 45 years are especially vulnerable to suboptimal diabetes care. 4) Programmatic activities should be developed to address challenges in providing post-partum follow-up care for women with a history of gestational diabetes.

HIV Prevention Programs: General monitoring and evaluation of HIV prevention programs is critical to the delivery of successful HIV prevention intervention to reduce the number of HIV infections among African American women. More funding is needed to provide outcome monitoring of HIV prevention programs.

Home Care Worker Safety: A larger scale initiative aimed at improving home care worker safety and health and decreasing worker turnover, would require a multi-agency initiative that brings together those responsible for coordinating and funding elder care services and those conducting research to develop successful intervention programs. Pilot research initiatives funded by governmental as well as non governmental agencies point to the need for coordinated intervention programs to improve training programs and other working conditions for home care workers.

Reproductive Health Awareness: Our program is striving for better awareness for workers and employers on protecting the reproductive health of women and their offspring. Additional resources are needed to better improve worker documents on worker reproductive health, and to raise awareness.

Global AIDS Program (GAP): In accordance with PEPFAR reauthorizing legislation (2008), future programming for women and girls should be elevated as a key program priority and include strategic gender programming planning, implementation, and progress reporting to measure impact.

Public Health Research Needs Related to Women:

Evaluate the immune response to highly pathogenic avian or other influenza and vaccines in high-risk populations, especially persons who are immuno-compromised, the elderly, children, and pregnant women.

Enhance pre-marketing study data on safety and effectiveness of pharmaceuticals by conducting appropriate post-marketing surveillance and pharmaco-epidemiologic studies to quantify the incidence of known adverse and beneficial effects of pharmaceutical therapy in diverse populations; these efforts should include populations that typically are not assessed in pre-marketing studies (e.g., the elderly, children, and pregnant women).

Develop and disseminate interventions to promote healthy behaviors among women before conception and during pregnancy and among all persons in every stage of life.

Effective interventions that promote pregnancy planning, preconception care, and safe motherhood and improve the health of all women and their infants also must be developed, implemented, and evaluated. Such interventions will prevent unintended pregnancy, teen pregnancy, and pre-term delivery; increase access to and quality of care before, during, and after pregnancy; and increase breastfeeding rates. Promoting healthy pregnancy and birth outcomes through the prevention and control of disability across the lifespan is critical to ensuring that infants and toddlers grow into healthy children and adults.

Initiate and assess research-to-practice initiatives to promote pregnancy planning and preconception care through a broad range of health-care programs and services for women, including women with disabilities. Initiatives should include assessment of maternal and paternal health history and behaviors before, during, and after pregnancy; delivery of vaccinations; screening for disease and genetic disorders; promotion of folic acid use; assessment and treatment of mental health disorders; management of existing illnesses (e.g., diabetes); and provision of health services to address risky behaviors (e.g., smoking, alcohol use, and obesity). Identify indicators of preconception care and women's health that have the greatest impact on birth outcomes.

Identify and assess interventions, including general health care for women, that can improve birth outcomes by a) preventing risk of unintended pregnancy, teen pregnancy, and pre-term delivery and b) elucidating the needs of near-term infants (i.e., infants born at 34–37 weeks' gestation). Identify and assess the impact of factors that contribute to adverse birth outcomes (e.g., birth defects and developmental disabilities), including those associated with genetics, maternal and paternal environmental exposures, cultural practices, maternal mental health, and socioeconomic status. Identify new risk factors for birth defects and other adverse birth outcomes during pregnancy planning, preconception, pregnancy, and the newborn period. Conduct studies to identify potential interventions to address adverse birth outcomes, including appropriate nutrition and physical activity.

Identify the major environmental causes of disease (including existing and emerging environmental health threats), especially among high-risk populations (e.g., children,

pregnant women, and the elderly), and obtain nationally representative prevalence and incidence data.

Determine the sociopolitical factors and descriptive epidemiology of exploitation, and identify the magnitude and scope of exploitation-related diseases. Examine the prevalence and trends of sexual exploitation, impact of public policy, role of the Internet in proliferation, resulting psychosocial and medical effects, cultural variations, and role of prevention education. Assess the impact and extent of sexual violence and sexual exploitation on women and children during armed conflict and other Complex Humanitarian Emergencies situations. Identify the unique health problems of women and children who are victims of exploitation (including child labor), and investigate the types of services most needed by these populations.

Develop and evaluate strategies of promoting pregnancy planning and preconception care to improve birth outcomes and reduce the life-long effects of poor birth outcomes.

Develop and evaluate strategies to enhance infant and maternal health by increasing access to and quality of care before, during, and after pregnancy. The implementation of these strategies will prevent unintended pregnancy, sexually transmitted diseases, teen pregnancy, and pre-term delivery. Understand the determinants of infant feeding behavior, including breastfeeding initiation and continuation and the impact of premature and near-term birth on breastfeeding rates. Conduct clinical trials of drugs to prevent mother-to-child transmission of human immunodeficiency virus (HIV) and other diseases. Identify the role of fetal development and infant care, including increasing breastfeeding practices and improving detection and treatment of maternal mental health disorders, on reducing chronic disease and disabilities in subsequent life stages.

Identify interventions to prevent physical inactivity, poor diet, tobacco use, alcohol use, risky sexual behaviors, and other factors that contribute to obesity, heart disease, type 2 diabetes, cancer, injury, violence, human immunodeficiency virus and other sexually transmitted diseases, and unintended pregnancy.

Conduct research to close gaps in knowledge pertaining to the occurrence of and risk factors for occupational diseases (e.g., respiratory diseases, cardiovascular diseases, dermatitis and other skin disorders, fertility and pregnancy abnormalities, and infectious diseases).

Identify, characterize, and assess effective strategies to prevent and control perinatal infections. These strategies will help ensure healthy pregnancies for both mothers and infants and prevent premature births, birth defects, and other morbidity and mortality that can affect the fetus, infant, and older child. Examine the relationship between particular maternal and infant infections, and determine the long-term outcomes for infected infants. Through interdisciplinary research, examine infectious processes, inflammatory responses, reproductive health, and genomics to identify novel strategies for preventing premature births. Develop point-of-care diagnostic methods for use in prenatal and obstetric health-care settings for various infections. Identify and evaluate effective

primary prevention strategies through health services research (e.g., maternal and infant screening, education, and treatment).

Conduct operational and evaluation research to obtain essential information needed to guide the development and implementation of programs to prevent deaths among mothers and young children. Priority topics include a) emergency obstetric care; b) the practice of spacing and limiting births; c) breastfeeding practices; d) diseases that affect newborns; e) the major causes of child mortality (e.g., malaria, diarrheal diseases, pneumonia, and measles); f) the major risk factors for mortality (e.g., malnutrition); g) critical areas of intervention (e.g., family planning and appropriate drug therapy); and h) health-system needs for providing effective interventions.

Centers for Medicare & Medicaid Services (CMS)

Programs That Improve the Lives of Women and Girls

Medicaid Immunizations for Girls and Young Women

Program Description:

Medicaid and CHIP have provided for the immunization of girls and young women as per Title XIX and XXI of the Social Security Act. Under Section 1928, within the Vaccines for Children (VFC) program, all immunizations recommended by the Advisory Committee on Immunization Practices (ACIP) are covered by Medicaid through the age of 18. For women age 19 to 21, immunizations are provided through the State Medicaid program as required by the Early Periodic Diagnostic Services and Treatment (EPSDT) Program. States also have the option to provide immunizations to adults covered under the terms of their Medicaid State plan. This varies from State to State.

One of the key advances benefiting low-income women and girls is the availability of a vaccine to prevent Human Papilloma Virus (HPV). With the recommendation of Gardasil in 2006, Medicaid is now able to provide a vaccine that will prevent four types of HPV that are known to cause cervical cancer and genital warts. This is a relatively new drug that was approved for use in girls and young women ages 9 – 26 years old.

Distribution and operations of the vaccine programs occur through the Centers for Disease Control and Prevention (CDC) while CMS determines the immunization policy for Medicaid and CHIP beneficiaries. The funding of all vaccines comes from the CMS budget for the VFC program and goes to CDC for the purchase of vaccines and program administration. CDC negotiates a contract price for the vaccines that States and other federal programs may take advantage of to purchase vaccine for non-VFC programs.

a) Relevant Statistics:

According to the *Lancet* and the *New England Journal of Medicine*, Gardasil is considered 100% effective in preventing the HPV virus from causing disease or genital warts for the virus strains the immunization targets. The CDC reported that 25.1% of adolescent females initiated the vaccine series in 2007.

(http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5740a2.htm?s_cid=mm5740a2_e). Further data is not available at this time.

b) Target Population(s):

Women and girls ages 9 – 26 will continue to be targeted to complete the three immunization series designed to prevent cervical cancer that is due to the four strains of HPV included in this vaccine. Each year a new age cohort is eligible for the vaccine. If they can be vaccinated before sexual debut, these young women can avoid development of cervical cancer and passing the virus to any future sexual partners.

c) Benchmarks:

The current evaluation mechanism for beneficiary access to the immunizations is data collected by the CDC on national usage of the vaccine. At the present time, Medicaid and CHIP programs do not require State Medicaid Program reporting on beneficiary immunization rates or projected prevention rates for cervical cancer.

d) Other:

Research is being conducted by Merck (the manufacturer of Gardasil) and submitted to the FDA for additional vaccines for other types of HPV. The four vaccine components featured in Gardasil are considered the most common strains to cause cervical cancer and genital warts. Also, data are being compiled on using this vaccine in young men and boys of ages similar to the girls. While women are the only gender diagnosed with cervical cancer, the HPV has been demonstrated to also cause cancer of the penis, throat and anus, according to CDC (<http://www.cdc.gov/std/hpv/STDFact-HPV-vaccine-young-women.htm>).

Overarching Recommendations:

Providing an immunization to protect people from various types of cancer associated with HPV improves the quality of life and reduces the burden of cost of the various types of cancer outcomes possible from this disease.

CMS is working to address the issue of Medicaid beneficiaries aging out of the VFC or EPSDT programs before the vaccine series is completed. (Some States do not provide immunizations for individuals older than 21.) We are looking for opportunities to connect with other programs or available insurance mechanisms that might be able to cover the cost of completing the series. Technical assistance is needed to help States, Medicaid/CHIP providers and beneficiaries identify ways to bridge the financial gap between programs. This is particularly important for those who started the series on Medicaid/CHIP but leave the program and cannot afford to pay for the remainder of the series and do not have health insurance to pay for it. The cost benefit of the HPV vaccine continues to be assessed, but it is evident that there is potentially significant impact on improving quality of life and reducing cost of treating cancers that can result when the vaccine is not provided.

Breast and Cervical Cancer Prevention and Treatment in Medicaid

Program Description:

On October 24, 2000, the Breast and Cervical Cancer Prevention and Treatment Act of 2000 (BCCPTA) was signed into law, giving states the option to establish access and to provide medical assistance through Medicaid for any uninsured woman under 65 who has been screened and diagnosed with breast and/or cervical cancer conditions, including precancerous conditions. Screening programs are funded by the Centers for Disease Control and Prevention (CDC) through the National Breast and Cervical Cancer Early Detection Program (NBCCEDP).

On January 15, 2002, President Bush signed the [Native American Breast and Cervical Cancer Treatment Technical Amendment Act of 2001 \(Public Law No. 107-121\). \(PDF-33KB\)](#) This bill amends title XIX of the Social Security Act to clarify that Indian women with breast or cervical cancer who are eligible for health services provided under a medical care program of the Indian Health Service or of a tribal organization are included in the optional Medicaid eligibility category of breast or cervical cancer patients added by the Breast and Cervical Cancer Prevention and Treatment Act of 2000.

NBCCEDP provides free breast and cervical cancer screening and follow-up diagnostic services to women in need, such as those who are uninsured or have low incomes. In 2000, CDC began its 10th year of this landmark program, supporting early detection programs in all 50 states, 6 U.S. territories, the District of Columbia, and 12 American Indian and Alaska Native organizations.

a) Relevant Statistics:

As of May 2004, all states had implemented this Medicaid option and extend Medicaid to the target populations.

b) Target Population(s):

Any uninsured woman under 65 who has been screened and diagnosed with breast and/or cervical cancer conditions through state screening programs funded by the NBCCEDP.

Overarching Recommendations:

Continued and ongoing outreach to providers and women to ensure knowledge regarding breast and cervical screening and treatment availability of BCCPTA under Medicaid. A focus group of participants in the State of California stress that knowledge about potential health coverage for cancer treatment would allay fears about paying for medical care if diagnosed.

Family Planning Section 1115 Demonstrations

Program Description:

Family Planning section 1115 demonstrations (“waivers”) improve the lives of America’s women by providing family planning services to enable women to better control the number and timing of their pregnancies. These demonstration projects extend eligibility for family planning services to uninsured women of childbearing age with family income up to 200 percent of the Federal poverty level (FPL) who are not otherwise eligible for Medicaid.

Family planning section 1115 demonstrations are approved by the Administrator of the Centers for Medicare & Medicaid Services (CMS) in the Department of Health and Human Services (HHS). The Family and Children’s Health Programs Group in the Center for Medicaid and State Operations at CMS works with States to develop and monitor these demonstration projects.

Family planning section 1115 demonstration projects are reviewed by a Federal Review Team that consists of members from a cross section of agencies within the Department of HHS as well as the Office of Management and Budget.

a) Relevant Statistics:

Twenty-two States currently operate stand-alone, targeted family planning section 1115 demonstration projects and five States operate expanded family planning programs as part of their comprehensive section 1115 demonstration projects. Approximately 3 million women each year obtain family planning services through these demonstration projects.

Studies have found that family planning demonstrations lead to a considerable decrease in unintended pregnancies. Additionally, family planning demonstrations help women lengthen the interval between pregnancies, which ultimately leads to healthier pregnancies and a reduction in infant mortality rates.

According to a 1999 Guttmacher Institute report, every dollar spent in helping women avoid and space pregnancies saves over \$4 in Medicaid expenditures that would have gone for pregnancy related care.

Overarching Recommendations: CMS continues to evaluate the results of these demonstration programs with participating States and is working with additional states interested in facilitating access to family planning services.

Medicaid Neonatal Outcomes Project

Program Description:

In response to a report from the Institute of Medicine on preterm birth (Preterm Birth, July, 2006). The Center for Medicaid and State Operations developed an initiative to reduce the mortality and morbidity attributable to premature birth in the Medicaid population. Medicaid pays for over 40% of US births (<http://www.statehealthfacts.org>); and premature birth is the leading cause of infant mortality in the US (Kaiser Family Foundation). Medicaid is uniquely positioned to improve access to prenatal care in this important area.

After convening a panel of expert obstetricians and neonatologists to recommend interventions to improve care, CMS awarded Medicaid Transformation Grants (available under the Deficit Reduction Act of 2005) to the Ohio, North Carolina, and Arkansas State Medicaid Agencies to implement initiatives to assess the impact of these interventions in the Medicaid program. The New York State Medicaid Agency expressed interest in the initiative, and joined the program utilizing State funds. These four States have selected some of the suggested interventions to pilot in their States. The national program is now underway.

a) Relevant Statistics:

The project is early in the implementation phase, with the four states in various stages of data collection. Early indications show that one of the goals (to reduce elective C-sections before 39 weeks of gestation) is being met in Ohio. Elective C-sections under 39 weeks in Ohio have declined by 50% since introduction of the program.

b) Target Population(s):

The initial focus of the project was on Medicaid mothers at high-risk of premature birth within the four States. Some of the interventions also target the premature infants born to these mothers.

c) Benchmarks:

In addition to the suggested clinical interventions, a measurement strategy package designed by the National Institute for Children's Healthcare Quality (NICHQ) to test the effectiveness of the interventions was provided to the four States at the onset of the project. The actual measurements used depend upon the State's choices of clinical interventions for implementation. The package consists of suggested outcome, process, and balancing measures tailored to the suggested clinical interventions.

d) Other:

This program presents a significant opportunity help reduce the national infant mortality rate. As the largest single payer for childbirth in the United States, Medicaid programs can act to reduce infant mortality and morbidity attributable to preterm birth.

Overarching Recommendations:

The Medicaid Neonatal Outcomes Pilot Project is a program with potential for national application. Upon completion, CMS will evaluate the results of the project with the four participating States and other national Stakeholders to finalize recommendations for additional opportunities in this clinical area, including the potential development of a national initiative.

Ensuring Quality Preventive Care for Women

Program Description:

The Division of Laboratory Services (DLS) in the Centers for Medicaid and State Operations/Survey and Certification Group is responsible for regulating laboratory testing of human specimens through the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program. One of the impetuses for the promulgation of the CLIA statute in the late 1980s was the highly publicized discovery of significant numbers of misread Papanicolaou (Pap) tests examined by individuals who worked in laboratories known as “Pap Mills.” These laboratories forced individuals to examine more Pap tests than they were capable of examining accurately. As a result of mistakes in cytology laboratories and to meet the statutory requirements of CLIA, CMS has conducted over 750 in-depth surveys in cytology laboratory since 1988 using contracted cytotechnologists and pathologists. This program is ongoing. (See relevant statistics below)

A second mechanism employed by DLS to protect women and girls who obtain Pap tests and meet the statutory requirements of CLIA was the implementation of a national cytology proficiency testing (PT) program for every individual who examines or interprets a Pap tests. Cytology PT was first conducted on a national basis in 2005. This program includes a testing component and, where necessary, a continuing education component in the event of individual test failure.

a) Relevant Statistics

- More than 60 million Papanicolaou (Pap) tests are performed on women and girls in the United States of America each year.
- Since the introduction of Pap testing the 1950s, the number of deaths from cervical cancer has decreased approximately 74%.
- Initial Cytology PT Failure Rates, 2005-2008* (see chart below)

Initial Cytology PT Failure Rates, 2005-2008*

Cytotechnologist	7%	5%	3%	3%
Pathologist without Cytotechnologist	33%	17%	11%	11%
Pathologist with Cytotechnologist	10%	5%	3%	3%

b) Future Programs:

1. CMS intends to continue performing in-depth cytology surveys in laboratories where complaints have been received, at the request of a CMS Regional Offices or State Agencies and at random.
2. CMS will continue to mandate cytology PT on a national basis.
3. CMS will continue to analyze the NPRM comments.

Overarching Recommendations:

CMS considers the protection of the health and safety of women and girls to be of paramount importance to its mission. We use a two-pronged approach to achieve this goal: in-depth surveys of cytology laboratories and cytology PT. These two programs help direct CMS to those laboratories where CLIA compliance may be questionable and to those individuals, cytotechnologist or pathologists, who may need continuing education to ensure the quality of the cytology testing performed in their laboratories. Women and girls who have Pap testing performed deserve to have accurate and reliable results.

The following is a list of Medicare National coverage policies related to women's health. CMS currently has one decision open for public comment and the others are existing coverage policies. The majority of these policies were set by statute. Also listed are CMS dental initiatives involving children.

I. Open

Positron Emission Tomography (FDG) for Cervical Cancer

Proposed Decision Memorandum due: 11/08/09

Medicare coverage of all other uses of FDG PET related to cervical cancer is restricted to beneficiaries who are enrolled in a prospective clinical study under Coverage with Evidence Development (CED). The requestors have asked CMS to reconsider the NCD and nationally cover FDG PET more broadly (without the CED restriction) for the staging of cervical cancer, i.e. in those women who have been diagnosed with cervical cancer but who do not otherwise meet the coverage criteria. The requestors also ask that the use of FDG PET be nationally noncovered to make the diagnosis of cervical cancer, as FDG PET imaging is not helpful to make the initial diagnosis.

II. Closed

1. Diagnostic Pap Smears 190.2

Effective date: 6/19/06

A diagnostic pap smear and related medically necessary services are covered under Medicare Part B when ordered by a physician under one of the following conditions:

- Previous cancer of the cervix, uterus, or vagina that has been or is presently being treated;
- Previous abnormal pap smear;
- Any abnormal findings of the vagina, cervix, uterus, ovaries, or adnexa;
- Any significant complaint by the patient referable to the female reproductive system; or
- Any signs or symptoms that might in the physician's judgment reasonably be related to a gynecologic disorder.

2. Screening Pap Smears and Pelvic Examinations for Early Detection of Cervical or Vaginal Cancer 210.2

Effective date: 6/19/06

A screening pap smear and related medically necessary services provided to a woman for the early detection of cervical cancer (including collection of the sample of cells and a physician's interpretation of the test results) and pelvic examination (including clinical breast examination) are covered under Medicare Part B when ordered by a physician (or authorized practitioner) under one of the following conditions:

- She has not had such a test during the preceding two years or is a woman of childbearing age (§1861(nn) of the Act).
- There is evidence (based on her medical history or other findings) that she is at high risk of developing cervical cancer and her physician (or authorized practitioner) recommends that she have the test performed more frequently than every two years.

High risk factors for cervical and vaginal cancer are:

- Early onset of sexual activity (under 16 years of age).
- Multiple sexual partners (five or more in a lifetime).
- History of sexually transmitted disease (including HIV infection).
- Fewer than three negative or any pap smears within the previous 7 years.; and
- DES (diethylstilbestrol) - exposed daughters of women who took DES during pregnancy.

3. Mammograms 220.4

Effective date: 5/15/1978

A diagnostic mammography is a covered service if it is ordered by a doctor of medicine or osteopathy as defined in §1861(r)(1) of the Act.

Payment may not be made for a screening mammography performed on a woman under age 35. Payment may be made for only one screening mammography performed on a woman over age 34, but under age 40. For an asymptomatic woman over age 39, payment may be made for a screening mammography performed after at least 11 months have passed following the month in which the last screening mammography was performed.

A radiological mammogram is a covered diagnostic test under the following conditions:

- A patient has distinct signs and symptoms for which a mammogram is indicated;
- A patient has a history of breast cancer; or
- A patient is asymptomatic but, based on the patient's history and other factors the physician considers significant, the physician's judgment is that a mammogram is appropriate.

Use of mammograms in routine screening of: (1) asymptomatic women aged 50 and over, and (2) asymptomatic women aged 40 or over whose mothers or sisters have had the disease, is considered medically appropriate, but would not be covered for Medicare purposes.

4. Breast Reconstruction Following Mastectomy 140.2

Effective date: 1/1/1997

Reconstruction of the affected and the contralateral unaffected breast following a medically necessary mastectomy is considered a relatively safe and effective noncosmetic procedure. Accordingly, program payment may be made for breast reconstruction surgery following removal of a breast for any medical reason.

Program payment may not be made for breast reconstruction for cosmetic reasons. (Cosmetic surgery is excluded from coverage under §1862(a)(10) of the Act.)

5. Percutaneous Image-Guided Breast Biopsy (220.13)

Effective date: 1/1/2003

A - Nonpalpable Breast Lesions

Effective January 1, 2003, Medicare covers percutaneous image-guided breast biopsy using stereotactic or ultrasound imaging for a radiographic abnormality that is nonpalpable and is graded as a BIRADS III, IV, or V.

B - Palpable Breast Lesions

Effective January 1, 2003, Medicare covers percutaneous image guided breast biopsy using stereotactic or ultrasound imaging for palpable lesions that are difficult to biopsy using palpation alone. Contractors have the discretion to decide what types of palpable lesions are difficult to biopsy using palpation

6. PET (FDG) for Breast Cancer (220.6.10)

Effective date: 1/28/2005

Effective for services performed on or after October 1, 2002, Medicare covers FDG PET only as an adjunct to other imaging modalities for: (1) staging breast cancer patients with distant metastasis, (2) restaging patients with loco-regional recurrence or metastasis, or (3) monitoring tumor response to treatment for women with locally advanced and metastatic breast cancer when a change in therapy is contemplated.

Limitations: Medicare continues to nationally non-cover initial diagnosis of breast cancer and staging of axillary lymph nodes.

Documentation that these conditions are met should be maintained by the referring physician in the beneficiary's medical record, as is normal business practice.

III. CMS Dental Initiatives Involving Children

- Dental requirements of the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA).
 - o Requires States to provide dental services to CHIP eligible children.
 - o Requires a listing of Medicaid and CHIP dental providers be posted on the Insure Kids Now webpage.
 - o Requires a listing of dental services covered under Medicaid and CHIP be posted on the Insure Kids Now webpage.
 - o Requires that oral health measures be included in a core set of child health measures being developed.
 - o Requires the reporting of additional dental data for Medicaid and CHIP services.

- Dental Quality Alliance
 - o CMS is working with ADA on forming a Dental Quality Alliance. An initial meeting should take place this summer.

- Oral Health Technical Advisory Group
 - o Working with the OTAG on various issues regarding dental care for Medicaid and CHIP eligible children

Program Description:

Ask Medicare began in September, 2008. An electronic newsletter and webpage help the caregiver navigate CMS on behalf of a friend or loved one. *Ask Medicare* will be highlighted by OPM/EAP so that all federal EAP programs can point to the information on *Ask Medicare*.

Relevant Statistics:

Family caregivers comprise 13% of the workforce, and the estimated economic value of their unpaid contributions is \$375 billion in 2007.

Evaluation/Feedback Mechanism:

- 1) In fourth months since launch of enewsletter, the subscriptions have grown to over 30,000.
- 2) Levels of leadership involved in overseeing program's success: Kim Kleine, Deputy Director, Office of External Affairs, CMS

Future Efforts

Program Description: Plans continue in 2009 to target the 45 year-old woman, caught in the sandwich generation caring for aging parents and growing children. The goal in the next twelve months is to boost online subscriptions to the newsletter to one million.

Food and Drug Administration (FDA)

Agency Overview

Women and girls use products regulated by FDA many times each day. The Food & Drug Administration (FDA) is one OPDIV within DHHS that improves the lives of American women and girls. FDA is the oldest comprehensive consumer protection agency in the U. S. federal government. FDA is one of the leading science based public health agencies in the world. FDA is a regulatory agency responsible for oversight of more than \$2 trillion in medical products, food, and other consumer goods. FDA's mission is to protect and promote public health, and hence the health of all women and girls. The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. In order to do this FDA must enforce a wide array of laws and regulations that govern the safety, efficacy, and security of these products. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

Specifically FDA is responsible for the following:

- Licensing of medical product manufacturing establishments
- Safety of the nation's blood supply
- Research to establish product standards and develop improved testing methods
- Safety & labeling for cosmetics
- Prescription and over the counter (OTC) drug approvals and product labeling
- Drug manufacturing standards
- Food labeling
- Safety of all food products (except meat and poultry), including bottled water
- Premarket approval of new medical devices
- Medical device manufacturing and performance standards
- Tracking reports of medical device malfunction and serious adverse reactions
- Radiation safety performance standards for microwave ovens, television receivers, diagnostic x-ray equipment, cabinet x-ray systems (e.g., baggage x-rays at airports), laser products, ultrasonic therapy equipment, mercury vapor lamps, sunlamps, and cell phones
- Accrediting and inspecting mammography facilities
- Animal feed (for pets and livestock)
- Veterinary drugs and medical devices

Programs That Improves the Lives of America's Women and Girls

1. Program Descriptions:

Given the broad list of FDA responsibilities, the way in which FDA improves the lives of women and girls is complex and multi-factorial. Women and girls have access to numerous FDA-approved medical treatments and diagnostics – some of which are unique to the health needs of females and others that are not. These include vaccines such as the HPV vaccine, only approved for women and girls, as well as all the full array of adult and childhood vaccines. Medications specific to women such as oral contraceptives as well as medications that women may take to treat diabetes, high blood pressure and high cholesterol are regulated by FDA. Medical devices regulated by FDA include items that women and girls are commonly exposed to such as tongue depressors and examinations gloves and devices or diagnostic tests unique to women such as pregnancy monitoring equipment and PAP tests. FDA recognizes the importance of pets or companion animals in the lives of many families and regulates pet foods, snacks, and medications for pets. In addition to those examples, it is unlikely that a day goes by when a woman or girl does not use a product that FDA regulates...toothpaste, deodorant, body lotion, make-up. FDA is also responsible for updates to a variety of product labelings, safety alerts, product recalls, and product withdrawals. For many of these FDA will issue a press releases, hold stakeholder teleconferences, or use a variety of other public alerting and social media mechanisms, e.g., internet, FaceBook, Twitter, etc. FDA has a food safety hotline which is staffed 24 hours a day. FDA has the MedWatch program where consumers can report adverse problems from medications or medical devices directly to FDA. FDA provides a vast array of consumer information about all the products FDA regulates on its newly launched website, www.fda.gov. There are areas of this website specific to the health interests of children and women.

Additionally FDA partners with stakeholders to address critical public health needs and bridge scientific gaps. Such collaborations can take place through contracts, cooperative agreements, or through innovative public-private partnerships. FDA's Critical Path Initiative has numerous public-private partnerships several of which are pertinent to the health of women and girls. For example, one program is evaluating the safety and long term health consequences of certain anesthetic drugs in children while another is looking at the risk factors (including age, sex, medications, etc.) for late closure of drug eluting stents frequently used in patients with cardiovascular disease. There are many examples of partnership and collaboration among the various DHHS OPDIVS with FDA including AHRQ, CDC, CMS, HRSA, and NIH, among others.

The vast majority of the regulatory work of FDA that improves the lives of women and girls -- approving drugs, vaccines, medical devices -- is conducted by the FDA Centers. In addition, there are several programs within the Centers that do work specific to the health of women and girls including the Mammography Quality Standards Act and Program in the Center for Devices and Radiologic Health (CDRH) and the Maternal Health Team in the Center for Drug Evaluation and Research (CDER). Two other programs are located in the Office of the Commissioner: the Office of Pediatric Therapeutics and the Office of Women's Health. These programs illustrate programs within FDA specific to women and girls but this is not a comprehensive list of programs across the Agency.

FDA's responsibilities to enforce the Mammography Quality Standards Act are housed in the Division of Mammography Quality and Radiation Programs (DMQRP) located in the Office of Communication, Education, and Radiation Programs (OCER) in CDRH. FDA's Mammography Program informs mammography facility personnel, inspectors, and other interested individuals about the implementation of the Mammography Quality Standards Act of 1992 (MQSA). Congress enacted MQSA to ensure that all women have access to quality mammography for the detection of breast cancer in its earliest, most treatable stages. Congress charged FDA with developing and implementing MQSA regulations. FDA's goal for the MQSA program is "To improve the quality of the nation's mammography services." To date, MQSA inspectors have completed a total of nearly 93,000 facility inspections. MQSA inspectors have proven to be dedicated professionals serious about ensuring that quality standards are met. Starting with each inspector's successful completion of the rigorous training and continuing through their performance of annual inspections for each mammography facility within their charge, MQSA inspectors and the entire inspection program are a vital part of the MQSA program. DMQRP is continually reviewing the many aspects involved in administering this nationwide program and considers what refinements or improvements are needed and in which areas: compliance activities; our partnership with the accreditation bodies and the States-As-Certifiers program; new modalities in mammography such as full field digital; and an FDA inspection electronic data systems, just to name a few. FDA hopes to achieve the goal of affording quality mammography services for all of our nation's women via an ever efficient and least burdensome approach to facilities. More information about this program is located at <http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/default.htm>.

The Maternal Health Team (MHT) is part of the Pediatric and Maternal Health Staff and is located in the Immediate Office of the Office of New Drugs (OND) in CDER. The MHT is responsible for developing regulations, guidance documents, and procedures related to how drugs are labeled for use during pregnancy and lactation. The MHT also works with, and responds to, consult requests from drug review divisions related to giving advice on postmarketing commitments for pregnancy exposure registries; writing the pregnancy and lactation sections of labeling; developing pregnancy prevention risk management programs; evaluating protocols and analyzing data from industry-sponsored pre- and postmarketing pharmacokinetic, clinical lactation, and safety studies in this area; and evaluating published case reports/case series and epidemiologic studies of possible drug-induced adverse pregnancy outcomes or effects in breast-fed infants.

The Office of Pediatric Therapeutics (OPT) is mandated by Congress and is located in the Office of the Chief Scientist in the Office of the Commissioner. Its primary mission is to assure access for children to innovative, safe and effective medical products. Historically, many medical products have not been tested for use in children, leading to an increase in adverse events and the use of ineffective products. Given its legislative mandate, OPT has developed four distinct yet interrelated programs to support FDA efforts to improve pediatric access: Ethics Program, Safety Program, Scientific Activities Program, and International Program. The OPT Ethics Program supports FDA efforts to assure that children are only enrolled in clinical studies which are both scientifically necessary and ethically appropriate. Children should not become a mere commodity in the world market in response to FDA efforts to foster pediatric drug and biologic labeling. The OPT Safety Program coordinates the mandated review by the Pediatric Advisory Committee of the safety of drug and biologic products one year after labeling changes in response to voluntary and required pediatric studies. The OPT Scientific Activities Program works with FDA scientists and reviewers to assure that pediatric studies are rigorously designed and conducted in accord with current scientific understanding of such issues as exposure-response and extrapolation. The OPT International Program facilitates communication and collaboration between FDA and partner regulatory agencies around the world as other regions, such as Europe, adopt legislation based on our US experience to stimulate pediatric product development. Pediatric clinical trials are necessarily global, given the incidence and distribution of diseases in the pediatric population, and thus FDA has a moral obligation to assure that children are not exposed to unnecessary, duplicative or poorly designed clinical trials world-wide. Through these four programs, OPT works to assure timely access to medical products proven to be safe and effective for children. OPT performs this core mission in a spirit of transparency, working closely with FDA partners to optimize the use of FDA advisory committees, communicate clearly the risks and benefits of FDA-regulated products marketed for children, and assess and publish FDA experience on which our regulatory decisions are based. More information about OPT can be found at <http://www.fda.gov/ScienceResearch/SpecialTopics/PediatricTherapeuticsResearch/default.htm>.

FDA's Office of Women's Health (OWH) was established in 1994 by Congressional mandate and is currently located in the Office of Science and Health Coordination in the Office of the Commissioner. OWH's mission is to protect and advance the health of women through policy, science, and outreach and to advocate for participation of women in clinical trials. OWH performs the following core functions: advises the Commissioner and other key officials on women's health issues; collaborates with and provides technical assistance to FDA Centers/Offices; develops a research agenda to identify and understand sex differences in FDA regulated products; monitors the inclusion of women and other demographic groups in products applications, reviews, and labels; and translates results of research and forms partnerships for the dissemination of information to FDA stakeholders. OWH serves as a champion for women's health by ensuring that FDA functions, both regulatory and oversight, remain sex/gender sensitive and responsive. OWH works to identify and correct sex/gender disparities in drug, device and biologics testing, and regulation policy. OWH monitors progress of priority women's health initiatives within FDA and promotes an integrative and interactive approach regarding women's health issues across all the organizational components of the FDA. Finally OWH forms partnerships with government and non-government entities, including consumer groups, health advocates, professional organizations, and industry, to promote FDA's women's health objectives. OWH funds research and education/outreach programs on pressing women's health issues. It utilizes a competitive peer review process for selection of the highest quality applied regulatory research projects, with a focus on addressing particular women's health issues that will have the highest regulatory impact. OWH is involved with tracking the participation of women in clinical studies and the analyses of trial data to look specifically at sex differences in medical product safety and efficacy. OWH has sponsored scientific workshops and conferences regarding the participation of women in clinical studies and has been involved with regulations and FDA guidance documents that address this issue. More information about OWH can be found at <http://www.fda.gov/ForConsumers/ByAudience/ForWomen/default.htm>.

Education and/or Careers in Science

- **(2009-2010) FDA Pharmacy Student Experiential Program**

The FDA Pharmacy Student Experiential Program provides an opportunity to learn about the FDA's multidisciplinary processes for addressing public health issues involving drugs, biologics, and medical devices. Pharmacy students who participate in the FDA Pharmacy Student Experiential Program acquire knowledge, skills, and abilities beneficial to their professional career. In the upcoming year, OWH staff will support this program by serving as preceptor for (three) final year Pharm.D. students scheduled to participate for 6 weeks each in the rotation.

- **(2009) 10th Annual Women Physicians' Conference at St. Luke's Hospital in Chesterfield, MO.**
 The focus of this presentation was to raise awareness among female physicians about OWH processes, issues related to the inclusion of women in clinical research, and the study and funding of research investigating the biological dimorphism that sets men and women apart with respect to treatment and response to therapeutic interventions
- **(2008) Medication Safety and Effectiveness Health Education Inter-Agency Partnership: HRSA's Office of Pharmacy Affairs**
 This collaboration targets underserved populations and individuals with special healthcare needs with medication safety and effectiveness information. FDA OWH and HRSA Office of Pharmacy Affairs are collaborating in developing a web-based course and information portal for pharmacists and other health professionals working at more than 6,000 urban and rural clinics across the country, and in creating guidance for best practice use with rural, Spanish-speaking, and aging populations.
- **(2008) "Exploration of Public Policy Development Regarding the Study and Analysis of Sex Differences in the Clinical Evaluation of Cardiovascular Medical Devices"**
 FDA OWH funded this two-part public workshop to explore strategies for improving the proportion of women in CVD trials, to develop recommendations for the analysis and reporting of safety and effectiveness by sex, and promote development of regulatory guidances on cardiovascular devices in women.
- **(2007) Follow up of Abnormal Clinical and Imaging Findings of the Breast: Five Self-Study Modules for Primary Care Clinicians**
 FDA OWH provided medical expertise and content towards the development of this program. The interactive training modules are designed to enhance clinical skills in the examination of the breast for early signs of breast cancer. For more information, go to: <http://www.medscape.com/editorial/public/breastcancer-cdc>
- **(2006) The Basic Science and the Biological Basis for Sex- and Gender-Related Differences**
 FDA OWH partnered with the Office of Research on Women's Health (ORWH) at the National Institutes of Health (NIH) to develop educational materials on the science of sex and gender differences. Researchers, clinicians, and members of academia completing the course gained a basic scientific understanding of the major physiological differences between the sexes, the influences these differences have on illness and health outcomes, and the implications for policy and medical research. Since June 2006, more than 2000 participants have completed the course. A second module is currently under development. This online course is offered free of charge. For more information, go to: sexandgendercourse.od.nih.gov/
- **(2005) Train-the-Trainer Course on Chronic Disease Prevention**

FDA OWH funded a two-day event at the University of Texas Health Science Center School of Public Health. Approximately 60 health promoters and representatives from community-based organizations and federal, city, and county agencies attended. Topics such as diabetes, cardiovascular disease, cancer, and menopause hormone therapy were discussed.

- **(2005) Health Professions Training, Education and Competency: Women's Health in the Pharmacy School Curriculum**

FDA OWH in collaboration with other government agencies, the American Association of Colleges of Pharmacy (AACCP), and an expert panel of pharmacy faculty members, helped to develop a health course to expand and enhance women's health instruction within colleges of pharmacy across the country. For more information, go to: <http://www.hrsa.gov/womenshealth/Pharmacy.htm>

- FDA OWH staff present at seminars, poster presentations, round table discussions, etc., in addition to exhibiting, at numerous scientific and medical society meetings around the US throughout the year. In FY2008 alone, OWH staff did so at approximately 150 different meetings.

2. Future Programs:

This section only reflects future programs for FDA's Office of Women's Health (OWH). OWH recently launched several new initiatives in collaboration with other HHS Agencies to improve the lives of women and girls.

HRSA Patient Safety and Clinical Pharmacy Services Collaborative

This Interagency collaboration involves FDA OWH and the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA). The purpose is to develop and implement a Medication Safety and Effectiveness Health Education Initiative targeting underserved communities and individuals with special health care needs including those diagnosed with HIV/AIDS. FDA OWH is providing free consumer information that will be disseminated as part of an educational tool kit to HRSA grantees. The primary goal of the collaborative is to ensure that patient care delivered by safety-net organizations becomes the safest and best in the nation. Improved patient-centered care will result by improving health outcomes, reducing harm and injury through enhancements in medication management, strong leadership, information management, and continuity of care. OWH has partnered in this work by making available health education materials that promote patient safety. This initiative will develop a web-based course and information portal for pharmacists and other health professionals working at more than 6,000 urban and rural HRSA clinics across the country, and in creating guidance for best practice use with rural, Spanish-speaking, and aging populations.

HRSA Tobacco Education and Smoking Cessation Project

The FDA OWH and HRSA Office of Minority Health and Health Disparities (OMHHD) signed an InterAgency Agreement (IAA) this year to develop and implement a Tobacco Education and Smoking Cessation Project. The goal of this project is to reduce the burden of cancer and chronic illness associated with tobacco use. This new initiative will target post-partum women, migrant workers, and their families with FDA and HRSA smoking cessation materials and other health information. Staff at HRSA funded health centers will be trained to educate program participants about the risks of tobacco use and second-hand smoke exposure. HRSA OMHHD will identify the sites and participants as well as lead this effort in the field and FDA OWH will provide free consumer health information.

SAMHSA: The 10 by 10 Initiative—A Mental Health Wellness and Medication Safety Collaboration

FDA OWH and Substance Abuse and Mental Health Services Administration (SAMHSA) are completing details for an IAA this year to collaborate on an initiative to reduce early mortality of individuals with mental illnesses by 10 years over the next decade. A major component of this initiative involves safe medication use and health promotion and wellness information to improve the morbidity and mortality of individuals with mental health problems. Through this collaboration, FDA OWH and SAMHSA will develop training materials and teleconference trainings for consumers, family members, providers, health care professionals and administrators working in partnership to build resilience and facilitate recovery across the Nation and make the vision of “A Life in the Community for Everyone” a reality for all. This initiative will coordinate a comprehensive social media and communications campaign to promote safe medication use and wellness for individuals with mental health problems.

In addition to these activities, FDA OWH is investigating other collaborative opportunities and hopes to launch these in the next year or two. First, FDA OWH is exploring opportunities to collaborate with the Centers for Medicare & Medicaid (CMS) to support Caregivers, the majority of whom are women. Additionally, we are in preliminary discussions with CDC regarding communications strategies for smoking cessation utilizing current OWH consumer health materials about FDA approved medications for smoking cessation. Outside of DHHS we have initiated discussions with the Veterans Affairs Center for Women’s Health, among other activities.

One of FDA’s congressional mandates is to track the participation of women in clinical trials. This has come about because of numerous reports over time – IOM, GAO, AHRQ, and the peer-reviewed medical literature – that have reported on the underrepresentation of women in clinical studies, especially drug studies. IT advances are underway at FDA to permit electronic review of clinical trial data for participation of women in clinical studies. Health IT and the electronic health record have received incredible attention recently in the stimulus package and in health care reform discussions. Companies that develop medical products are also looking for ways to streamline their IT requirements and systems. Finally, OWH is proposing to investigate how well new data standards for “sex” are being incorporated into electronic clinical trial data submitted to FDA.

Overarching Recommendations

From the high level overview of FDA provided in Section 1 (Program Description) it is evident that numerous parts of the Agency are involved in activities that improve the lives and further the health of women and girls. Improved coordination of these activities – or at least the end result of these activities, e.g., information about new product approvals – within the Agency may provide a more transparent understanding of the impact of FDA’s daily regulatory activities on the lives of all Americans, regardless of their sex or age.

Beyond FDA, there are numerous activities in all the DHHS OPDIVS related to improving the lives of women and girls that many of us are not even aware of. Better coordination and communication across the OPDIVS, possibly conducted at the Department level, may facilitate dialogue, information sharing, and stimulate innovative cross Agency collaborations in the future.

Finally, the term “Women’s Health” frequently boxes in and too narrowly defines efforts to improve the lives of women (and girls). Traditionally, “Women’s Health” is regarded as reproductive health limited to such things as contraception, pregnancy, menopause, and breast health (or cancer). Over time the focus of women’s health has expanded to include diseases that affect women exclusively or disproportionately from men. Unfortunately these definitions of women’s health fail to define the totality of health needs for women. However, simply flipping the words to the “Health of Women” provides a more accurate term taking into account women as a distinct patient population with unique health concerns and needs throughout their lifespan – from girls to women. Both professionals and lay persons will generally appreciate the health implications of appropriate prevention, detection, and treatment of disease as critical determinants to improve the lives of women and girls.

Health Resources and Services Administration (HRSA)

CURRENT PROGRAMS AND POLICIES [24 Current Activities]

Programs That Improve the Lives of the Federal Workforce

HRSA-Wide Management Programs and Policies [7 Activities]

Telework Program:

Description: HRSA allows employees to participate in the Telework Program. This program is available to all employees, but HRSA's experience has been that more female employees utilize the program.

Outcome: In 2008, 67 men and 238 women participated in the Telework Program.

Alternative Work Schedule:

Description: HRSA allows employees to have Alternative Work Schedules.

Lactation at Work:

Description: HRSA allows female employees time and a private location to pump and store breast milk. This program is administered by Federal Occupational Health and run through the Health Unit. All employees in the Parklawn Building, from various HHS agencies, may utilize this service.

Child Care Subsidy:

Description: HRSA employees are eligible for child care subsidy.

Women's History Month:

Description: In honor of Women's History Month, HRSA, along with other HHS Operating Divisions: AHRQ, FDA, IHS, PSC and SAMHSA, co-sponsored a workshop entitled, "Michelle Singletary Says: You Have to Spend Well to Live Well!" The Women's History Month Parklawn Complex Committee also had a mistress of ceremony and a representative to speak about organ donation.

Outcome: Approximately 112 individuals joined us for an hour workshop on March 18 in the Parklawn Building, and helped us answer the call of our President. Participants gained value-added information that was particularly beneficial during these economic times, "Money Mantra Tools" which helps them to:

1. Manage personal finances to get out of debt
2. Raise money smart kids
3. Mentor others as “Prosperity Partners”

Respondents to our program evaluation also respondents said that the following were valuable learning tools for them:

1. Saving and stop spending
2. Making ourselves rich by making our wants few
3. Understanding that there is no such thing as good debt
4. Establishing an emergency funds
5. Adopting principles on how to spend well
6. Abiding by the overall comments that Ms. Singletary shared
7. Budgeting

Take Our Daughters and Sons to Work:

Description: Take Our Daughters and Sons to Work Day is an event designed to enlighten youth of the many career opportunities that await them as they enhance individual self-worth, learn the value of higher education, and pursue careers in science and technology. Children of HRSA staff have the opportunity to benefit from this positive experience and glean skills to help them prepare for the future. This year’s theme was “***Building Partnerships To Educate and Empower.***” This annual celebration has been occurring for the last 16 years. Parents, grandparents, siblings, uncles, and aunts will have an opportunity to participate in HRSA’s Take Our Daughters and Sons to Work Day.

Outcome: HRSA had a total of 40 students who were pre-registered by 25 parents and guardians of HRSA employees to attend the Take Our Daughters and Sons to Work Day.

Federal Equal Opportunity Recruitment Program Report:

Description: HRSA, in accordance with requirements set by title 5, United States Code, section 7201, is required to submit an annual Federal Equal Opportunity Recruitment Program (FEORP) report through the Department of Health and Human Services to Congress. Within the context of this report, HRSA is required to provide statistical data on employment in HRSA’s workforce, which includes the participation of women and minorities. FEORP does not include the Commissioned Officers.

Outcome: HRSA’s 2009 FEORP report will highlight some of the actions that HRSA has taken to eliminate any barriers to the employment of ethnic/racial groups and women within the organization. HRSA as an Agency is committed to building a high-performing workforce that gleans from the strengths of American’s diversity. As an equal employment opportunity organization, HRSA strives to increase its recruitment efforts using good faith efforts to include qualified applicants in mission-critical positions identified as underutilized job groups.

Programs That Improve the Lives of America's Women and Girls

HRSA Program-Specific Programs and Policies [17 Activities]

HRSA Core Measures Set:

Description: The HRSA Core set includes measures targeting health outcomes specifically for women cared for through HRSA programs. Measures that are geared towards women include the Cervical Cancer Screening measure (one for Health Center grantees, and another measure for HIV positive women), as well as the First Trimester Entry into Prenatal Care measure. There is collaboration with IHS regarding measures alignment work because we have some shared grantees and common interests.

The Tobacco and Young, Low SES Women: Federal Collaboration to Make a Difference:

Description: The Tobacco Collaborative is a group of Federal agencies working in partnership to address issues related to tobacco use. As a part of this Tobacco Collaborative, HRSA is working with HHS's Office of Women's Health to target low socio-economic status women of child-bearing age between the ages of 12-44, and their partners. These projects are still being developed and will be performed at HRSA sites that provide clinical services such as the Federally Qualified Health Centers, Maternal and Child Health service sites, and Ryan White funded service sites.

Outcome: Currently, only 57% of HRSA funded health centers have tobacco cessation programs, as indicated in the Unified Data System in 2007.

Ryan White Part D: Coordinated HIV Services and Access to Research for Women, Infants, Children, and Youth (Public Law 109-415):

Description: Part D of the Ryan White program targets women, infants, children, and youth infected with and affected by HIV/AIDS. Grant funds are legislatively designated as payor of last resort; filling service gaps for under- and uninsured patients. This program has a strategy to "eliminate barriers to care for Part D female clients age 13 and older" with a performance goal to "increase the number of female clients provided comprehensive services, including appropriate services before or during pregnancy, to reduce perinatal transmission."

Outcome: Table: Women Served by Ryan White HIV/AIDS Program, Part D – 2007

Age	HIV-positive	HIV-negative	Total
Less than 2 years	2,011	592	2,603
2 – 12 years	1,749	3,392	5,141
13 – 24 years	5,873	3,300	9,173
25 – 44 years	22,432	2,120	24,552
45 – 64 years	12,311	989	13,000

65 years or older	632	229	861
Age unknown	533	66	599
Total	45,541	10,688	56,229

Ryan White Part D:

Description: There are four technical assistance cooperative agreements that support the development of guidelines and information for Ryan White Part D grantees. These activities are largely internal to HRSA, but there is collaboration with NIH on Perinatal and Pediatric HIV Guidelines Working Groups.

Ryan White Quality of Care Measures:

Description: Two Quality of Care measures target HIV-Infected women. One measure assesses the percentage of pregnant women with HIV infection who are prescribed antiretroviral therapy; the other measure assesses the percentage of women with HIV infection who have a Pap screening in the measurement year. NIH and CDC information and statistics are used regarding these measures. More detailed information about these measures can be found at <http://hab.hrsa.gov/special/habmeasures.htm>.

Health Center Program:

Description: Section 330 of the Public Health Service Act requires that all health centers that receive grants must provide comprehensive preventive and primary health care services, including prenatal and perinatal services, to all members of their targeted patient population. In addition, health center “Look-Alikes” (organizations that meet all of the Section 330 requirements but do not receive Federal grant funds) also provide these services. Health Center Program grantees are also required to collect and report data on cervical cancer screening, low birth weight, and access to prenatal care in the first trimester. These specific requirements affect and are targeted towards the girls and women of child-bearing age who reside in a health center’s service area. The Health Center Program activities are coordinated with other agencies within the Department, such as CMS for reimbursement, CDC for prevention activities, IHS for tribal issues, and SAMHSA for mental health issues. AHRQ and CMS were also involved in the development of the clinical performance measures used.

Outcome: Health Center Program grantees are required to submit a core set of information annually that is appropriate for monitoring and evaluating performance and for reporting on annual trends. Since 1996, these have included the following clinical measures:

1. The number of Pap tests provided and the number of female patients who received Pap tests;
2. the percentage of births to health center prenatal care patients that were very low birth weight and low birth weight (less than 2,500 grams);
3. the percentage of prenatal care patients whose first prenatal visit began in the first trimester; and

4. the percentage of women between 21-64 years of age who received one or more Pap tests during the measurement year or two years prior (beginning in the 2008 report year, data will be available in August).

These data will be based on a chart audit or, if possible, data available through an electronic health record.

In 2007:

1. nearly 1.6 million patients received Pap tests at HRSA-funded Health Centers,
2. 7.8% of births to prenatal care patients were low or very low birth weight (less than the national average), and
3. 64.2% of prenatal patients received a prenatal visit in the first trimester of their pregnancy.

In addition, grantees provide an annual Health Care Plan to HRSA. The three clinical measures described here are included in the Plan, with the grantee providing a baseline figure, a target and data from the most recent report to show actual performance. Grantees are expected to improve their performance on these measures by engaging in quality improvement activities. Their progress is monitored by HRSA, and guidance and technical assistance is provided to improve grantee performance as necessary.

Title V Block Grant:

Description: Enacted in 1935 as a part of the Social Security Act, the Title V Maternal and Child Health Services Block Grant program is the Nation's oldest Federal-State partnership. For over 70 years, the MCH Block Grant has provided a foundation for ensuring the health of the Nation's mothers and children. Today, State MCH agencies, which are usually located within a State health department, apply for and receive a formula grant each year. Every \$4 of Federal Title V money received must be matched by at least \$3 of State and/or local money. This "match" results in there being more than \$5 billion annually available for MCH programs at the State and local level. At least 30 percent of Title V Federal funds is earmarked for preventive and primary care services for children, and at least 30 percent is earmarked for services for children with special health care needs. Title V MCH Block Grant requirements include:

1. Reducing infant mortality and incidence of handicapping conditions among children;
2. Increasing the number of children appropriately immunized against disease;
3. Increasing the number of children in low-income households who receive health assessments and follow-up diagnostic and treatment services;
4. Providing and ensuring access to comprehensive perinatal care for women; preventive and child care services; comprehensive care, including long-term care services for children with special health care needs; and rehabilitation services for blind and disabled children under 16 years of age who are eligible for Supplemental Security Income (SSI); and
5. Facilitating the development of comprehensive, family-centered, community-based, culturally competent, coordinated systems of care for children with special health care needs and their families.

Healthy Start:

Description: To reduce the factors that contribute to the Nation's high infant mortality rate, particularly between African-American and other disparate minority groups, Healthy Start (HS) provides intensive services tailored to the needs of high risk pregnant women, infants and mothers in communities with exceptionally high rates of infant mortality. Based on the premise that community-driven strategies are needed to address factors contributing to infant mortality, low birth weight, and other adverse perinatal outcomes, the 102 HS programs focus on improving maternal and child health outcomes by increasing access to and use of health services for women and their families while strengthening local health systems and increasing consumer input to those systems of care. Beginning with prenatal care and continuing through the infant's second year of life, each community that is awarded funds is responsible for assuring the availability of a core set of services and activities for the perinatal population in their project area. These services include case management, home visiting and links to health care and other needed services for mothers and their infants; direct outreach and peer mentoring by trained community members; screening and referral for perinatal/postpartum depression; and strong coordination with and access to substance abuse, domestic violence, mental health, job readiness, early intervention, parenting and other critical services for high-risk women and families. In addition, each Healthy Start project is required to have a community-based consortium composed of individuals & organizations & that includes women and families served by their project, to collaborate with their State Title V (MCH) Agency and community organizations to implement a local health system action plan to improve the quality, cultural competence of, and access to services and/or to address other problems in the local system of care. The Healthy Start program collaborates with many different HHS agencies, including: ACF, AHRQ, CDC, CMS, FDA, IHS, NICHD, OS-OMH, OS-OPA, OS-OWH, SAMHSA; as well as many of the offices and bureaus within HRSA.

Outcome:

1. 89% of women participating in Healthy Start programs have an ongoing source of primary and preventive care services for women.
2. 77% of women participating in HS programs requiring a referral, receive a completed referral.
3. Approximately 27,000 women were screened for and received risk prevention/reduction counseling for risks such as depression, domestic violence, smoking, and STDs.
4. HS programs are located in 102 high risk communities in 38 States, the District of Columbia and Puerto Rico.

Community-based Doula Program:

Description: The Community-based Doula (CbD) program is a quasi-experimental designed evidence-based home visitation program that trains indigenous community workers to serve as "doulas" (labor support) and mentor women from the prenatal period to at least 6 months after delivery. This program targets low income pregnant/parenting women, and the indigenous community workers who are trained are primarily female. There is collaboration with ACF regarding policy discussions on home visitation.

Outcome: Data has not yet been compiled. The program will complete its first year of funding August 31, 2009.

Business Case for Breastfeeding:

Description: Business Case for Breastfeeding (BCBF) is a comprehensive resource kit designed to promote lactation support programs in businesses, large and small, and in other organizations and public agencies employing women of childbearing age. The kit consists of five sections:

1. The Business Case for Breastfeeding, a tri-fold brochure designed for business managers;
2. Easy Steps to Supporting Breastfeeding Employees, a 24-page brochure designed for human resource managers and others who would have responsibility for implementing a lactation support program;
3. The Tool Kit: Reproducible Resources for Building a Lactation Support Program, which contains eight items including promotional flyers, a worksite breastfeeding support policy, a poster and template materials, including a CD-ROM;
4. Employees' Guide to Breastfeeding and Working, an 8-page brochure for pregnant or breastfeeding employees and partners of male employees; and
5. Outreach Marketing Guide, designed for community breastfeeding educators, public health professionals, breastfeeding coalitions and others engaged in outreach activities to businesses.

This has been formatted in a tri-fold piece that contains an 8-page overview of research findings, a pocket for templates, and a CD-ROM with a PowerPoint presentation and electronic versions of the template. Vignettes of businesses that already have well-established employee breastfeeding programs are interspersed throughout the resource kit. At the beginning of 2008, a three-year training and technical assistance program geared towards State breastfeeding coalitions and Healthy Start communities was initiated to enable them to approach businesses in their States and localities to encourage them to establish programs which would enable employees returning to work after childbirth to continue supplying their milk to their babies. CDC, FDA, USDA, and the Office of Women's Health in the Office of the Secretary were consulted during the creation of this resource kit.

Outcome: From the HRSA Info Center from 3/5/2008 through 6/26/2009, the number of publications distributed include:

1. BCBF: For Business Managers – 14,791 distributed

2. BCBF: Employees' Guide to Breastfeeding and Working – 13,122 distributed
3. BCBF: Easy Steps to Supporting Breastfeeding Employees – 9,885 distributed.
4. BCBF: Bottom Line Benefits [Kit] – 8,978 distributed.
5. The Business Case for Breastfeeding was just posted on the web April 1, 2009. So far, the site has had 6,701 visitors. These visitors looked at 9,678 pages within the BCBF.

Innovative Approaches to a Healthy Weight in Women:

Description: The Innovative Approaches to a Healthy Weight in Women projects develop and demonstrate creative, innovative approaches that are effective at reducing the incidence and prevalence of overweight and obesity in women by increasing the number of women who adopt positive healthy lifestyles. The interventions include nutrition, physical activity and mental health/wellness components administered via hands-on participatory activities and health education sessions over the course of several weeks. These projects specifically target low-income women. HRSA collaborates with CDC on this project.

Outcome: Since 2004, 17 grants in 15 States have been awarded. Improvements in the participants' overall health have been noted; increased health literacy and improved health behaviors have been demonstrated. The role of social support and its impact on the participants has been noted in terms of impact on self esteem/mental health, increased employment and education, and the transfer of knowledge to the entire family including the children.

Parental Mental Health Activities:

Description: Parental Mental Health Activities include an NAS/IOM report on Depression in Parents, Parenting, and Children; a Depression During and After Pregnancy booklet (English and Spanish); and State Perinatal Depression grants. These activities target preconceptional, pregnant, and parenting women and girls. There was collaboration with NIH, SAMHSA, CDC, IHS, the HHS Office of Women's Health, and HRSA's Office of Women's Health in developing these materials.

Outcome: Although the products are all evidence-based with reference to epidemiologic data, the products themselves have not been systematically evaluated. To date, over 700,000 copies of the English version of the Depression During and After Pregnancy booklet have been disseminated. The NAS/IOM report on Depression in Parents, Parenting, and Children was released in June 2009.

Taking Care of Mom: Nurturing Self as well as Baby:

Description: These materials are available in the form of a consumer booklet, a provider pocket card, and a community poster. It is available in both English and Spanish. Preconceptional, pregnant, and parenting women and girls are targeted; the provider card targets perinatal and women's health providers; and the poster targets programs providing services to preconceptional, pregnant and parenting women and girls. NIH, SAMHSA, CDC, IHS, and the HHS Office of Women's Health were all consulted for the production of these materials.

Outcome: Although these materials are all evidence-based, the products themselves have not been systematically evaluated. The English version was released in May 2009 and the Spanish version is scheduled for release later in 2009.

First-time Motherhood/New Parents Initiative:

Description: The First-Time Motherhood/New Parents Initiative (FTMNP) demonstration grant program provides funding to State agencies to develop, implement, evaluate, and disseminate novel social-marketing approaches that concurrently increase awareness of existing preconception/interconception, prenatal care, and parenting services/programs and address the relationship between such services and health/birth outcomes and a healthy first year of life. This initiative targets expectant mothers to include teens, young adults, and adult women, as well as new parents including men who will be fathers for the first time.

Outcome: At this time, we do not have any statistics, data or other outcome measures for this program. The First-time Motherhood/New Parents Initiative started in Fall 2008. During the initial year, projects held various focus groups to test their messages around preconception/interconception health, family planning and healthy pregnancies. Process evaluations were conducted and we are currently awaiting some results from each of our projects. During the second year which begins Fall 2009, projects will be able to implement intensive evaluation (Outcome and Impact measures) of their programs and provide data to the bureau on how the preconception/interconception, family planning and healthy pregnancy social-marketing campaigns were received by the public.

Some questions that may be answered include:

1. Did the initiative increase awareness about issues to consider for family planning?
2. Did the initiative increase the number of women seeking preconception and interconception care?
3. Did the initiative change maternal behaviors known to be related to poor birth outcomes (e.g., reduce alcohol use, reduce smoking, increased use of vitamins/folic acid intake, increase nutritional awareness/diet, etc.)?

Tobacco Education and Smoking Cessation:

Description: The Tobacco Education and Smoking Cessation Interagency Agreement is between the FDA Office of Women's Health and the HRSA Office of Minority Health and Health Disparities. This new initiative will target women, migrant workers, and their families with FDA and HRSA tobacco education smoking cessation materials and other health information.

Outcome: Currently, 57% of HRSA funded health centers have a tobacco cessation program, as indicated in the Unified Data System in 2007.

Bright Futures for Women's Health and Wellness:

Description: The mission of the Bright Futures for Women's Health and Wellness (BFWHW) is to plan, develop, implement, and evaluate a variety of culturally competent, evidence-based consumer, provider, and community tools for women across their lifespan. Materials help women of all ages achieve better physical, emotional, social, and spiritual health by encouraging healthy practices. The tools cover three domains: Physical Activity and Healthy Eating, Emotional Wellness, and Maternal Wellness. There is collaboration with AHRQ, SAMHSA, the HHS Office of Women's Health, as well as all of HRSA's Bureaus. For more information please visit <http://mchb.hrsa.gov/about/owhbf.htm>.

Outcome:

1. Taking Care of Mom Nurturing Self as Well as Baby
 - a. Brochure - 6,633 copies distributed
 - b. Poster - 1,681 copies distributed
 - c. Healthcare providers guide - 3,402 copies distributed
2. My Bright Future: Physical Activity and Healthy Eating for Young Women (Revised) - 9,276 copies distributed
3. BFWHW. Healthy Women Build Healthy Communities Toolkit: For Physical Activity and Healthy Eating - 3,417 copies distributed
4. My Bright Future: Physical Activity and Healthy Eating. Guide for Adult Women - 18,082 copies distributed
5. Mi Futuro Será Brillante: Actividad Física y Alimentación Saludable: Para mujeres adultas - 16,396 copies distributed
6. Mi Futuro Brillante: Actividad Fisica Y Como Alimentarme Sanamente Para Mujeres Jovenes. My Bright Future: Physical Activity and Healthy Eating Guide for Young Women - 852 copies distributed
7. My Bright Future. Physical Activity & Healthy Eating: For Rural Young Women - 3,295 copies distributed
8. My Bright Future. Physical Activity & Healthy Eating: For Rural Adult Women - 4,449 copies distributed

Women's Health USA 2009 Databook:

Description: The Women's Health USA Databook, now in its seventh edition, is a concise reference for policymakers and program managers at the Federal, State, and local levels to identify and clarify issues affecting the health of women. The Databook brings together the latest available information from various agencies within the Federal Government, including the US Department of Health and Human Services, the US Department of Justice, the US Department of Labor, and the US Department of Agriculture. For more information, see <http://www.mchb.hrsa.gov/whusa08/>.

Outcome: 4,850 copies of the 2008 Databook were distributed. Additionally, the 2010 Databook is currently in the planning stage with distribution estimated for August 2010.

Future Programs [3 Future Activities]

HRSA Program-Specific Programs and Policies

HRSA Core Measures Set:

Description: The measure for cervical cancer screening, which is currently only a program-specific measure, will be incorporated in the HRSA core set so that it can be used by all of HRSA's service delivery grantees. There are also plans to adopt measures on breast cancer screening and perinatal HIV screening.

Outcome: Measuring prenatal HIV screening is important because HIV and AIDS are leading causes of death in the US and only 40% of the US population has been tested. Perinatal transmission of HIV can be reduced by 70% with antiretroviral therapy. The data for the adopted measures will be available within the next few months.

Special Projects of National Significance:

Description: In FY09, Special Projects of National Significance (SPNS) is funding an initiative entitled "Enhancing Access to and Retention in Quality HIV Care for Women of Color." This initiative will award funds for up to five years to support organizations that provide quality HIV/AIDS care and services in underserved communities, which include areas where the proportion of women of color living with HIV is increasing. The goal of these demonstration sites is to implement and evaluate effective, focused interventions designed to improve timely entry and retention into quality HIV care for women of color. Applicants must propose to: 1) provide a comprehensive continuum of quality HIV care and services; and 2) conduct empirically based interventions based on research findings from other studies on retention and access to care. Awardees will be expected to provide or facilitate access to core medical services and services identified by the Ryan White Program.

Outcome: Awardees will be expected to conduct an evaluation to assess the effectiveness of the selected model(s) in providing culturally competent and quality HIV care and services to the target population, integrating those services within the community's HIV continuum of care, and maximizing reimbursement for health care services, when available.

State and Community Perinatal Depression and Intimate Partner Violence Project:

Description: The goal of this project is to develop provider training materials, policy templates, and program guidelines applied via extensive State and local networks to improve both perinatal depression (PPD) and intimate partner violence (IPV) screening and intervention (SI) rates by maternal and child health providers in order to reduce the preventable morbidity and mortality associated with PPD and IPV. This project builds on the previous findings of separate programs previously administered by HRSA, CDC, SAMHSA/CMS, NIH/NIMH and ACF. The target populations will be perinatal women and girls with or at risk for PPD and/or IPV.

Overarching Recommendations

HRSA strives to improve access to high quality, comprehensive primary and preventive health care and improve the lives of the population served by HRSA programs. Women and girls are a significant subset of the population served by HRSA.

In order to keep informed of ongoing activities and increase the number of women and girls served, HRSA would be open to increased opportunities for collaboration with other Federal agencies. Collaboration with other Federal agencies would allow these programs and activities to reach more women and girls, and would also serve to increase the awareness and marketing of these programs and activities.

Indian Health Service (IHS)

Programs That Improve the Lives of Women and Girls

The Indian Health Service (IHS) programs for women and girls are within a unique system that integrates personal and public health care services. The IHS Office of Clinical and Preventive Services (OCPS) provides national consultation and leadership, including one half-time employee focused on women's health and one full-time employee focused on maternal and child health (MCH). Women's health and MCH consultants and advocates provide services throughout the Indian Health System. Following are program descriptions and goals:

The IHS Women's Health Demonstration Cooperative Agreement Program

According to the Department of Justice, Bureau of Justice Statistics, one in three American Indian and Alaska Native women will be raped or domestically abused during their lifetime, more than any other ethnic group in the United States. Funded at \$700,000 per year, the IHS Women's Health Demonstration Cooperative Agreement Program supports three Tribal organizations and one urban Indian Health Center to improve access to trauma care for women and female adolescents by integrating mental health and substance abuse counselors into primary care.

The IHS Children and Youth Demonstration Cooperative Agreement Projects

The IHS Children and Youth Demonstration Cooperative Agreement Projects provide \$650,000 in grants for mentoring girls and promoting their academic success:

- a. The Boys and Girls Club of Lac Courte Oreilles offers Images, a mentoring program that encourages girls to set goals, develop self-control, avoid peer pressure, achieve academic success, and engage in community service and volunteer work.
- b. The Lac du Flambeau Band of Lake Superior Chippewa Indians helps girls who are considered high-risk to develop educationally, physically, culturally and spiritually.
- c. The Snoqualmie Tribe teaches girls how to make herbal medicines, traditional foods, and healthy meals from native plants grown in gardens.

The IHS Domestic Violence / Sexual Assault (DV/SA) Pilot Program

The IHS and the Administration for Children and Families (ACF) each provide \$200,000 a year to the IHS Domestic Violence / Sexual Assault (DV/SA) Pilot Program designed to improve responsiveness to females 13 years old and above who are the victims of DV/SA. The program's purpose is to strengthen collaboration among clinical staff, Tribal/community advocates, and emergency shelter personnel. The IHS serves as the lead agency for this program that was appropriated \$7.5 million in FY 2009 and is expected to expand.

Training, Conferences, Meetings

1. Sexual Assault Nurse Examiner (SANE) training improves the clinical response to sexual assault. This training is new to IHS; two trainings were provided in FY 2008, and several trainings are planned for FY 2009. SANE training will expand substantially in FY 2010 with Area-wide and local Service Unit trainings.
2. Sexual Assault Response Team (SART) training improves the clinical, public safety and judicial response to sexual assault. All SANE programs have accompanying SART programs. This training is also new to IHS; 16 scholarships to the SART conference were offered this fiscal year. SART training will expand substantially in 2010 with national SANE/SART training provided for IHS and Tribal staff.
3. “Advances in Indian Health” is an annual four day IHS clinical continuing education conference for primary care providers serving AI/AN populations. The conference includes sessions on Obstetrics (OB) and Gynecology (GYN); family planning; sexually transmitted diseases; domestic violence; Fetal Alcohol Spectrum Disorder; and the role of trauma in mental illness, substance abuse and chronic illness in women.
4. Post Graduate Course in OB, GYN, Neonatal and Women’s Health is a specialty training conference conducted by the American College of Obstetrics and Gynecology for clinicians providing reproductive health care. It includes sessions on GYN, contraception, prenatal, labor and delivery, postpartum, female cancers, infectious diseases and chronic disease relevant to women’s reproductive health.
5. MCH/Women’s Health conference focuses on women’s health and maternal/child health. The IHS plans and conducts this international and collaborative conferences that included the First Nations and Inuit Health Branch (Health Canada), and midwifery, pediatric, obstetric and indigenous women’s organizations. Recorded presentations are available at the University of New Mexico CME web site and at the American Academy of Pediatrics Committee on Native American Child Health webpage.
6. “An Invitational Gathering on Indigenous Birthing and Midwifery” was hosted by the IHS and brought participants from Mexico, Canada and the U.S. to discuss “women’s ways of knowing,” indigenous cultural practices, creation stories as the basis for “knowing,” contemporary education, scope of practice, training and comparative practice across North America.
7. The IHS DV Conference focused on strategies to improve the IHS, Tribal and Urban Indian Health community health centers’ prevention, screening and treatment of violence against Native women.
8. A new portal on the National Oral Health Resource Center webpage was developed with links to web resources on domestic violence and oral health (see <http://www.mchoralhealth.org/AZ.html>). The IHS dental website also includes dental peer review publications and a dental training DVD on DV injuries and screening. Initial and annual training on DV screening will be required of all IHS oral health providers; training will be available through national IHS oral health training venues.

Data and Measurement

1. The IHS Resource Patient Management System (RPMS) includes software packages for a well child module, a prenatal module, a system to track breast and cervical cancer, and a system for scheduling procedures. IHS clients include approximately 300,000 children from birth to age 20 and approximately 20,000 AI/AN pregnant women. The IHS data reveal deep health disparities between AI/AN women and the U.S., birth defects from diabetes and alcohol exposure during pregnancies; and elevated tobacco use during pregnancy, the most preventable risk factor for low birth weight.
2. The IHS' Clinical Reporting System (CRS) is able to track key women's health and MCH indicators impacting women and girls, including screen for alcohol use during the child bearing years, mammography, pap smears, and domestic violence.

IHS is developing two survey instruments that will collect health care system data on DV and on policies for treating victims of SA. The IHS, CDC and DOJ will work together to study the incidence of violence against women in Indian Country as well as the resulting injuries and cost.

Women's Health and MCH Link with Tribal Epidemiology Centers

1. The MCH Program funded Tribal and Urban Indian epidemiology centers to expand epidemiology and promote outreach. This program enabled the Aberdeen Area Tribal Chairman's Health Board Tribal Epidemiology Center and the Yankton Sioux Tribe to gain further funding from the CDC in order to conduct a point-in-time Pregnancy Risk Assessment and Monitoring System (PRAMS) with a greater than 70% response rate at the individual Tribal level. Comparing Tribal aggregate data with Pennington County (Rapid City) data provided a new assessment of MCH issues.
2. Seattle Urban Indian Health Board's Urban Indian Health Institute Epidemiology Center completed multi-State PRAMS assessments, developed a Periods of Perinatal Risk Profile for their urban women, and initiated a large data set analysis of the National Survey on Family Growth to assess AI/AN women's social and economic status related to their reproductive health issues.
3. The Great Lakes Inter-Tribal Epidemiology Center (GLITEC) is working with three recipients of a mini-grant in the area of sexual assault, sexually transmitted diseases, and HIV. The three projects are: (1) developing a local sexual assault surveillance system; (2) initiating a coordinated community response team (CCR), a SART and SANE program; and (3) promoting community education and awareness of HIV/STDs and sexual assault, and developing and strengthening partnerships with local organizations on these issues.

4. The GLITEC is also working with a consultant to develop a doula program(s). MCH provides a Federal liaison to HRSA funded Doula demonstration projects. With partners, GLITEC developed and conducted the first State-wide survey of AI youth's tobacco use (commercial and traditional); this sample included girls. A GLITEC epidemiologist and officials in Minnesota are reviewing sudden infant death syndrome, sleep accidents, racism, and teen pregnancy.

IHS Professional Development

1. The IHS Scholarship Program provides significant financial support for nursing, medical, optometry, physical therapy, and other health science students. Most IHS nursing staff are AI/AN women with bachelor's degrees. The Public Health Nurse (PHN) Program serves AI/AN people in their homes and consists of many women who are strongly committed to their communities.
2. Nurse midwife programs were introduced as demonstration programs into IHS in the late 1960s. Now, forty years later, the majority of AI/AN infants delivered in IHS hospitals are delivered by nurse-midwives. These obstetrical providers have proven themselves to be safe and culturally competent and are well accepted by AI/AN families and communities. One study credits nurse-midwifery care within IHS as the central factor in keeping Cesarean section rates below 15 percent. In 2003, the IHS and CDC studied IHS maternal morbidity at five Tribal and IHS hospitals with obstetric surgical capacity; 90 percent of all women who delivered had a nurse midwife involved in their care. Preeclampsia, diabetes and post partum hemorrhage led complication rates. Family nurse practitioners and women's health nurse practitioners provide OB and GYN services in women's clinics, in pediatric clinics, in urgent care clinics and in emergency departments. Mostly female, advanced practice nurses provide a wide range of services, including reproductive GYN, pediatric, emergency and chronic disease health care. APNs are also IHS public health nurses and clinical leaders and administrators.
3. The IHS MCH Program coordinates perinatal, neonatal, infant, child and adolescent health to improve the quality of clinical care, public health programming and Headquarters leadership.

National Collaborations

1. The DHHS Office on Women's Health BodyWorks is a women and girls health and fitness program. The AI/AN adaptation of this program emphasize healthy meal planning. The use of commodities, presence of food insecurity and dependence on WIC by a large sector the AI/AN population is noteworthy.

2. AI/AN women have some of the highest rates of tobacco use, and their use of chewing tobacco is on the rise. The Office on Women's Health and DHHS OPDIVS will launch a demonstration project regarding the problem of tobacco use, for low socioeconomic women receiving services from HRSA and IHS. The IHS National Programs Tobacco Coordinator and the University of Arizona are preparing to bring training and technical assistance to this project.
3. Project Choices is a program to teach women about the risks surrounding drinking and pregnancy.
4. A Comprehensive Strategic Plan to Maintain a Healthy Weight Across the Life Span emphasizes individual, family, community, IHS Tribal and Urban program roles and responsibilities. The IHS has a lactation support policy.

Overarching Recommendations

1. Sustain doula programs and group prenatal care, otherwise known as "centering pregnancy," which has taken root in diverse native communities.
2. Reinstigate a program for preventing child abuse and forensic exam training. Ten thousand substantiated AI/AN child abuse victims were reported in 2006.
3. Provide access to age-appropriate school health care services while fostering confidentiality and trust. Teen depression screening needs a point of entry.
4. Fund a focus group gender specific survey together with comprehensive data on risky behavior among youth. A large sample (n=15,000) national survey of AI/AN adolescents (in urban areas and on and off reservations) was last conducted more than twenty years ago.
5. Implement a gender-specific study and surveillance of incarcerated and residential treatment center (RTC) youth. Co-morbidities of female clients and their response to treatment are less understood than those of their male peers. About 1000 AI/AN youth enter RTCs annually.
6. Focus on improving education and graduation rates for young women, which is known to improve health status. Interagency and Bureau of Indian Education collaboration is necessary to address the complex social issues.
7. Support the obesity workgroup and related website and messaging programs to ensure public health approaches and Tribal leaders' involvement. Obesity is a health emergency.

8. Implement Nursing Child Assessment Satellite Training (NCAST), to provide intensive effective home visitation through our community health representatives (1600 staff mostly women) and public health nurses. Regional trainers are available for this intensive training and preceptorship.
9. Train staff in motivational interviewing and assessing clients for tobacco cessation and risky drinking. Current models exist, interagency collaboration is underway, but more resources are needed.
10. Support IHS public health infrastructure for women and children through WH/MCH coordination at the HQ, Area and field levels, this includes supporting core staff and programming at Tribal and Urban epidemiology centers.
11. Provide assistance to Tribal and Urban Indian programs for improving the built environment for children to grow and develop.

National Institutes of Health (NIH)

Agency Overview

The National Institutes of Health (NIH) is the steward of medical and behavioral research for the Nation. As the nation's medical research agency, the National Institutes of Health supports scientific pursuits which provide fundamental knowledge, promotes the application of that knowledge to extend healthy life, and reduces the burdens of illness and disability for all. NIH scientists investigate ways to preserve health and promote wellness, expanding understanding of the causes, diagnosis, prevention, and cure of human diseases, including conditions that impact the health and well-being of girls and women across the lifespan. The NIH has a broad research portfolio incorporating investigations on the health of girls and women throughout the Institutes and Centers (ICs) and program offices. Research funded by the NIH has provided clues and insights into sex and gender factors that impact health and disease; these advances have provided opportunities to develop the most appropriate preventive and therapeutic approaches for the health of girls and women. Additionally, the NIH is committed to training the next generation of women and men scientists to ensure sustained scientific advancement. This report provides examples of NIH research and career development programs that benefit the health of girls and women.

The Office of Research on Women's Health (ORWH), the first office devoted specifically to women's health in DHHS, was established as the focal point for women's health and careers for the NIH within the NIH Office of the Director in September 1990 to ensure the participation of women in clinical research funded by the NIH; to establish the research agenda for women's health, expanding the context of women's health beyond the reproductive system and reproductive years; to expand and promote research on the health of women and girls across the many components of the NIH; to promote the recruitment, retention, advancement, and reentry of girls and women in biomedical careers; and to provide outreach for matters related to inclusion as well as research education to the extramural community and women's advocacy organizations. The NIH/ORWH utilizes a number of mechanisms to integrate the focus on women's health across the NIH and for the extramural community. Two major advisory committees, established in statute, are central to the efforts both for institutionalizing women's health programs across the NIH as well as to evaluate accomplishments. An Advisory Committee on Research on Women's Health, composed of non-Federal members as delineated in statute, provides leadership to the NIH by advising the ORWH Director on appropriate research activities in women's health, reviewing, and advising on matters related to research priorities, the women's health research portfolio for NIH, career development, inclusion of women and minorities in NIH-funded clinical research, and other ORWH or NIH programs related to women's health.

The NIH also benefits from the Coordinating Committee on Research on Women's Health (CCRWH), also established in statute in the 1993 NIH Revitalization Act and is composed of Institute and Center Directors or their

designees as a direct liaison for ORWH with NIH ICs. The CCRWH as a liaison to IC Directors provides a valuable and successful coordinating mechanism for communication with all components of the NIH for eliciting or submitting information on collaborative efforts, and for evaluation and monitoring efforts. Both the ACRWH and the CCRWH provide valuable guidance, collaboration, and support for activities of the NIH in women's health research, career programs, and outreach efforts. As statutorily mandated, the ACRWH in cooperation with the CCRWH prepares a biennial report that summarizes all activities in research, career development and inclusion efforts, of the ORWH as well as the highlights of such efforts from all components of the NIH, and provides a review and comments of such efforts. This provides a mechanism for evaluation and monitoring. In addition, the ORWH solicited a formal 10 year evaluation of its research accomplishments by an independent contract team, providing a formal evaluation of the ORWH. The ORWH is planning now a follow-up formal evaluation of the ORWH's and NIH's research accomplishments, and to also include a study of ORWH's career development programs for girls and women.

In addition to these mechanisms, the ORWH has convened for many years a trans-NIH committee on the inclusion and tracking of women and minorities in clinical research. Working with and through this committee, as well as the Office of Extramural Research and the Office of Intramural Research, the ORWH has prepared an annual report on the monitoring of inclusion of women and minorities, and a biennial report that reviews the NIH efforts for consistency in compliance across the NIH as well as statements from each IC Advisory Council certifying compliance with the NIH inclusion policies. The annual and biennial reports on tracking and inclusion are then reviewed by the ACRWH for approval and comment.

The ORWH has as central to its mandate to promote careers in science for girls and women, as well as to give attention to intramural women scientists. The ORWH has many programs to address career development and advancement for women in the extramural community, which are described in some detail as part of this report. The ORWH has worked with intramural scientists and provided support for programs to advance their careers such as supporting brown bag seminars, training on how to write about science or negotiate for positions or prepare grant applications, among other topics, and supporting diverse seminars and student programs. Recently, the NIH, through the Working Group on Women in Biomedical Careers established by the NIH Director and currently chaired by the Acting Director, NIH, and the ORWH Director, has developed and implemented a number of activities to advance careers for women in science that are described in some detail within this report. In addition, NIH has undertaken a number of efforts to address work/life balance for members of the NIH community, and these are addressed with this report as well.

The ORWH, representing the NIH, has been among the original and continuing

members of the HHS Coordinating Committee on Women's Health (CCWH), and through that mechanism, both communicates the programs and activities related to women's health to other HHS components as well as collaborating with the CCWH to address the department's programs and policies for both the HHS community as well as the general public. In addition, the ORWH and many other components of the NIH are in constant communication with other agencies for collaborative projects, activities and sharing of information.

The NIH Health Reform Act of 2006 established a new Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) within the NIH Office of the Director (OD). ORWH retains its statutory authorities but is now located within DPCPSI along with other OD program offices. <http://opasbnih.gov/>.

I. NIH / Office of the Director/ Office of Research on Women's Health (ORWH)

A. Programs That Improve the Lives of America's Women and Girls

1. A Trans-NIH Program to Foster More Research on Women and Girls: Advancing Novel Science in Women's Health Research (ANSWHR)

The Office of Research on Women's Health (ORWH) serves as the focal point for women's health research at NIH. ORWH was established in September 1990 within the Office of the Director, National Institutes of Health (NIH) to strengthen and enhance research on women's health across the lifespan, ensure that women are appropriately represented in clinical research studies supported by NIH, and to develop opportunities for the advancement of women in biomedical careers.

The Office of Research on Women's Health (ORWH), which coordinates women's health research across the NIH, developed and partnered with 21 co-sponsoring NIH institutes and centers (ICs) to launch a grants program entitled *Advancing Novel Science in Women's Health Research (ANSWHR)*, to encourage innovative, interdisciplinary research that promotes new concepts in women's health research and the study of sex/gender differences. This program has confirmed the broad, women's health research appeal across the NIH. Based on responses to this program, ANSWHR is becoming an important scientific tool that is being used by both early-stage investigators and veteran researchers to test nascent scientific concepts that can help improve women's health research and the study of sex and gender differences. Researchers can apply for support to promote innovative, interdisciplinary research to answer unresolved questions about how to prevent and treat diseases in women and girls. This grant program supports pilot research efforts which serve to gather data, and to create new research teams. The ANSWHR program maximizes the scientific freedom of researchers that will help us learn more about the health differences between males and females.

a) Relevant Statistics:

There are several areas of Women's Health Research that were funded by

the ANSWHR program (11 awards) in the initial year of funding (FY 2008), including the genetics of reproductive life and the impact on health status; genetic pathways in systemic lupus erythematosus (Lupus); sex differences in stress; sex differences relating to the vulnerability to cocaine addiction; factors that regulate the timing of pubertal onset and reproductive maturation; novel ovarian cancer detection agents; evaluation of diagnostic techniques for cardiovascular events; inflammation and insulin sensitivity in obese pregnant women; sex differences and cognitive function; estrogen receptors and Lupus; and sex differences in HIV/AIDS antiretroviral treatment.

Future Programs:

ORWH and its scientific partners across the NIH plan to continue to support this program because of its effectiveness in Women's Health Research, and at encouraging researchers to explore relevant topics in this area. The program has been very well received by researchers across the US, and women and girls as volunteers to clinical studies.

a) Target Population(s):

The target populations for this program are researchers from across the US and internationally. For FY 2009, many more grants have received competitive scores for scientific relevance and merit that cross the full continuum of research on women and girls, as well as the study of sex and gender factors. It is expected that by September 30, 2009 more than sixty research grant awards will be made, in partnership with fifteen NIH institutes and centers.

Overarching Recommendations:

The ANSWHR program has successfully attracted researchers from a wide variety of scientific areas to the field of women's health research, and is expanding the breadth of researchers who are addressing the health and wellness of women and girls across the life span as well as providing opportunities to learn more about differences or health similarities between males and females. Through this funding mechanism, investigators can capitalize upon novel scientific approaches and explore emerging concepts with the potential for broad scientific import.

2. Specialized Centers of Research (SCOR) on Sex and Gender Factors Affecting Women's Health

The Office of Research on Women's Health (ORWH) serves as the focal point for women's health research at NIH. ORWH was established in September 1990 within the Office of the Director, National Institutes of Health (NIH) to strengthen and enhance research on women's health across the lifespan, ensure that women are appropriately represented in clinical research studies supported by NIH, and to develop opportunities for the advancement of women in biomedical careers.

The ORWH promotes, stimulates, and supports efforts to improve the health of girls and women through biomedical and behavioral research.

ORWH recognizes that research integrating knowledge from multiple

areas of scientific expertise is needed to advance women's health. Each SCOR is designed to develop an interdisciplinary research agenda bridging basic and clinical research on sex/gender factors underlying a priority women's health issue. Each SCOR promotes interdisciplinary collaborations and develops a research agenda on sex/gender factors underlying a targeted health issue of girls and women and learns more about the etiology of these diseases fostering improved approaches to treatment and/or prevention.

The ORWH SCOR program represents an excellent model for stimulating interdisciplinary research and for human translational research with significant applications to gender-specific human health care. The SCOR mechanism promotes collaborative research among scientists with diverse expertise to provide a scientific base for a less fragmented approach to women's health. Support for the SCOR program is also from NICHD, NIAMS, NIMH, NIDA, NIDDK and the Food and Drug Administration.

a) Relevant Statistics

There are currently 11 SCORs addressing sex/gender interdisciplinary research in the areas of depression, pain, urinary tract, reproductive issues, substance abuse, and osteoporosis. In 2008, the SCORs report publishing 113 journal articles, 144 abstracts, and 30 other publications.⁴¹

Future Programs:

The ORWH plans to continue the SCOR program with new centers that may develop new areas of pertinent research on women's health and sex and gender research.

a) Target Population(s):

The health of the nation will benefit with special emphasis on women and girls resulting from the research gleaned from these centers.

b) Benchmarks:

It is expected that new collaborations and publications will be developed and increasing investigators moving into the arena of sex/gender research.

Overarching Recommendations:

The SCOR program is an innovative, inter-disciplinary research program that addresses basic, clinical and translational interdisciplinary research. With a focus upon sex and gender research, this program will improve the lives of girls and women by securing critical data on the differences between women and men, and between girls and women, as well as how such differences affect diagnosis, and the progression and treatment of diseases across the lifespan. By integrating sex and gender specific research data into broad experimental methodologies and scientific approaches, new therapies and diagnostic tools will become available, and, ultimately influence the future practice of health care. As our knowledge base expands, it will be possible to expand the focus of the SCOR program areas of interest to investigate sex/gender differences for girls

⁴¹ Internal NIH SCOR Annual Progress Reports, 2009.

and women in additional areas such as the microbiome, genetics, stem cells and neurobiological factors affecting aging, addiction, and behavior. As the Centers progress, collaborations and resource sharing which are an integral part of the work of the SCOR researchers, research results can multiply, and further expand the contributions of these SCORs to medical knowledge and improved health care.

The disparities of health and disease among diverse populations of women from adolescence to old age remain a critical area in need of continued focus and renewed attention. Further biomedical and behavioral research are necessary to better understand how cultural, ethnic and racial differences, influence the cause, presentation, diagnosis, progression, treatment, and outcome of diseases among different populations of girls and women including the effects of environments and of poverty.

3. Research Enhancement Awards Program (REAP)

The Office of Research on Women's Health (ORWH) serves as the focal point for women's health research at NIH. ORWH was established in September 1990 within the Office of the Director, National Institutes of Health (NIH) to strengthen and enhance research on women's health across the lifespan, ensure that women are appropriately represented in clinical research studies supported by NIH, and to develop opportunities for the advancement of women in biomedical careers.

The ORWH developed a research enhancement award program (REAP) to increase the numbers of new research studies of girls' and women's health by collaborating with the NIH institutes and centers to identify meritorious research that would not otherwise be funded; the ORWH then funds or co-funds these studies, thereby increasing research that can address gaps in knowledge about the health or treatment of diseases for girls and women.

a) Relevant Statistics:

From 1996 through 2009, more than 335 new research studies were funded through this program that otherwise would not have been possible. A few examples of new research funded through this program include studies of endometrial and ovarian cancer, contraceptives, disparities in lupus nephritis, malaria in pregnancy, and the HPV Vaccine. Further, the majority of the investigators of these studies were women, further increasing career opportunities for women researchers. The total amount awarded over the 13 years for the REAP is \$44,156,434.

Future Programs:

ORWH plans to continue and expand REAP as a valuable mechanism to increase our knowledge about women and girls' health issues through the funding of research proposals that can expand our understanding of the health of girls and women, and of sex/gender differences in health and disease.

a) Target Population(s):

This program is intended to address health issues for all subpopulations of

women and girls and to reach more investigators who may then conduct research on women and girls' health issues.

b) Benchmarks:

This program will continue to co-fund research that will increase our knowledge about health issues that are germane to all subpopulations of women and girls, and in future years will determine areas of research priorities for which new research studies should be sought through this program.

c) Other:

This is a successful program to support to increase medical knowledge that can improve health for girls and women from all populations by informing standards of healthcare, modification of personal behaviors and public health policy.

Overarching Recommendations:

REAP has been a very successful mechanism to support research to further our understanding and knowledge on many diseases that affect girls and women that would not have otherwise been funded. This program should continue as it provides a trans-NIH mechanism to increase information of value for the health and wellness of girls and women.

4. Inclusion of Women and Minorities as Subjects in Clinical Research

The Office of Research on Women's Health (ORWH) serves as the focal point for women's health research at NIH. ORWH was established in September 1990 within the Office of the Director, National Institutes of Health (NIH) to strengthen and enhance research on women's health across the lifespan, ensure that women are appropriately represented in clinical research studies supported by NIH, and to develop opportunities for the advancement of women in biomedical careers. ORWH was established in response to concerns that federally funded research should include women in clinical studies of all conditions that may affect them to determine if women and men respond differently to interventions. Therefore, a major program area continues to be that of ensuring the inclusion of women (and minorities) as participants in clinical research. The NIH policy for inclusion (Federal Register, March 1994) was strengthened in response to the NIH Revitalization Act of 1993 (Public Law 103-43) to ensure that women, minorities and their subpopulations are included in research involving human subjects in sufficient numbers to allow for subset analysis by sex (or race). The intended purpose of the policy is to determine if there are differences in disease or responses to interventions based upon gender or race.

In March 1998, the NIH published and implemented a policy on the inclusion of children as participants in research involving human subject with the aim of collecting meaningful data on children relative to the scientific question being asked, the purpose of the study and the risk involved.

The ORWH continues to lead NIH programmatic efforts to ensure inclusion policies are through a trans-NIH committee composed of representatives from each NIH Institute and Center (IC), the Office of the Director (OD), the Office of Extramural Research (OER), and the Office of Intramural Research (OIR). This committee works collaboratively for consistent implementation of these policies across the NIH as well as to monitor inclusion.

a) Relevant Statistics:

All Clinical Research including Phase III Clinical Studies
In FY2008, there were 15,598 clinical research protocols, including Phase III and other clinical studies, of which 11,045 protocols reported human subject participation. Approximately 15.4 million participants were enrolled in research studies of which approximately 60.0% were women and 40% were men.⁴²

Phase III Clinical Research

In FY2008, there were 726 Phase III clinical research protocols, of which 639 protocols reported human subject participation. Approximately 793,000 participants were enrolled in Phase III research studies of which approximately 57 % were women and 43 % were men.⁴³

Future Programs:

a) Target Population(s):

One of the mandates of the ORWH is to ensure the inclusion of women (and minorities) as subjects in federally funded clinical research. Thus, the NIH inclusion policy is applicable to women and men of all ages, diverse populations and their subpopulations. The inclusion of these populations aids researchers in looking at whether there are differences in the diagnosis and treatment between women and men, differences among women based on racial and ethnic identification or age, as well as if there are differences between children and adults.

NIH conducts outreach that specifically addresses diseases, conditions and disorders that may disproportionately affect women and girls throughout the lifespan. The ORWH continues to publish and distribute scientific information on research studies addressing women and girls to the research community, healthcare organizations, advocacy groups, and the general public. For example, the NIH Publications on Women's Health Issues provides information on all NIH publications specifically addressing women's health research. The Women of Color

⁴² Pinn V, Roth C, Bates A., Wagner R, Jarema K. Monitoring adherence to the NIH policy on the inclusion of women and minorities as subjects in clinical research: Comprehensive report tracking of human subjects research as reported in fiscal year 2007 and fiscal year 2008. Bethesda (MD): Department of Health and Human Services, National Institutes of Health (US). September 2009 at p.172.

⁴³ Id.

Health Data book provides general and statistical information on women and girls from diverse racial and ethnic backgrounds. NIH continues its efforts at community outreach so that women understand the importance of biomedical and behavioral research as well as their serving as voluntary participants in research studies. The results of research will ultimately affect the healthy lives for American girls and women.

b) Benchmarks:

NIH uses several benchmarks to monitor adherence to the NIH Inclusion policy as stated below.

A trans-NIH Tracking and Inclusion committee meets on a regular basis to monitor adherence to the inclusion policy and discuss issues that may arise regarding the collection and reporting of inclusion data.

A comprehensive report is prepared annually that analyzes fiscal year inclusion data in order to assess policy compliance and to look at trends in the participation of women and minorities in clinical research studies. Biennially, each IC prepares a report certifying and documenting that their IC is in compliance with the NIH policy on the inclusion of women and minorities as subjects in clinical research.

Additionally, ORWH prepares a biennial report to Congress, Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research. This report is a compilation of NIH efforts to monitor adherence to and ensure compliance with the NIH Inclusion policy and to meet the mandate as addressed in the 1993 NIH Revitalization Act.

Overarching Recommendations:

NIH continues to urge researchers to understand the importance of designing clinical studies for inclusion of women, conducting sex/gender analysis as appropriate for all clinical studies, and for researchers to address issues that may arise in efforts to accomplish compliance with the NIH inclusion policies. NIH continues to confront the challenges of recruiting volunteers for clinical studies, especially for women and girls from diverse populations, the elderly, and women of childbearing age.

For future programs, the NIH will continue to look for ways to improve the understanding by participants and researchers of the importance of designing and conducting research studies for sex/gender differences, the benefits of involving the community in all phases of research, and reaching out and encouraging women, men and children of diverse populations to voluntarily participate in clinical research.

5. Office of Research on Women's Health Strategic Planning for the Next Decade

The Office of Research on Women's Health (ORWH) serves as the focal point for women's health research at NIH. ORWH was established in September 1990 within the Office of the Director, National Institutes of Health (NIH) to strengthen and enhance research on women's health

across the lifespan, ensure that women are appropriately represented in clinical research studies supported by NIH, and to develop opportunities for the advancement of women in biomedical careers.

To ensure that women's health research is continually dynamic and works at the future frontiers of biomedical science, the Office of Research on Women's Health is in the process of leading NIH efforts in a third iteration of a revised NIH research agenda on women's health. The over-arching theme for this effort is "Moving Into the Future: New Dimensions and Strategies for Women's Health Research." Two previous agenda setting meetings helped to redefine the parameters of women's health and expanded concepts of women's health research beyond the limited and traditional perception that women's health is primarily defined by reproductive issues.

Current planning focuses upon identifying new dimensions and strategies for women's health and sex/ gender research priorities for the National Institutes of Health in the coming years. Such efforts include a renewed emphasis on normal processes; developmental biology in girls; aging in women; the recognition of emerging diseases and conditions that may affect girls and women, or affect girls and women differently across the lifespan; potential application of new technologies to optimize the health of girls and women; and the implications of research for advancing cutting edge diagnostic and therapeutic therapies in health care delivery. Clinical questions that girls and women may have about their bodies and health for which science has not provided answers will be considered priorities.

a) Relevant Statistics:

Developing the new strategic plan for women's health research offers tremendous opportunities not only for re-energizing science, but in hearing from a wide cross-section of society. The format that ORWH uses to develop its strategic plan involves four regional scientific workshops and public hearings in St. Louis, San Francisco, Providence, and Chicago. This format ensures an interactive discussion that invites leading scientists, women's health advocates, public policy experts, healthcare providers and the general public to be active participants in contributing to the ORWH strategic plan. To date two regional meetings have been held in St. Louis and San Francisco with more than 615 participants. Public testimony was received from 104 advocacy groups, academic institutions, health care organizations and private individuals. It is anticipated that approximately 1500 individuals nationally will participate in the total ORWH strategic planning effort and that public testimony during the two subsequent meetings will elicit over 100 additional oral and written testimonies.

Future Programs:

The goal is to craft a research agenda that will serve as a catalyst to further advance our understanding of science and disease pathogenesis and ignite the translation of such findings to promote the health and wellbeing of girls and women of all ages, races, ethnicities and

socioeconomic strata. The revised research agenda in women's health will be available early in 2010.

Overarching Recommendations:

While the lifespan of women in general exceeds that of men, the differences are narrowing because of some conditions that continue to affect the longevity of women. Furthermore, while women may live longer, the quality of life and the role of disability, behavior and environment in the health of elderly women warrant further, in-depth attention. Consequently, an important area of research that needs greater emphasis involves sex differences in aging.

As science and technology advance and fields such as computational biology and others demonstrate the true power of interdisciplinary research, it remains critical for sex and gender factors to be integrated into broad experimental methodologies and scientific approaches, such as, genomics, the Human Microbiome Project, and stem cell research to maximize the value of these comprehensive and powerful approaches.

The disparities of health and disease among diverse populations of women remain a critical area in need of continued focus and renewed attention. Further biomedical and behavioral research are necessary to understand how cultural, ethnic and racial differences influence the cause, presentation, diagnosis, progression, treatment, and outcome of disease among different populations, including women of diverse geographic locations and socioeconomic backgrounds. For example, two populations that need greater attention by the research community are women in the military and immigrant women and girls. Greater attention is now being given to these two groups since women in the military are increasing in numbers with emerging, new health issues, and the immigrant populations are of different origins than 50 years ago. These two groups represent unique challenges to understanding disease progression resulting from changed circumstances and environments.

Yet another area that the women's health research is focusing on is the expanded role of the community in community based clinical research projects. As society has become more interested in personal health, NIH is focusing more attention upon clinical trials, especially those that relate to women, children and their families. With women functioning as the "portals" for their families regarding health information and health care, they play a key role in clinical trials to secure better cooperation, adherence to protocols, and more effective follow-up.

6. Building Interdisciplinary Research Careers in Women's Health (BIRCWH) Program

The Office of Research on Women's Health (ORWH) serves as the focal point for women's health research at NIH. ORWH was established in September 1990 within the Office of the Director, National Institutes of Health (NIH) to strengthen and enhance research on women's health across the lifespan, ensure that women are appropriately represented in clinical research studies supported by NIH, and to develop opportunities

for the advancement of women in biomedical careers.

ORWH developed and implemented the Building Interdisciplinary Research Careers in Women's Health (BIRCWH) program, an NIH mentored career development program, in collaboration with NIH Institutes and Centers and the Agency for Healthcare research and Quality (AHRQ). BIRCWH supports the training of junior faculty in an interdisciplinary mentored environment by pairing junior researchers with senior investigators in women's health. Mentors are established in their research fields and each scholar has at least two mentors from different disciplines that are part of their interdisciplinary mentoring team. The BIRCWH scholars learn not only research techniques, but also the skills to become independent investigators and mentors. Scholar research areas cover a variety of topics including mental health, diabetes, cardiovascular health, neurological disorders, trauma, health disparities, reproductive health, menopausal hormone therapy, substance abuse, cancer and arthritis/musculoskeletal health.

a) Relevant Statistics

To date, 50 BIRCWH career development programs have been established. This program has developed a cadre of over 335 scholars who will further advance and perpetuate an interdisciplinary team approach to science and health care which can contribute to overcoming the fragmentation of women's health care delivery. Over 1300 publications have resulted from this program increasing our knowledge of conditions that affect girls and women and improving the ability to provide gender appropriate healthcare.⁴⁴

Future Programs

The program will be continued with funding of additional programs during FY 2010.

a) Target Population(s):

The target population for this program is early investigators, junior faculty, who are interested in pursuing research careers in women's health issues. This program will expand the pool of investigators across the U.S. who are able to address high priority research areas in women's health that will ultimately lead to improvement in the health of women and girls.

b) Benchmarks:

ORWH is the lead for this initiative and monitors and tracks the progress of scholars who are appointed to the BIRCWH programs (diversity of backgrounds, disciplines and specialties) and their outcomes (academic placement, NIH funding and types of research being done and its relevance for women's health).

Overarching Recommendations:

The BIRCWH is an institutional mentored career development award with a focus on promoting interdisciplinary research in women's health. The program serves as a model of interdisciplinary research training that integrates knowledge from members of the research team who come from multiple disciplines and different

⁴⁴ Internal NIH BIRCWH Annual Progress Reports, 2009.

areas of expertise to address complex problems in women's health. Further, it has served as a successful model of the value of dedicated mentoring in contributing to successful careers in science as well as being productive contributors to filling gaps in medical knowledge about girls and women.

7. NIH Working Group on Women in Biomedical Careers

The Office of Research on Women's Health (ORWH) serves as the focal point for women's health research at NIH. ORWH was established in September 1990 within the Office of the Director, National Institutes of Health (NIH) to strengthen and enhance research on women's health across the lifespan, ensure that women are appropriately represented in clinical research studies supported by NIH, and to develop opportunities for the advancement of women in biomedical careers.

The NIH Working Group on Women in Biomedical Careers was established as a trans-NIH committee by the NIH Director in response to National Academies report *Beyond Bias and Barriers: Fulfilling the Potential of Women in Academic Science and Engineering* which was cofunded by ORWH along with Eli Lilly and Co., the National Science Foundation, the Ford Foundation, and the National Academies. The report called for an urgent, broad, national effort to maximize the potential of women scientists and engineers in academia, offering a broad range of recommendations for universities, government agencies, and Congress. The Working Group was charged with responding to the issues raised in the National Academies report as well as the concerns raised by NIH intramural women scientists. The NIH Director and the ORWH Director were designated as co-chairs of this trans-NIH Working Group which includes NIH Deputy Directors, Institute and Center Directors, intramural researchers, and extramural program staff. This Working Group is developing innovative strategies and tangible actions for implementation to promote the advancement of women in research careers both within the NIH intramural community and throughout the extramural community of research institutions and universities.

The Working Group has held two national meetings; the *National Leadership Workshop on Mentoring Women in Biomedical Careers*, cosponsored by ORWH, and *Women in Biomedical Research: Best Practices for Sustaining Career Success*, co-sponsored by ORWH and the National Center for Research Resources. There were over 500 registered participants at each of the two national workshops and over 1400 hard copies of each report have been distributed.⁴⁵ The reports from these workshops have been published and are available for download from the Working Group Web site. The Working Group is incorporating the recommendations from these workshops in its new initiatives and is

⁴⁵ The reports are also available for download from the Working

reaching out to the research community, including professional societies and grantee networks, to publicize and promote implementation of the mentoring programs and best practices for supporting women's careers in science discussed at the workshops.

Through the efforts of the NIH Working Group, the NIH joined in the establishment of a regional chapter of the National Higher Education Recruitment Consortium (HERC), which hosts a web-based search engine of all job listings at member institutions, which can be searched using two sets of criteria simultaneously to facilitate dual career couples job searches. The Mid-Atlantic HERC is a network of 24 colleges, universities, and federal agencies in Maryland, Virginia, and Washington, D.C.

The Working Group has developed a grant program entitled *Research on Causal Factors and Interventions that Promote and Support the Careers of Women in Biomedical and Behavioral Research* in order to gather data leading to a better understanding of the current patterns observed in the careers of women in biomedical and behavioral science and engineering and variation across different subgroups. This grant program also examines the efficacy of programs designed to support the careers of women in these disciplines. Potential causal factors include individual characteristics, family and economic circumstances, disciplinary culture or practices, and features of the broader social and cultural context. Research on career development among underrepresented minority women and socioeconomically disadvantaged women is also supported. Through this research program, the NIH aims to garner new insights for enhancing the efficacy of career development programs for women in science.

The Working Group, in collaboration with the Office of Extramural Research is tracking and making available online data on the involvement of women in NIH grant programs and has modified the parental leave policy for the Ruth L. Kirschstein National Research Service Awards to allow trainees and fellows to receive stipends for up to 60 calendar days of parental leave per year for the adoption or birth of a child when those in comparable positions at their institutions have access to this level of paid leave for this purpose. Either parent is eligible for leave.

The Working Group, in collaboration with the Office of Intramural Research (OIR) has focused on child care and family leave, mentoring,

Group Web site. Barone, Jory (Educational Services, Inc., Bethesda, MD). E-mail to: Joslyn Kravitz (Office of Research on Women's Health, Office of the Director, National Institutes of Health, Bethesda, MD). 2009 Jan 6.

and diversity at the NIH. For example, recognizing that the availability of child care is a major factor in recruiting women scientists, the NIH, in collaboration with the Foundation for Advanced Education in Sciences (FAES) has secured priority placement for the children of new NIH scientists at a local day care center.

To address issues surrounding family leave, OIR has instituted a new program that allows NIH investigators to employ a temporary lab manager to oversee the day-to-day operations of their laboratory during extended family or medical leave. Additionally, NIH-wide e-mail messages were sent in December 2007 and 2008 by the NIH Deputy Director for Intramural Research, encouraging the use of the Voluntary Leave Transfer Program (VLTP) by all employees but especially for maternity leave. Data indicate that raising awareness of the program led to an increase in enrollment and leave donations to the VLTP.

The Trans-NIH Intramural Mentoring Committee was established to ensure that all trainees and tenure-track investigators receive high-quality mentoring; to establish guidelines and methods for evaluating the quality of mentoring received; and to develop programs help NIH scientists to be better mentors. The Office of Intramural Training and Education has also implemented additional professional development training for all levels of staff.

To better understand and address the issues of importance to women and men of color at the NIH, focus groups were held with NIH tenure-track investigators, postdoctoral fellows and staff clinicians/scientists to gather their input on recruitment and retention of minority scientists. The Working Group is also developing initiatives to help promote bioengineering, computing, and physical sciences as a career choice for women and girls.

ORWH maintains a Web site and publishes a monthly e-newsletter that highlights issues related to women's careers and the activities of the Working Group.

a) Relevant Statistics

The activities of the NIH Working Group on Women in Biomedical Careers have resulted in modification of three family leave policies associated with career development programs as well the creation of two innovative mechanisms to support NIH employees on extended family or medical leave.

The NIH Office of Human Resources has tracked the number of hours of annual leave donated to the VLTP by NIH employees. In 2006, prior to the reminder message being sent out by the NIH Deputy Director for Intramural Research 52,118 hours were donated and in 2008, after messages has been sent out for 2 year, 75,105 hours were donated – an

increase of approximately 45% in the number of hours donated.

The Working Group's website is visited by an average of 2652 individuals each month. The e-newsletter currently has 510 subscribers, 78% of whom have been receiving the e-newsletter since 2008. In 2009, self-subscription has increased by approximately 14 people per month.

Future Programs

The Working Group intends to launch a new website that will serve as a resource for women in science as well as institutional leaders by collecting and organizing the most up-to-date NIH policies affecting women in science and also best practices for recruiting, retaining, and advancing women in science. The NIH is also seeking to form partnerships with other federal agencies as well as professional societies in order to leverage the resources of each to reach the widest possible audience by increasing the type and number of outreach programs.

The Working Group is considering the feasibility of an award which would reward excellence in mentoring by an NIH grantee by extending the grantee's research funding for a period of time. This type of award would make clear the commitment of the NIH to supporting time spent by researchers on mentoring the next generation of scientists.

Due to the overwhelmingly positive reaction received by the grant solicitation *Research on Causal Factors and Interventions that Promote and Support the Careers of Women in Biomedical and Behavioral Research* from the research community, the NIH plans to reissue the solicitation in coming years.

Later this year, the NIH will begin construction of an additional child care center on the Bethesda campus to help meet the growing demand for child care from its employees.

a) Target Population(s):

The programs developed and implemented by the NIH Working Group on Women in Biomedical Careers are intended to encourage women and girls to pursue careers in science. They also target undergraduate, graduate and medical students, postdoctoral fellows, tenure-track investigators at NIH, and junior faculty throughout the extramural community. In addition, the Working Group programs at the NIH are intended to serve as models for the extramural community, targeting leadership at universities, academic health centers, and public and private institutions.

b) Benchmarks:

The NIH Working Group on Women in Biomedical Careers will continue to generate tangible programmatic efforts to eliminate any barriers to the recruitment, retention, reentry, and advancement of women scientists through change in the climate of academic and federal research environments. These may include partnerships with professional societies, publication and promotion of resources and best practices, changes to NIH policies both intramurally and extramurally, and development of professional development and

mentoring programs.

Overarching Recommendations:

Through the efforts of the NIH Working Group on Women in Biomedical Careers, the NIH strives to serve as a model for the performance of the best science in an environment that values diversity, mentoring, and support for the career advancement of women. While the NIH has become a leader among federal funding agencies in developing initiatives to maximize the potential of women scientists and engineers, there is still more to be done. Even though women are trained in the biomedical sciences in equal proportion to men, they have still not achieved parity at the junior faculty level and are even more underrepresented in senior faculty and leadership positions. This high degree of attrition may discourage women and girls from considering careers in science, and this departure represents a loss of the investment on training women who do not pursue research careers. The health of the nation would be best served by capitalizing on the investment in the education of girls and boys in science, technology, engineering, and medicine and the training of the next generation of women and men scientists to face the challenges of the future.

There are many agencies and institutions throughout the country that have attempted to develop work environments that are more supportive of women, but such a systematic problem can not be solved in isolation. A coordinated, national policy with support from the highest levels of leadership which places a premium on mentoring and flexibility, incorporates forward thinking parental leave and child care policies, and includes a focus on removing the unique barriers that may be faced by women of color is required to fully maximize the potential of women and girls in biomedical careers.

8. Reentry into Biomedical Careers Program

The Office of Research on Women's Health (ORWH) serves as the focal point for women's health research at NIH. ORWH was established in September 1990 within the Office of the Director, National Institutes of Health (NIH) to strengthen and enhance research on women's health across the lifespan, ensure that women are appropriately represented in clinical research studies supported by NIH, and to develop opportunities for the advancement of women in biomedical careers.

Based on a pilot program developed by ORWH, the NIH now has a supplement program to support individuals to reenter an active research career after taking time off to care for children or attend to other family responsibilities. These supplements to existing NIH research grants support full-time or part-time research by these individuals to update their research skills and knowledge such that the reentry scientist will be able to successfully apply for her or his own independent research support. This program also provides mentoring and guidance to reestablish careers in biomedical, behavioral, clinical or social science research. While this program is open to both women and men, over 97% of the reentry supplement recipients have been women.⁴⁶

⁴⁶ Internal NIH ORWH data, 2009.

Future Programs

This NIH supplement program will continue to offer researchers who have interrupted their scientific careers to attend to family or other responsibilities an opportunity to reenter the laboratory in a mentored, supportive environment.

a) Target Population(s):

The target populations are women and men whose research careers have been interrupted because of family responsibilities and who desire to become active researchers again.

b) Benchmarks:

Opportunities for training and mentoring are part of this program with the expectation that the reentry candidate will be successful in obtaining individual research grants.

Overarching Recommendations:

The reentry program addresses one of the most relevant issues facing young scientists who want to pursue a career in research while starting their families, caring for ill or disabled relatives, and/or moving with spouses. The reentry supplements increase the opportunities for these researchers and prevent them from seeking other careers. It is hoped that this program will enable them to fulfill their goals to remain in research.

9. The Science of Sex and Gender in Human Health Online Course:

The Office of Research on Women's Health (ORWH) serves as the focal point for women's health research at NIH. ORWH was established in September 1990 within the Office of the Director, National Institutes of Health (NIH) to strengthen and enhance research on women's health across the lifespan, ensure that women are appropriately represented in clinical research studies supported by NIH, and to develop opportunities for the advancement of women in biomedical careers.

ORWH, in collaboration with the Food and Drug Administration (FDA) Office of Women's Health (OWH), has produced a self-paced, web-based course available to the public on the importance of considering sex and gender in human health in all research. "The Science of Sex and Gender in Human Health" offers participants a basic scientific understanding of the major physiological differences between the sexes, their influence on illness and health outcomes, and their implications for policy, medical research, and health care. The course is comprised of six lessons: Definitions of Sex and Gender; The Development and Implementation of Federal Research Regulations; Cell Physiology; Developmental Biology; Pharmacodynamics and Pharmacokinetics; and Clinical Applications of Genomics.

a) Relevant Statistics:

This course has served as a valuable resource for students, researchers, and members of the public to understand the importance of federal research policies in distinguishing males and females. As of 2009, 2961

individuals have registered for this course and 657 have completed and met the requirements for CME credits.

Future Programs

Efforts are underway to update this course and create a second module that will address specific conditions or organ systems where sex differences play a significant role: Cardiovascular Disease; Autoimmune; Bone Metabolism; Pregnancy; Mental Health; Irritable Bowel Syndrome; Polycystic Ovary Syndrome/Metabolic Syndrome; HIV/AIDS; Pharmacokinetics/ Pharmacodynamics; and Biostatistics.

a) Target Population(s):

The target population for this course includes biomedical researchers, clinicians, members of academia, students in health professional schools and others with an interest in women's health or the science of sex and gender.

b) Benchmarks:

Fall 2009 has been set as the target date for launching an update of the original Science of Sex and Gender course, to be followed by the launch of the new module.

Overarching Recommendations:

Despite all the attention that has been given to the importance of including sex and gender factors in the design of scientific research, for some there still remains a need to understand why this should be routine. Many others fail to recognize the importance of analyzing research data for sex and gender differences. This course has been well received. Preparations for publicity and future educational efforts will highlight key points from the course that encourage researchers to adopt the study of biological sex differences as a routine scientific requirement and not simply to meet a legal requirement.

10. Office of Research on Women's Health Career Development and Education/Training Programs

The Office of Research on Women's Health (ORWH) serves as the focal point for women's health research at NIH. ORWH was established in September 1990 within the Office of the Director, National Institutes of Health (NIH) to strengthen and enhance research on women's health across the lifespan, ensure that women are appropriately represented in clinical research studies supported by NIH, and to develop opportunities for the advancement of women in biomedical careers.

A major part of the mandate of the Office of Research on Women's Health (ORWH), is to develop opportunities and support for the recruitment, retention, reentry, and advancement of girls and women in biomedical careers. To accomplish these goals, ORWH has initiated numerous programs to nurture the participation and advancement of girls and women in biomedical careers in order to ensure that interest and priorities in women's health remain at the forefront of our nation's research agenda.

ORWH supports a range of efforts by scientific and public health societies to promote the advancement of women in science careers as well as promoting women's health. Some examples include support of a yearly seminar series on strategies for success in science for the Association for Women in Science (AWIS) Bethesda Chapter, support of career development workshops and printed materials for the Women in Cell Biology Committee of the American Society for Cell Biology, as well as the Environmental Mutagen Society Women's Group. The Women's Reproductive Health Research (WRHR) Career Development Program was initiated by the National Institute of Child Health and Human Development (NICHD) in 1998. The ORWH joined NICHD in cosponsoring this initiative. This institutional career development award supports research career development of WRHR Scholars, who are obstetrician-gynecologists that have recently completed postgraduate clinical training, and are commencing basic, translational, and/or clinical research relevant to women's reproductive health. The goal of this initiative is to promote research that will benefit the health of women by bridging clinical training with research independence, increasing the number and skills of obstetrician-gynecologist investigators at awardee institutions through a mentored research experience leading to an independent scientific career addressing women's reproductive health concerns. There are currently 20 WRHR Program sites located in Departments of Obstetrics and Gynecology throughout the nation with the primary goal of increasing the research capacity of clinically trained obstetrician-gynecologists. Since 1998, a total of 136 Scholars have been appointed to the program.

ORWH, in collaboration with the Office of Intramural Research, supports workshops for NIH trainees on topics such as teaching skills, science communication, science writing, career planning, and assertiveness training; the Israeli-NIH Graduate Student Program for pre-doctoral students; Fellows Award for Research Excellence (FARE) 2008 – a competitive research travel award program; and an NIH High School Summer Student Program.

ORWH, in conjunction with the NIH Office of Science Education, has supported the creation of a science curriculum and video series to encourage girls to consider careers in research and science. These videos, aimed at middle school students, include: *Women are Researchers*, *Women are Dentists*, *Women are Surgeons*, *Women are Pathologists*, and *Women Scientists with Disabilities*.

Future Programs:

Yearly reviews and program updates will take place as the intramural community defines its needs and concerns.

a) Target Population(s):

The purpose of these programs is to encourage girls to consider careers

in science and to support the advancement of women who are at all level and stages of careers in science. They are also meant to serve as an example to the women and men who oversee career development programs and are responsible for institutional career oversight.

Overarching Recommendations:

The ORWH develops and supports opportunities for the recruitment, retention, advancement, and reentry of girls and women in biomedical careers. The ORWH initiated a number of programs to nurture the participation and advancement of girls and women in biomedical careers in order to ensure that interest and priorities in women's health remain at the forefront of our nation's research agenda. ORWH will continue to develop new strategies and innovative programs to address career issues, barriers, and concerns of girls, women, and minorities in science.

11. Office of Research on Women's Health Outreach Programs

The Office of Research on Women's Health (ORWH) serves as the focal point for women's health research at NIH. ORWH was established in September 1990 within the Office of the Director, National Institutes of Health (NIH) to strengthen and enhance research on women's health across the lifespan, ensure that women are appropriately represented in clinical research studies supported by NIH, and to develop opportunities for the advancement of women in biomedical careers.

ORWH works in partnership with the NIH Institutes and Centers, other federal agencies, and various national, state, and community organizations utilizing a variety of outreach efforts to disseminate information on research on girls' and women's health. Working together, the ORWH and its partners ensure that timely and relevant information is distributed to advocacy groups, public and private institutions as well as concerned individuals interested in girls' and women's health research. ORWH continues to update its website with the most current information for scientists and the general public pertaining to issues of interest concerning women's health research, inclusion of girls and women in clinical trials, career development, and upcoming events.

As part of its e-government approach to research dissemination, ORWH has widely expanded access to advances resulting from women's health research for the public and scientific community through its podcast series, *Pinn Point on Women's Health*, hosted by Dr. Vivian W. Pinn, Associate Director for Research on Women's Health and Director of ORWH. This monthly podcast provides the latest news in women's health research and includes conversations with NIH scientists providing topical updates focused on improving the health of women and girls. Recently, ORWH and the National Library of Medicine (NLM) launched an innovative Web portal on women's health research. The Women's Health Resources uses the *NIH Research Priorities for Women's Health* to

identify overarching themes, specific health topics, and research initiatives in girls' and women's health. Within each section of the Web site are topics with links to relevant and authoritative resources and research initiatives for girls' and women's health. NLM has created specific user-friendly strategies for these topics to ease searching ClinicalTrials.gov and PubMed. Other Web resources used include AIDSinfo, American Indian Health, Arctic Health, Household Products Database, MedlinePlus, and NIHSeniorHealth. Search strategies for major studies related to girls' and women's health research have also been created and will be linked between the new Web site and the ORWH Web site. As with the topical search strategies, ClinicalTrials.gov and PubMed searches for each major report are also included.

The Women's Health Seminar Series includes several symposia a year on the results and clinical applications of ongoing girls' and women's health research. For 2008-2009, the symposia focused on topics supported by the research in the Specialized Centers of Interdisciplinary Research on Sex and Gender Factors Affecting Women's Health (SCOR) program. The symposia were *Sex and Gender Research: Substance Abuse*; *Sex and Gender Research: Pain*; *Sex and Gender Differences in the Urinary Tract*; *Sex and Gender Research: Metabolic Dysfunction*; and *Sex and Gender Research: Depression with Other Diseases*. These seminars are open to the public and made broadly available through archival NIH VideoCasts.

ORWH also produces a series of fact sheets which summarize women's health research findings on a number of topics including chronic fatigue syndrome, the health of women and girls across the lifespan, sexually transmitted infections, and interdisciplinary research in women's health and presents them in plain language for distribution to the general public. ORWH is the agency lead at NIH for National Women's Health Week. ORWH coordinates activities to celebrate and expose staff, patients, and researchers to information and topics on women's health and women's health research. ORWH also provides materials on women's health to community health fairs such as the Telemundo's Feria de al Familia, the National Women's Heart Day Health Fair, and the U.S. Department of Housing and Urban Development Breastival Festival.

In 2008, ORWH provided financial support for an outreach activity to increase awareness of HIV/AIDS within the minority women communities – specifically African-American women. This was a collaborative outreach activity between federal and community partners through the play, *In The Continuum* written by 2 black women (1 South African, 1 US resident) and presented the ramifications for women and their entire constellation of respective networks. Washington, D.C. has the highest rate of persons living with AIDS in a major U.S. city and African-American women, who are only 58% of the District's female population, account for 90% of all

new female HIV cases. The play was held at the Atlas Theatre in Washington DC, an area that was the focus of the outreach activity. Open discussions with the actresses, production staff and production team were held after each showing. Additionally, 2 mobile testing units were parked outside the theatre for rapid testing.

a) Relevant Statistics

In 2008, ORWH produced 7 podcast and 4 scientific fact sheets. So far in FY2009, outreach materials have been provided to 18 government and community health fairs. Three seminars were held showcasing the research being done at the SCOR Centers.

The play, *In The Continuum* was well received by the audience who gave the performers standing ovations at each show. There was overall attendance of 381 people in the audience (~ 170 people attended the afternoon show and ~216 for the evening show).

Future Programs

ORWH will continue producing podcasts on a monthly basis and may also include vodcasts. The Women's Health Resources Web site is in the process of being upgraded to include web 2.0 features. At least three new fact sheets will be released in 2009. ORWH will continue to focus its seminar series on interdisciplinary sex/gender research supported by the ORWH.

ORWH is preparing a user-friendly resource guide to provide reliable, current information to women and their families covering common health problems and concerns—such as heart disease, stroke, cancer, and diabetes—as well as how to prevent or manage these health problems. The *Women's Health Research Resource Guide* will address the health of all family members, including children and men, as women serve as the portal to family health. It will promote a healthy lifestyle and offer practical, relevant information on the basic steps families can take every day to reduce their risk of developing many illnesses that threaten women's lives. It will also include corresponding toll-free numbers and Web sites for Federal agencies, organizations, and health information clearinghouses where readers can obtain more in-depth information on the women's health issues referenced in the resource guide.

a) Target Population(s):

The outreach materials, such as the podcast and fact sheet series, as well as the Women's Health Research Resource Guide and the Women's Health Web portal are intended to educate women about the current research on factors affecting their health. The seminar series is aimed at researchers in all fields since women's health is interdisciplinary.

b) Benchmarks:

ORWH has developed and continues to provide information to the public and the NIH community through its numerous outreach activities. ORWH will continue to expand its ORWH interactive research e-mail address to provide a mechanism to the outside community to have an interactive dialogue with ORWH on issues of interest.

Overarching Recommendations:

Outreach through ORWH Web site and various activities continues to be utilized to

disseminate the latest information and research findings on women's health. The ORWH will broaden its efforts to provide science-based information on women's health research to the public, health professionals, voluntary organizations, and other key stakeholders. The goal is to encourage women and clinicians to seek and use information from research on women's health and to see the ORWH as a central resource at NIH on women's health research.

II. NIH / Office of the Director / Office of AIDS Research (OAR)

A. Programs That Improve the Lives of America's Women and Girls

1. Program Description:

While the Office of AIDS Research (OAR) in the Office of the Director (OD), National Institutes of Health (NIH) does not have specific program initiatives targeting women and girls, OAR coordinates a number of activities that improve the lives of women and girls in America.

OAR annually convenes a trans-NIH Coordinating Committee on Women and Girls comprised of scientists from NIH and a Planning Group of experts from other government agencies, academia, foundations, and community constituency groups, to review the state-of-the-science, assess newly emerging and critical public health needs, and identify scientific opportunities, needs, and priorities in the area of HIV/AIDS research relevant to women and girls.

OAR uses this input to develop the Women and Girls section of the annual Trans-NIH Plan for HIV-Related Research. The annual Plan identifies the scientific priorities and opportunities for NIH AIDS research and serves as the framework for developing the annual trans-NIH AIDS research budget, for determining the use of AIDS-designated dollars, and for tracking and monitoring all NIH AIDS research expenditures. This plan also is used as a reference guide by NIH scientists and administrators in research institutions around the world to guide the development of new and innovative research on HIV in women and girls.

OAR conducts the same activities for microbicides research, a crucial potential tool in the armamentarium of HIV prevention approaches for women.

OAR maintains a centralized database to track and monitor all NIH AIDS research expenditures using a coding system tied to the appropriate objective(s) of the Trans-NIH Plan for HIV-Related Research. A special interest code allows OAR to monitor and track AIDS projects involving women and girls. The OAR database also serves as the primary resource for AIDS research information in the new Research Conditions and Diseases Categorization (RCDC) system.

OAR uses information from the centralized database to review the relevance of current project funding and to guide the development of new initiatives to address gaps and emerging issues relevant to HIV/AIDS in women and girls. OAR assists in the development and conduct of conferences and workshops designed to identify HIV/AIDS research on women and girls

and identify the resources used to conduct that research.

2. Future Programs: In the future, OAR anticipates convening representatives of the current HIV/AIDS research networks that have targeted women and girls activities in the United States to discuss the coordination of resources, scientific gaps and opportunities, sharing information, and shared objectives.

a) Target Population(s):

While the women and girls HIV/AIDS research agenda is designed to better understand the epidemic in all populations, the nature of the epidemiology of the HIV epidemic in the U.S. results in research that targets African Americans and Latinas. Around the world, women represent half of all people living with HIV. All of the research coordinating efforts conducted by the OAR is designed to meet the needs of the epidemic around the world including prevention in all communities.

b) Benchmarks:

The annual OAR budget review enables tracking of research relevant to the current and future needs of the epidemic in women and girls.

B. Overarching Recommendations: Research that addresses HIV in women and girls is conducted in specific targeted initiatives and in general HIV/AIDS research including the basic, behavioral, social, and clinical sciences, and in translational and implementation research. The non-specific allotment of HIV/AIDS funding facilitates the most flexible response to the rapidly changing needs of the epidemic in women and girls.

III. NIH / Office of the Director / Office of Behavioral and Social Sciences Research (OBSSR)

A. Programs That Improve the Lives of America's Women and Girls

1. Health Literacy

The Department of Health and Human Services, in its Healthy People 2010 initiative, defines health literacy as, “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.”⁴⁷

Low health literacy is a wide spread problem, affecting more than 90 million adults in the United States, where 43% of adults demonstrate only the most basic or below-basic levels of prose literacy⁴⁸. Low health literacy results in patients' inadequate engagement in decisions regarding their

⁴⁷ <http://www.healthypeople.gov/document/HTML/Volume1/11HealthCom.htm>.

⁴⁸ Nielsen-Bohman L, Panzer AM, Kindig DA (eds). Health Literacy: A Prescription to End Confusion. Committee on Health Literacy, Board on Neuroscience and Behavioral Health, Institute of Medicine. Washington, DC: National Academies Press (2004) at 346.

health care and can hinder their ability to realize the benefits of health care advances. Research has linked low or limited health literacy with such adverse outcomes as poorer self-management of chronic diseases, fewer healthy behaviors, higher rates of hospitalizations, and overall poorer health outcomes.

OBSSR is leading a trans-NIH effort to support research to increase scientific understanding of the nature of health literacy and its relationship to healthy behaviors, illness prevention and treatment, chronic disease management, health disparities, risk assessment of environmental factors, and health outcomes. This effort supports both basic research and interventions that can strengthen health literacy and improve the positive health impacts of communications between healthcare and public health professionals and consumer or patient audiences that vary in health literacy.

a) Relevant Statistics:

The FOA active 2004-2006 funded 52 grants and the current FOA active since 2007 has supported 55 grants. While most grants target adult or child populations, several have specifically focused on women: Culture and Cancer Literacy among Immigrant Women, Health Literacy in a Panel of New Mothers, Refining Entertainment Education for Cancer Literacy in African American Women, Health Literacy for Hispanic Immigrant Women, Framing Effective Cervical Cancer Messages for Vietnamese American Women, Maternal Health Literacy & Child Health Program Participation.

2. Future Programs:

OBSSR expects to reissue a trans-NIH FOA on health literacy in 2010.

a. Target Population(s): Low literate populations and their health care providers

B. Overarching Recommendations: Additional research elucidating the mechanisms through which health literacy influences the health of women and girls and better strategies for improving the health literacy levels of women and girls is needed.

2. Research on Causal Factors and Interventions that Promote and Support the Careers of Women in Biomedical and Behavioral Science and Engineering.

OBSSR participated in a funding opportunity to support research on: 1) causal factors explaining the current patterns observed in the careers of women in biomedical and behavioral science and engineering and variation across different subgroups and 2) the efficacy of programs designed to support the careers of women in these disciplines. Causal factors include individual characteristics, family and economic circumstances, disciplinary culture or practices, and features of the broader social and cultural context

a) Relevant Statistics:

NIH is funding 14 grants. OBSSR funded an R01, Advancement of Women in STEMM: A Multi-level Research and Action Project. This project examines the effect of department climate on productivity, job satisfaction, intent to leave and attrition in 90 STEMM departments. It will also examine reception and resistance to an equity intervention.⁴⁹

IV. NIH / Office of the Director/ Office of Disease Prevention (ODP)

A. Programs That Improve the Lives of America's Women and Girls

1. The NIH Consensus Development Program: A trans-NIH/HHS Program to Enhance Evidence-based Approaches to U.S. Health Care.

The Office of Medical Applications of Research (OMAR) is the focal point of evidence-based medicine at the NIH and is the home of the NIH Consensus Development Program. For each biomedical issue taken up by the Program, OMAR convenes a multidisciplinary, financially and academically objective, independent panel to evaluate the available scientific evidence and develop a collective statement to advance understanding of the issue among health professionals, researchers, and the public. One member of each panel is a public representative, who brings the patient's perspective to the panel's deliberations. The evidence they consider is drawn primarily from three sources: 1) presentations from invited experts; 2) a formal systematic literature review provided by the Agency for Healthcare Research and Quality's (AHRQ) Evidence-based Practice Centers (EPC) program; and 3) testimony from the general public including patients, their families, and advocates. The resulting statement is an independent report of the panel and is not a policy statement of the NIH or the Federal Government; the panel is not an advisory body to NIH. An NIH Institute or Center sponsors the conference with OMAR, with other NIH/HHS/government entities acting as co-sponsors and partners.

*Highlighted Recent Conference - NIH State-of-the-Science Statement on Tobacco Use: Prevention, Cessation and Control
June 12-14, 2006, Bethesda, Maryland*

The Panel's key findings: Tobacco use remains a very serious public health problem. Coordinated national strategies for tobacco prevention, cessation, and control are essential if the United States is to achieve the Healthy People 2010 goals. Most adult smokers want to quit, and effective interventions exist. However, only a small proportion of tobacco users try treatment. This gap represents a major national quality-of-care problem. Many cities and states have implemented effective policies to reduce tobacco use; public health and government leaders should learn from these experiences. Because smokeless tobacco use may increase in the United States, it will be increasingly important to understand net

⁴⁹ NIH IMPAC II database.

population harms related to use of smokeless tobacco. Prevention, especially among youth, and cessation are the cornerstones of strategies to reduce tobacco use. Tobacco use is a critical and chronic problem that requires close attention from health care providers, health care organizations, and research support organizations.

Other Recent Conferences (details available at <http://consensus.nih.gov>)

- NIH Consensus Development Conference: Management of Hepatitis B (October, 2008)
- NIH Consensus Development Conference: Hydroxyurea Treatment for Sickle Cell Disease (February, 2008)
- NIH State-of-the-Science Conference: Prevention of Fecal and Urinary Incontinence in Adults (December 10-12, 2007) NIH State-of-the-Science Conference: Multivitamin/Mineral
- Supplements and Chronic Disease Prevention (May 15-17, 2006)
- NIH State-of-the-Science Conference: Cesarean Delivery on Maternal Request (March 27-29, 2006)

V. NIH / Office of the Director / Office of Equal Opportunity and Diversity Management (OEODM)

A. Programs That Improve the Lives of America's Women and Girls

1. Federal Women's Program, Office of Equal Opportunity and Diversity Management at the National Institutes of Health (NIH):

The Federal Women's Program housed under the Office of Equal Opportunity and Diversity Management at the National Institutes of Health (NIH) assists management in eliminating any barriers to the recognition, development, promotion, understanding, and utilization of the abilities, skills, and knowledge of women in the workforce. The Federal Women's Program Network Committee, an employee advisory committee to the Federal Women's Program, sponsors career development workshops for women in the NIH workforce.

a) Relevant Statistics:

Currently, the NIH employs over 10,000 women.

2. Future Programs:

Three workshops are currently scheduled. The first workshop entitled "Moving On Up: Tools for Redesigning Your Career" will be held July 16, 2009. This is a career planning session designed to provide valuable tools to help participants identify their marketable skills. The objective is for participants to match their skills with various career and growth opportunities. An outside consultant specializing in coaching, personal and professional empowerment will conduct this workshop. Topics for future workshops include resume writing, interview skills and leadership preparation. The Federal Women's Program Network Committee will collaborate with the NIH Work Life Center to conduct the future workshops. Workshops will be evaluated using Likert scale instruments designed to determine how well each workshop meets its stated goals.

B. Overarching Recommendations:

The NIH strives to promote equal employment opportunities for women in the workforce and to promote career development.

VI. NIH / Office of the Director / Office of Extramural Research (OER)

A. Programs That Improve the Lives of America's Women and Girls

1. Encouraging Early Transition to Research Independence:

Modifying the NIH New Investigator Policy to Identify Early Stage Investigators.

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-121.html>.

Frequently Asked Questions About the NIH Early Stage Investigator (ESI) Policy,

http://grants.nih.gov/grants/new_investigators/investigator_policies_faqs.htm.

This policy was implemented by the Office of Extramural Research, Office of the Director in 2008. Under this policy, New Investigators within ten years of completing their terminal research degree or within ten years of completing their medical residency are designated Early Stage Investigators (ESIs). Traditional research grant (R01s) applications from ESIs are identified and the career stage of the applicant will be considered at the time of review and award. Extensions of the ten-year period can be granted for family care (e.g. maternity leave), and medical issues, among other reasons. All NIH Institutes and Centers (ICs) must comply with this policy.

a) Target Population(s):

Extensions are not granted based on gender, however many of the requests for extension are made by women who have temporarily exited the scientific workforce for maternity leave, and/or to care for young children.

B. Overarching Recommendations:

NIH has been involved in the development of programs to remove any barriers that might exist to recruitment, retention, re-entry, and advancement of women in biomedical careers. In response to the recommendations contained in the National Academies report "*Beyond Bias and Barriers, Fulfilling the Potential of Women in Academic Science and Engineering*," and issues raised by grantee institutions and professional organizations, NIH has revised several policies to address any barriers that women might face accessing and negotiating extramural programs. While the issues were initially raised in response to women's concerns, the new policies have helped to address issues faced by women and men.

2. Program Description:

NIH has generated new policies, or modified existing policies to address work-life issues raised by women. Below are two:

--NIH Policy Concerning Career Development (K) Awards: Leave, Temporary Adjustments to Percent Effort, and Part-Time Institutional

Appointments (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-036.html>).

This notice was issued by the Office of Extramural Research, Office of the Director in 2009. NIH career development (K) awards support a period of mentored or independent career development in preparation for a role as an independent researcher. The notice modified the existing policy by permitting short term adjustments to the minimum effort requirement for personal or family situations such as parental leave, child care, elder care, medical conditions, or a disability. The time frame is not to exceed one year. All NIH Institutes and Centers (ICs) must comply with this policy.

--Research Supplements to Promote Re-entry into Biomedical and Behavioral Research Careers (<http://grants1.nih.gov/grants/guide/pafiles/PA-08-191.html>). This funding opportunity was released in 2009 by the Office of Research on Women's Health (ORWH), participating Institutes and Centers (ICs) of the National Institutes of Health (NIH), and the Office of Dietary Supplements (ODS), and provides administrative supplements to existing research grants to support individuals with high potential to re-enter an active research career after a qualifying interruption for family or other responsibilities. For a comprehensive listing of qualifying interruptions, see Section III.1.B.

a) Target Population(s):

The policy and funding announcement permits persons of any sex/gender to participate. They have proven to be very beneficial for women in particular to plan for maternity leave and child care while continuing to contribute to and progress in scientific research.

3. Program Description:

NIH continues to implement and clarify policies designed to facilitate parental leave and child care for participants in extramural programs.

--Frequently Asked Questions: Policies Related to Parental Leave and Child Care (http://grants.nih.gov/training/faq_childcare.htm)

This policy was updated by the Office of Extramural Research, Office of the Director in 2007. Under the revised policy, NIH clarified the circumstances under which child care and family care needs can be addressed. Some of the issues addressed include whether: (1) grantees can use grant funds for dependent care expenses; (2) grant funds can be used to pay for child care during project-related conferences and meetings; (3) researchers can take a leave of absence for care-giving responsibilities, etc. All NIH Institutes and Centers (ICs) must comply with this policy.

--Revised NIH Parental Leave Policy for the Ruth Kirschstein NRSA Awards (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-064.html>)

This notice was issued by the Office of Extramural Research, Office of the Director in 2008. The notice modified the existing policy by permitting trainees and fellows to receive stipends for up to 60 calendar days

(equivalent to 8 work weeks) of parental leave per year for the adoption or the birth of a child when those in comparable training positions at the grantee organization have access to this level of paid leave for this purpose. All NIH Institutes and Centers (ICs) must comply with this policy.

a) Target Population(s):

Participation in either program is open to all. However, this policy does appear to address barriers that women's groups have identified as a barrier to negotiating scientific careers, and remaining competitive with their male counterparts.

B. Overarching Recommendations:

NIH has been involved in the development of programs to eliminate any barriers that might exist to recruitment, retention, re-entry, and advancement of women in biomedical careers. In response to the recommendations contained in the National Academies report "*Beyond Bias and Barriers, Fulfilling the Potential of Women in Academic Science and Engineering*," and issues raised by grantee institutions and professional organizations, NIH has revised several policies to address barriers that women face accessing and negotiating extramural programs. While the issues were initially raised in response to women's concerns, the new policies have helped to address issues faced by women and men.

4. RePort: Women in Extramural Programs

In addition to carrying out its scientific mission, NIH exemplifies and promotes the highest level of public accountability. To that end, the Research Portfolio Online Reporting Tool (RePort) provides access to reports, data, and analyses of NIH research activities, including information on women as Principal Investigators (PIs), trainees and as other participants in NIH supported research. The web site provides information about average grant awards made to women, as well as participation and success rates.

a) Relevant Statistics:

Statistics are available under the "Investigators and Trainees" link, regarding Sex/Gender in the Biomedical Science Workforce (http://grants2.nih.gov/grants/policy/sex_gender/q_a.htm), and Women in the Biomedical Science Workforce

(<http://report.nih.gov/WRTAS/WRTAS.pdf?slide=11>).

Additional reports may be generated by submitting a query to the system.

2. Future Programs:

NIH will continue to generate similar data as it becomes available.

a) Target Population(s):

The data contained in these reports are disaggregated by sex/gender.

VII. NIH / Office of the Director / Office of Intramural Research (OIR)

A. Programs That Improve the Lives of America's Women and Girls

1. Women Scientist Advisors Committee

The Women Scientist Advisors Committee (WSA) is a group of senior women scientists from the intramural program who oversee issues that impact intramural women scientists and suggest programs to advance their ability to work well. The Committee reports to the DDIR/OIR. One example of WSA efforts is providing training in 'Influence, Self-Promotion & Negotiation' targeted at NIH intramural tenure-track female investigators, to enhance their ability to navigate the NIH system. Other examples include: extension of NIH intramural tenure-track clock by one year, to allow flexibility with respect to family and/or medical issues; development of a pilot Leave Bank – an activity that is a collaboration between the NIH Working Group on Women in Biomedical Careers Intramural Committee and the Office of Human Resources, to develop a better mechanism for employees to receive leave for family-related needs; (NIH-wide but will be piloted in one Institute); the Margaret Pittman Lecture, part of the NIH Director's Wednesday Afternoon Lecture Series –which recognizes an outstanding woman scientist at an extramural institution – selection made by Scientific Directors and approved by NIH Director; and the Anita B. Roberts Lecture Series: "Distinguished Women Scientists at NIH" – which recognizes an outstanding senior intramural woman scientist – selection made by Women Scientist Advisors Committee (the goal of both of these lectures is to provide outstanding female role models for our women scientists).

VIII. NIH / Office of the Director / Office of Management (OM)

The challenge of balancing work and life continues to increase as our workplace becomes more complex and demanding. The leadership of the National Institutes of Health has made clear that policies, programs, services and events that support NIH work/life balance are supported, encouraged and valued. Dr. Raynard Kington, Acting Director of the NIH, and the NIH Leadership Team champion the assertion made in June of 2008,

"The NIH has always been an excellent workplace for scientists, clinicians, administrators, and support staff but there is always room for improvement. We would like to facilitate a culture at the NIH that nurtures our workers, including women, as well as our work by recognizing that our outstanding staff often have diverse interests and responsibilities outside of their labs and offices. The NIH is known for producing great science and great scientists, but we also want to enhance the family-friendly atmosphere and recognize the cultural diversity and the variety of perspectives that are part of our research environment....Alternative work schedules, flextime, and teleworking are tools that may help employees maximize their work productivity and minimize commuting time, to free up time for family, including children, spouses/partners, and parents, and pursuit of other interests. Resources ... are available to all employees to help them manage the balance between dedication to their work and

dedication to their families....The NIH Leadership Team is committed to making this Agency a model for other research institutions of how science can be done in a family-friendly environment”.

NIH offers programs that promote this viewpoint and positively impact employees. The Alliance of Work-Life Progress, an entity of WorldatWork Association that defines, recognizes and promotes work-life innovation, best practices, and thought leadership, categorizes work-life effectiveness into seven distinct categories:

- Workplace flexibility (e.g., telework)
- Paid and unpaid time off
- Health and well-being (e.g., EAP services, wellness events and services)
- Caring for dependents (e.g., childcare, resource and referral)
- Financial Support
- Community Involvement (e.g. large fitness events with the public)
- Management involvement/culture change interventions (e.g., management involvement is essential and critical for all components above)

Multiple offices within NIH play a role in the development and delivery of specific work/life programs. These offices collaborate to provide comprehensive and seamless access to the services. Several of these are highlighted below with a program description along with relevant statistics. Where available, women related statistics were given. Each highlighted program has unique achievements while in combination weave a story of organizational innovation and commitment to the health of NIH employees.

1. NIH Telework Program

The National Institutes of Health (NIH), a part of the U.S. Department of Health and Human Services, is the primary Federal agency that conducts and supports biomedical and behavioral research to improve people’s health and save lives. Flexibility is a practiced principle at NIH, necessary to accomplish research and research support at multiple locations. Employees must have an adaptable work environment to effectively support mission-related needs. The NIH Telework Program helps meet those needs and also improves the quality of life for employees in ways that lead to improvements in employee satisfaction, morale, productivity, and retention.

Telework initially began many years ago at NIH as a flexible workplace arrangement benefit that was primarily used by employees as an accommodation to meet short-term medical needs. A successful one year pilot implemented in 2001 to examine telework benefits, costs, and impacts on employees, management, and the organization resulted in an expansion of the early initiative to a fully comprehensive program. Participation has grown steadily as a result of several aspects: recruiting and retention efforts, a new leadership team, and continuity of operations

planning.

a) Relevant Statistics / Outcomes:

_ Significant increases in participation rates, e.g., rising from 50 participants in the 2001 pilot to 18% of the eligible population in 2007 and then to 21% in 2008.

_ Reduced management resistance to telework (The main barrier to telework has changed from management resistance to office coverage challenges)

_ Better prepared workforce to continue to function and operate during emergencies, whether national in scope (e.g., Pandemic Flu, H1N1 Flu) or local (e.g., power outages, flooding in buildings)

_ NIH uses information obtained through the annual OPM survey and other internal surveys to examine where improvements are needed and discover best practices that can be shared.

Examples of comments received from program participants:

Managers:

_ “Great! We do grant review, progress reports, etc. and telework lends itself to this work – the teleworker is able to better meet deadlines.”

_ “We have gone from having a 7-8 day backlog to a 2 day backlog.”

_ “In one customer service-based group, telework has allowed them to move to a paradigm where customers can get answers from all staff, rather than relying on getting in touch with a particular person. This has enhanced co-worker and customer satisfaction, and they’ve received positive comments from customers.”

_ “Even non-teleworkers see this as a big step forward for the IC – it demonstrates a genuine interest in employees’ quality of work life, and they think that even if telework doesn’t work for them, something will come along that will. It’s a big morale booster.”

Teleworkers:

_ “I start day with less stress and have time to get errands and other tasks done (since I don’t have to commute).”

_ “I still have energy at the end of the day.”

_ “I’m able to focus and get more done in a shorter time.”

_ “I’m able to accommodate clients in different time zone better.”

_ “I’ve gained new skills with electronic resources and am not so dependent on paper.”

The NIH Telework Program is fortunate to enjoy support from the highest leadership and management levels to line supervisors, for example, the Director of the NIH, Institute/Center (IC) Directors, the Associate Director for Management, the Director of the Office of Human Resources, and IC Executive Officers as

well as office managers, and program supervisors, all of whom recognize it as a valuable recruitment and retention tool that also serves the important purpose of helping employee better meet the demands of their work/life.

2. Guidelines for Services and Amenities within the NIH Facilities

The Guidelines for Services and Amenities document is the culmination of a two year study conducted by the Office of the Director, Office of Research Services and the Office of Research Facilities Development, to provide a standard guideline and framework for the planning of future employee amenities at the NIH. The employee amenities involved in this study included employee fitness centers, worksite lactation programs, child care, food services, employee stores, banks, and conference services. This document summarizes best practices and applicable codes, regulations, and specifications for the planning design, and build of all of the employee amenities at the NIH.

The Guidelines for Services and Amenities within the NIH Facilities also summarizes an extensive benchmarking study of other federal agencies that actively participated and provided input into this document. The guidelines summarize some of the other Federal Agencies best practices as it relates to their provision of amenities within their responsibility. This benchmarking study as allow for NIH to identify its strengths and weakness in providing employee amenities at the NIH.

a) Relevant Statistics / Outcomes:

_ Provides a comprehensive planning document for employee amenities

_ Utilized extensive benchmarking study of other federal agencies in comparison with current amenities that NIH offers

3. Career Management Services

The NIH Work/Life Center (WLC) is a recognized provider of employee services offering work/life balance, career enrichment, and professional development opportunities. As part of the Office of Human Resources organization, WLC programs contribute to increased employee, including women, retention and improved job satisfaction levels. Serving as a committed resource for adult learning and development, the Center assists individuals with career related needs and supports initiatives to promote workplace flexibilities. In addition, the WLC sponsors helpful education and training services for the NIH workforce and encourages self-development opportunities.

The WLC Career Management services is an on-going program established over 10 years ago that includes individualized career and skills assessments, one-on-one career consultations with a certified career specialist, support for individual development planning, assistance using job-search strategies, KSA development, interview preparation, and career transition planning. Other related services include workshops on

Using MBTI in the Workplace, Writing Effective Federal Resumes, Enhancing Interviewing Skills, Managing Workplace Change, Building and Empowering a Successful Team, and Mentoring - A Key to Professional Development. The Center manages an on-campus work center offering computers, email access, phones, printers/faxes free of charge to give staff a space to work remotely while away from their main duty station, and administers a resource library containing multiple work/life topics, career planning tools and other reference materials.

a) Relevant Statistics \ Outcomes:

- _ 550 women have participated in a one-on-one career management services (Resume Development, KSA Assistance, IDP Support) making up 85% of clients during FY2009
- _ 65% of the clientele of Work/Life Seminars is female
- _ Enhanced employee skill sets and awareness of job interests and options
- _ High rate of satisfaction with services as indicated in the 74 % of returning clients
- _ Over 70 individuals have successfully changed jobs following an organizational restructuring activity and received intensive support for transitioning to new positions
- _ Career Transition Success Story was highlighted in the FY2006 HHS PMA Report to Employees
- _ Provided more than 60 customized workshops year to date in FY2009 for diverse NIH IC organizations and supported more than 400 individual career consultations
- _ Doubled the rate for workshop requests and referrals for career management services and related topics over FY2008 levels
- _ Effectively sponsored monthly seminar and training events on multiple topics, increasing the rate of participation by 150% in comparison with FY2008
- _ Numerous referrals and testimonials from NIH Leaders and managers stating the WLC is one of the best employee services available at NIH

4. NIH Yoga Week

The goal of Yoga Week is to provide opportunities to learn about the benefits of yoga, to experience the techniques first-hand through stretching and practice sessions, and to offer beginners' classes. The week includes twelve presentations on the evidence-based benefits of yoga from NIH grantees, including *NCI Research Portfolio on Yoga Research, Therapeutic Applications of Iyengar Yoga for Low Back Pain, Yoga and Meditation in the Management of Stress, and Yoga Research: Past, Present, and Future*. NIH Yoga Week was a trans-NIH with collaboration from other institutes, offices, and centers. Six free yoga sessions are held throughout the week at various locations around NIH

campus. Yoga Week is a partnership between the Office of Research Services, NIH Recreation and Welfare Association, National Heart, Lung, and Blood Institute, National Cancer Institute, and National Center for Complementary and Alternative Medicine.

Employee feedback spoke volumes about the past success of *NIH Yoga Week*, including the following: “*NIH Yoga Week* was a watershed event. It was the first of its kind as it married the science and practice of a fitness event for our employees.” More than 1,300 people attended the week’s events and participation in the on-campus NIH Fitness Center yoga classes increased by 20% percent.

a) Relevant Statistics / Successes:

_ Resulted in the creation of “National Yoga Month” as designated by the Department of Health and Human Services Office of Disease Prevention and Health Promotion

_ Press included coverage in *The Washington Post*, *The Washington Post Express*, and several yoga magazines

_ Expansion into NIH Mind-Body Week for 2009, scheduled for September 8-11, 2009

5. NIH Conditioning and Relaxation (CORE) Week

The goal of NIH Conditioning and Relaxation Week (CORE) is to expose NIH employees and the general public to the science and practice of different modes of physical activity and their relaxing counterparts, in hope that they will incorporate one or more activities into their daily lives. Modeled after the Department of Health and Human Services (HHS) Physical Activity guidelines, NIH CORE Week attendees have the opportunity to learn about and engage in various styles of physical activity and relaxation. In addition to exercise, NIH CORE Week provides techniques for stress management and overall healthy living. The five day event consisted of a comprehensive series including over thirty participatory classes taught by leading fitness instructors and 10 workshops conducted by NIH experts. NIH CORE Week is a trans-NIH collaborative effort from other institutes, offices, and centers and is part of the NIH HealthierFeds initiative. NIH employees accounted for about 60 percent of attendees.

Highlights from CORE week will be presented on a future HHS webinar and conference call to federal partners as an example for best practices for other federal employers to follow with respect to workplace wellness.

a) Relevant Statistics / Outcomes:

_ Generated press coverage in *The Washington Post*, article titled “A Free Opportunity to Give your Brain and Body a Boost”

_ Served as the impetus for future NIH Health weeks (i.e. Mind-Body Week)

_ Highlighted numerous forms of physical activity, including running, walking, pilates, yoga, dance, tai chi, stretching, etc

_ Increased number of Institute-led walking groups, as well as fitness center classes in pilates and yoga.

6. Employee Assistance Program

The Employee Assistance Program (EAP) at NIH is part of Occupational Medical Services. The EAP is a confidential service that was established at NIH 20 years ago to respond to issues that affect the quality of work and family life. The EAP offers services for employees and supervisors, in the following content areas: assessment, consultation, referral and follow-up. EAP consultants are available to assist with confidential personal assistance, organizational issues, problem solving in individuals or groups, and personal growth and development. The EAP works with a large number of adult children of aging parents around elder care and elder support issues. The Coordinator of the EAP has post-doctorate work in Aging Studies from the University of Maryland and is active in Aging Services related organizations. Two EAP consultants have certificates as retirement coaches. Two EAP consultants are veterans and have an interest in working with returning veterans and their families. They both have experience and training in working with trauma. The EAP has focused a great deal lately on the broader issues of Transition Management which encompasses services on adult development transitions, grief and loss work, situational transitions such as job loss, career development (creative a future), and anxiety and stress management.

7. NIH Federal Employees Health Benefits (FEHB) Wellness Day Fair

The goal of the 2 day FEHB wellness day was to provide valuable information and various health screenings to support NIH employees' health and wellness needs.

a) Relevant Statistics / Outcomes:

- Provided 200 participants information on quality, comprehensive fitness and wellness services by promoting the awareness of positive life-style changes as a means to improve employees' health and well being.

8. Worksite Lactation Program

The NIH Work/Life Center is renowned for its Lactation Support Program established over a decade ago for employees, contractors, and fellows. This is a valued employee support service with NIH having an above average rate of employees breastfeeding compared to the national and state averages. The program offers dedicated lactation coaches for one-on-one consultations, conducts prenatal education and breastfeeding classes, offers telephone support during maternity leave, provides return to-work conferences, and manages 28 lactation rooms at multiple NIH campus buildings and Frederick and Poolesville, MD. The program consistently services more than 300 participants year over year, with more

than 250 new enrollees in FY 2009, and offers regular workshops on lactation education, training, and research providing 15 sessions year to date in FY 2009.

a) Relevant Statistics / Outcomes:

- _ 100% of participants are women
- _ 427 participants in FY2008 with 375 participants to date in FY2009
- _ Significant increase year after year in lactation program participants; 15% increase from FY2008 participation rates
- _ Serves more than 300 women per year on average, and a recent survey of participants showed 96% of respondents would recommend the program to a coworker and 97% said the program improved their quality of work/life at NIH
- _ Supports the National Breastfeeding Awareness Campaign objective to increase the proportion of women breastfeeding in the early postpartum period. 75% of NIH participants in the lactation program have gone beyond the six month mark with 20% of participants still breastfeeding at 12 months
- _ Collaboration with the NIH Child Care Board to meet the breastfeeding needs of NIH parents.

9. NIH Child Care Services

The National Institutes of Health (NIH) supports the morale and well being of its diverse work force through many work/life resources and opportunities to include high quality Child Care and parent support resources. The availability of quality child care and parent support services play a key role in the recruitment and retention of NIH staff. A unique aspect of the Child Care and Parent Support on the NIH is the Child Care Board which advises the NIH Director on child care issues, parent education program development and service implementation. The board is comprised of 12 appointed volunteer members who represent the interests of the diverse NIH employee population.

Parent Support Services made available by the Board have been the cornerstone to high parent involvement and satisfaction in the child care program. In addition to the 450 child care spaces on campus (in three nationally accredited child care centers), NIH has a resource and referral support system. This service assists parents in identifying accessible, affordable and quality child care in the D.C. metro area and nationally, in order to serve employees at all NIH sites in the U.S.

10. NIH Child Care Subsidy Program

Federal Employees of the NIH may be eligible to receive a child care tuition subsidy if their children are enrolled in licensed child care programs

and their total household income is \$60,000 or less per year. For Fiscal Year 2009, the NIH budget provides \$300,000 to this program with the goal of making high quality child care affordable to NIH Federal employees with lower incomes. Child care subsidy benefits are limited to \$5,000.00 per year, per family.

11. NIH Child Care Referral Service

The NIH has contracted with a private vendor to provide referrals to many types of alternative child care services and resources.

12. NIH Child Care Subsidy Program

- _ NIH Employees served (October 2008 – June 2009) = 104
- _ Children of NIH Employees served = 133
- _ 95 % of employees using the program are single mothers
- _ Regular and timely updates to the NIH Director on child care, parenting issues, and parenting policy through The NIH Child Care Board

13. NIH Child Care Referral Service

- _ NIH Employees served (January- June 2009) = 139
- _ 80% of callers were female
- _ 83% of callers were seeking care for newborns or children under age 2

14. General Program

- o Attained a membership of 1000 individuals in the “Parent List Serve”, an interactive electronic community of NIH parents, where they can share information and resources about children, child development, child health and everything related to raising children
- o Coordinate a system of resources accessed by several hundred employees including Child Care Resource & Referral Service (150 inquiries), summer camp guides (700 copies distributed), special needs resources, adoption resources, and college planning assistance
- o Provide unique “Ask the Parenting Specialist” events which provide “mini” personal consultation on specific parenting issues in informal lunchtime settings
- o Offer webinars on Parent Education Support – Child Development and Child Health which can be viewed at their desk. The spring series of 3 was viewed by 375 employees
- o Organize an Annual Parenting Festival showcasing child health and parenting resources and research from a variety of NIH Institutes. Over 220 employees participated this year
- o Assist 104 employees with 133 children with tuition assistance through the NIH Federal Child Care Subsidy Program aimed at lower income Federal employees
- o Manage a comprehensive web site to assist employees, current or future, to navigate the NIH child care system:
<http://does.ors.od.nih.gov/childcare/index.htm>

15. Financial Planning Seminars

In partnership with DHHS, the NIH Office of Human Resources sponsors a series of financial/retirement planning seminars annually. The purpose of the seminars is to provide our employees with valuable information and resources to guide and assist them in being financially prepared for the future. This year, speakers will be on hand to provide valuable information on a variety of financial topics including Investing Wisely, Debt Management, Financial/Retirement planning, Social Security, Long Term Care Insurance, and Flexible Spending Accounts. In past years, topics have also included Early-Career Financial Planning, Mid-Career Financial Planning, Estate Planning, College Funding, Money Smart, High-Deductible Health Plans, Tips for Avoiding Fraud, and the Thrift Savings Plan. Additionally, Financial Expos have been held in past years in conjunction with the seminars.

a) Relevant Statistics / Outcomes:

Occurs annually with approximately 550 participants

16. NIH Career and Leadership Development (Administrative)

Under the direction of the Office of Human Resources' NIH Training Center, career development programs offer participants a systematic approach to professional growth and self-improvement. They are designed to increase participants' job competency and to support career planning.

NIH Administrative Fellows Program

NIH STRIDE Program

NIH Management Intern Program

OPM Presidential Management Fellows Program

HHS Emerging Leaders Program

17. NIH Senior Leadership Program

The NIH Senior Leadership Program provides senior NIH scientific and administrative leaders with the opportunity, working with a select group of peers and scholar-practitioners to:

_ Assess individual leadership skills and attributes with data and multiple feedback opportunities, including one-on-one sessions with executive coaches

_ Design and implement a personal leadership development plan

_ Enhance capacity to lead for scientific results at the NIH, including the ability to use data efficiently to drive organizational decision making

_ Assess and address the organizational capacities of one's IC

_ Develop a systematic approach to negotiation and cross-organizational ventures at the NIH

_ Think analytically about challenges and strategies for leading organizational change at the NIH

_ Enhance capacity to analyze and operate effectively in the political systems that impact the NIH

The program focuses on several SES Executive Core Qualifications and also complements the NIH Leadership and Management competency

model.

IX. NIH / Office of the Director / Office of Strategic Coordination (OSC)

A. Programs That Improve the Lives of America's Women and Girls

1. Program Description:

The Interdisciplinary Research Program, the Human Microbiome Program, and the Building Blocks, Biological Pathways and Networks Program are part of the National Institute of Health's (NIH) Director's Roadmap for Medical Research initiative that was designed to transform the way research is conducted by fostering new ways of doing research, filling fundamental knowledge gaps, and encouraging risk taking to solve complex problems. These Roadmap Programs include funded research in biomedical areas that are important to improving the health and therefore the lives of America's women and girls. The Roadmap initiative is paid for by the NIH Director's Common Fund and is housed within the Office of Strategic Coordination (OSC), which is one of five programmatic offices within the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) in the Office of the Director (OD).

(1) The Oncofertility Interdisciplinary Research Consortium is part of a much broader Interdisciplinary Research Program that aims to improve the lives of women and girls that have been diagnosed with cancer by developing new ways to preserve their fertility, to share the new methods with clinicians, and to educate women and girls about different fertility preservation options before they undergo cancer treatments that usually reduce or eliminate the chances of a future pregnancy in cancer survivors. Fertility preservation methods are needed for pre-pubescent girls that cannot undergo ovarian hormone stimulation protocols to collect eggs that can be frozen for later use and also for women with estrogen positive breast cancer for which these protocols are dangerous. A longitudinal survey will evaluate the fertility concerns and treatment choices of patients throughout their cancer treatment, and will compare these concerns and decisions by gender, racial/ethnic background, religious affiliation, family status, and socioeconomic status, which may reveal potential health disparities.

In addition to educating cancer patients about their fertility options, the Oncofertility Consortium also includes an "Oncofertility Saturday Academy" that is an informal science education program geared towards students in the Young Woman's Charter Leadership School, a predominantly minority population inner city high school in Chicago. The two year science program not only teaches students about Oncofertility and the scientific method in general but also provides guidance and mentoring in scientific and medical careers and the college admission process.

a) Relevant Statistics:

The Oncofertility Research Consortium has authored an article that

will be published in the journal of Human Reproduction shortly on the in vitro culture of human follicles, which are the structures within an ovary that house individual eggs. Data will show that follicles encased within a supportive biological matrix produce mature eggs that are healthy. This methodology circumvents the need to administer estrogen to women with estrogen positive breast cancer to stimulate their ovaries to produce mature eggs and would allow for the collection of a small piece of an ovary from a pre-pubescent girl with a cancer diagnosis such that she may have children later in life.

Twenty-nine students participated in the Oncofertility Interdisciplinary Research Consortium's "Oncofertility Saturday Academy" in 2009 with eight sessions taking place at Northwestern University on Saturdays as well as mandatory after-school workshops held at the school. A special session offered the parents/guardians of the participants the opportunity to develop their awareness, knowledge, and skills to support their daughters' interests and pursuits in science and medicine. Analysis of the college application choices showed a statistically significant increase in the number of colleges applied to (5.1 for participants vs. 3.3 for non-participants) as well as the number of acceptances (3.2 vs. 1.9).

(2) The Human Microbiome Program develops resources to facilitate research into the microbes, including bacteria and viruses, which inhabit our bodies. Although it has been appreciated for years that microbes cause disease, it has become clear only recently that microbes can help us maintain health. The genetic composition of the multitude of microbes that inhabit us is termed "the microbiome." To determine whether healthy people have a common microbiome, and to decide whether changes in one's microbiome correlate with changes in one's health status, a reference set of several hundred microbial genomes is needed. The program will isolate and characterize microbes from the vagina, as well as four other body sites.

a) Relevant Statistics:

Dozens of microbial genomes were sequenced in the Human Microbiome Project in 2008, including several from microbes that inhabit the vagina. The reference sequences will be used by many researchers, including those that will be funded by the Human Microbiome Program to examine whether changes in the human microbiome correlate with changes in health and disease.

(3) The Building Blocks, Biological Pathways and Networks Program consists of two initiatives designed to develop new technologies to allow

molecular events in cells to be studied in high resolution in real time, one of which has contributed to research on women's health. The Metabolomics initiative is developing and applying technologies to detect comprehensive profiles of metabolites including carbohydrates, lipids, and amino acids within a single cell or even a specific part of a single cell. These improved methods can detect metabolic differences between normal and diseased cells, helping to predict the human body's response to disease, injury or infection. The Metabolomics initiative supports a research project focused on identifying the metabolic changes that make certain breast and ovarian cancer cells more able to spread.

b) Relevant Statistics:

Several new metabolic pathways were discovered in the Building Blocks, Biological Pathways and Networks Program in 2007 and 2008 that have the potential to result in novel biomarkers that indicate cancer metastatic potential, in addition to, yielding new targets for cancer drug therapies. The NIH Director grants the final approval to launch all new Roadmap programs. Each Roadmap program is co-chaired by two or more NIH Institute Directors and in some cases senior NIH program staff: Dr. Lawrence Tabak (NIDCR) and Dr. Patricia Grady (NINR) for the Interdisciplinary Research Program; Dr. Anthony Fauci (NIAID), Dr. Griffith Rogers (NIDDK), Dr. Lawrence Tabak (NIDCR), and Dr. Jane Peterson (NHGRI) for the Human Microbiome Program; and Dr. Richard Hodes (NIA) and Dr. Griffin Rodgers (NIDDK) for the Building Blocks, Biological Pathways and Networks Program. No other agencies/departments are involved in the current NIH Roadmap programs.

2. Future Programs:

a) Target Population(s):

Roadmap programs are developed via a lengthy process involving the external scientific community and the NIH Leadership and extramural program staff. No future Roadmap programs are currently under development therefore there are no target populations of women and girls under consideration. Existing Roadmap programs that include projects that are relevant to women's health as described here are not supported in perpetuity. The Roadmap for Medical Research can be thought of as a short-term "incubator space" or a "catalyst" that fosters new ways of doing research including at the interface of disciplines and provides the resources and infrastructure that are critical to filling fundamental knowledge gaps that in turn have the potential to jumpstart or transform a field of biomedical or behavioral science. Roadmap programs are therefore not permanent fixtures but rather five to ten year ventures that by their nature promote short-term risk taking that may be necessary to make a fundamental break through.

b) Benchmarks:

Roadmap Programs are short five to ten year ventures that exist to

jumpstart new areas of biomedical and behavioral science, to develop new scientific approaches to tackle intractable problems, and to foster new ways for scientists and scholars to work together in multi- and interdisciplinary ways and for these interactions to receive institutional recognition. Evaluation mechanisms during the short lifetime of a Roadmap program are tailored to the specific goals of each program. For example, for the Interdisciplinary Research Program, which was launched just under two years ago, the outcomes likely to be measured will be whether the program yielded new or improved research methods/scientific models/theories, whether new “inter-disciplines” emerged, whether new organizational models for team science were developed, and what types of skills did the trainees develop in an interdisciplinary program vs. a traditional one. All Roadmap programs at their sun-setting are expected to have some measure of what the program achieved with respect to scientific goals, so for the programs described here, this would include new fertility methods developed and implemented in the clinic, new insights into what constitutes a healthy vaginal microbiome, and the identification of new molecules that enable cancer cells to metastasize.

Overarching Recommendations:

The NIH Director’s Roadmap for Medical Research through a balanced portfolio of programs supports potentially transformative avenues of science and scientific approaches. The Roadmap is dedicated to supporting and promoting innovative high risk/high reward science, interdisciplinary approaches to the conduct of research and its management, and to providing the necessary resources and infrastructure to jumpstart new areas of science. The fundamental nature of Roadmap Programs has also required the development and implementation of new approaches to the peer review of research applications in order to identify those that best meet the stated program goals. In addition, Roadmap Programs have encouraged a greater level of interaction between staff across the NIH Institutes and Centers in the management of awarded grants that collectively cover a spectrum of biomedical and behavioral disciplines within a given Roadmap Program with the intent that this greater level of coordination will help the investigators best achieve the goals of each program.

Regarding opportunities for improvement, we can increase our focus on providing greater training opportunities for women and girls in our varied Roadmap Programs, using the successful “Oncofertility Saturday Academy” as just one model for how to recruit more girls in to scientific disciplines and careers.

X. NIH / Institutes and Centers / National Center for Complementary and Alternative Medicine (NCCAM)

A. Programs That Improve the Lives of America’s Women and Girls

1. Program Description:

The National Center for Complementary and Alternative Medicine (NCCAM) within the National Institutes of Health (NIH) has lead responsibility for conducting rigorous research on complementary and alternative medicine (CAM). While NCCAM does not support any programs targeted specifically to women's and girls' health, the Center:

- Funds a substantial portfolio of basic, translational, and clinical research on the use CAM for a number of diseases and conditions that affect women
- Carefully tracks women's accrual to clinical research trials to ensure their appropriate participation
- Collaborates with other Institutes and Centers of the NIH on:
 - *Menopause Strategies: Finding Lasting Answers for Symptoms and Health (MsFLASH)*, an initiative of the National Institute on Aging
 - The NIH Coordinating Committee on Research on Women's Health
 - The Trans-NIH Women's Urology Planning Committee.

2. Future Programs:

NCCAM will continue to support basic, translational, and clinical research on women's health.

B. Overarching Recommendations:

According to recent data from the National Health Interview Survey, nearly 4 in 10 adults (43 percent of women) and 1 in 9 children used some form of CAM practices in the preceding 12 months to promote health and wellness and for treatment of specific conditions. Women are more likely to use CAM than men. This highlights the importance of NCCAM's support for rigorous research on CAM as it affects women's health.⁵⁰

XI. NIH / Office of the Director / National Cancer Institute (NCI)

A. Programs That Improve the Lives of America's Women and Girls

1. WSA (Women Scientist Advisors): This program, which resides in the NCI Center for Cancer Research (CCR), is designed to eliminate barriers to the development and retention of women scientists as scientific and institutional leaders. They represent all women in science (students, postdoctoral fellows, tenure-track investigators, and senior investigators). Among the duties of the WSA are to:

- i. inform women scientists on issues which will affect them and solicit their opinions
- ii. organize meetings for the women scientists, to discuss issues of general concern, or to present programs of general interest
- iii. serve, or designate an alternate woman scientist to serve, on tenure-track, tenured scientist, or lab/branch chief IC search committees

Senior scientific investigators serve as representatives to this organization on a rotating basis with support from the CCR. This organization is part of

⁵⁰ Barnes PM, Bloom B, Nahin R. CDC National Health Statistics Report #12. Complementary and Alternative Medicine Use Among Adults and Children: United States, 2007. December 2008.

a larger intramural NCI effort, which includes divisional representatives from the DCEG, as well as a larger NIH effort with representatives from the different institutes that comprise the NIH as a whole.

Future Programs

a) Target Population(s): The WSA will be sponsoring high school internships for local schools. As a pilot, the WSA plans to sponsor three from the Madeira School in McLean, Virginia interested in obtaining laboratory experience.

b) Benchmarks: The WSA will conduct surveys that would be analyzed for positive impact.

A. Programs That Improve the Lives of America's Women and Girls

The breast cancer therapy program in Cancer Therapy

Evaluation Program, DCTD, NCI has approximately 25 active phase III clinical trials, 8-10 trials in development over 40 additional earlier phase 1, 2, and pilot studies. Approximately 10, 000 women per year enroll in NCI CTEP sponsored breast cancer trials. These trials are designed to evaluate new anti-cancer agents and strategies with a particular emphasis on translational research to elucidate molecular mechanisms of breast cancer and treatment effects. This program interacts with other programs involving breast cancer in the NCI (DCP, DCCPS, DCEG, CCR) as well as other agencies within DHHS (FDA). Partnership with cancer advocacy and the appropriate pharmaceutical and diagnostics industry members is essential. Both men and women are eligible for breast cancer clinical studies. The predominant target population is women over the age of 18.

1. Future Program:

Program plans include the incorporation of genomic profiles and signatures into breast cancer clinical trials in our efforts to personalize anti-cancer therapy. This will include the need for sophisticated information technologies in the clinical trial research structure.

A. Programs That Improve the Lives of America's Women and Girls

1. The Cancer Therapy Evaluation Program (CTEP) within the Division of Cancer Treatment and Diagnosis (DCTD) of the National Cancer Institute (NCI) at the National Institutes of Health (NIH) in the U.S. Department of Health and Human Services (HHS) is responsible for coordinating the largest, publicly funded oncology clinical trials organization in the world. CTEP-sponsored research spans phase 1,2, and 3 trials in all cancers and treatment modalities, including chemotherapy, biologic therapy, immunotherapy, radiation, and surgery with over 900 active trials enrolling approximately 30,000 study participants annually. A major focus within CTEP is the development of specific treatment modalities and clinical trials associated with malignancies that specifically impact women and girls, including breast cancer and gynecologic cancers. CTEP also interacts with other programs within the NCI, including the Division of Cancer Prevention,

Division of Cancer Control and Population Sciences, Division of Cancer Epidemiology and Genetics, and the Center for Cancer Research), as well as other Federal agencies within HHS, including the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP). CTEP also partners with cancer advocacy and pharmaceutical and diagnostic industry members in public-private partnerships to enhance research into malignancies that affect women and girls.

a) Relevant Statistics: Over the past 5 years, approximately 79,000 women/girls have been enrolled in phase 1, 2, and 3 clinical treatment trials that specifically affect women and girls, as outlined below. In addition, all phase 3 trials include exploratory analysis to see if gender plays a role in the clinical outcome of the treatment under investigation. About 5,000 women have been enrolled in CTEP-sponsored clinical treatment trials in the first half of 2009.

Calendar Years: 2004 to 2008

Adult CTEP-sponsored Clinical Trial

Enrollment - Women

Phase

1/2

Phase

2

Phase

3

Total

(All

Phases)

Breast Cancer 321 1,622 43,557 45,500

Gynecologic Cancers 463 2,955 6,204 9,622

All Other Cancers (Excluding Breast &
Gynecologic Cancers) 3,513 7,796 12,677 23,986

Total 4,297 12,373 62,438 79,108

2. Future Programs:

a) Target Population(s): Given the rapid changes in oncology and our increasing knowledge of molecular mechanisms, CTEP has several initiatives evaluating female patient populations, including evaluating new agents for women with BRAC1 and BRAC2 breast and ovarian cancers as well as new agents for women with triple-negative breast cancer. Examples of other, special target populations for clinical research include evaluation of therapies for HIV-infected women with cervical cancer.

b) Benchmarks: CTEP actively monitors accrual, safety, and outcome results of all its clinical trials in order to advance the field of oncology.

B. Overarching Recommendations:

CTEP is striving to further identify the molecular characteristics and genomic profiles/signatures of malignancies that specifically affect women and to clinically develop appropriate therapies to address the underlying biology of these cancers in order to advance oncology treatment.

A. Programs That Improve the Lives of America's Women and Girls

1. Program Description: The Translational Research Program (TRP) of the National Cancer Institute oversees the Specialized Programs of Research Excellence (SPOREs), a team science-based grants program focusing on translational cancer research in specific organ systems. This program resides in the NCI's Division of Cancer Treatment and Diagnosis, headed by Dr. James Doroshow. Currently, there are a number of SPORE grants dedicated to women's health. These are the breast, cervical, endometrial, and ovarian SPOREs. Examples:

Breast Cancer Specialized Programs of Research Excellence (SPOREs). Eleven breast cancer SPORES conduct collaborative, multidisciplinary research to develop novel agents and technologies for breast cancer treatment and prevention and to identify biomarkers for diagnosis, prognosis, screening, prevention, and targeted treatments. For example, Bay Area Breast Cancer SPORE researchers have identified a new promising prognostic biomarker combination, which, after appropriate validation, may be able to predict the development of invasive breast cancer in women diagnosed with ductal carcinoma in situ (DCIS), a common pre-cancerous condition. Baylor Breast Cancer SPORE investigators recently provided clinical evidence for a subpopulation of chemotherapy-resistant breast cancer initiating cells and their sensitivity to a tyrosine kinase inhibitor lapatinib.

Cervical Cancer SPORE. The SPORE for cervical cancer research, located at the Johns Hopkins University School of Medicine, is focused on development of new vaccines intended for treatment and prevention of cervical cancer, and has multiple interactions with the NCI Rapid Access to Intervention Development (RAID) and Intramural Programs, as well as outside companies, foundations and universities.

Gynecologic Cancer SPORE: The SPORE in Endometrial Cancer at The University of Texas M.D. Anderson Cancer Center conducts innovative translational research for the prevention and treatment of uterine tumors. SPORE investigators recently identified serum adiponectin as a strong predictor of endometrial cancer risk.

University of Texas - MD Anderson Cancer Center, Robert Bast, PI (Grant: P50CA083639)

- PIs are developing and evaluating new statistical techniques, which could combine information in multiple biomarkers over time to detect early ovarian cancer.

Dana Farber/Harvard Cancer Center, Daniel Cramer, PI (Grant: P50CA105009)

- Using the samples of Nurses' Health Study and New England based Case-Control study, investigators noted a 36% increase in risk of ovarian cancer and a 60% risk of serous invasive cancer among the women who used talc on a regular basis (>once/week). FDA is in touch with the PI to add a potential warning on the Talcum Powder.

Fred Hutchinson Cancer Research Center, Nicole Urban, PI (Grant: P50CA083636)

- PIs are developing and validate statistical models for estimating ovarian cancer risk in post-menopausal women participating in Women's Health Initiative.

In addition, there are other SPOREs that have projects within the grant that focus on women's health. An example of this type of research is the Lung SPORE at the University of Pittsburgh which has a project that examines the role of the estrogen receptor in the development of lung cancer.

Lung

INTERSECTION OF ESTROGEN RECEPTOR SIGNALING AND EPIDERMAL GROWTH FACTOR RECEPTOR SIGNALING IN LUNG CANCER

(Project 1 of the University of Pittsburgh Lung Cancer SPORE grant 5-P50-CA090440; Jill Siegfried, PI)

Estrogen receptor beta (ER β) has been detected in non-small cell lung cancer (NSCLC) cell lines and tumor specimens. The ER downregulator, fulvestrant, blocked estradiol-stimulation of tumor growth and gene transcription in NSCLC preclinical models and showed additive effects with the epidermal growth factor receptor (EGFR) inhibitor gefitinib. The safety and tolerability of combination therapy with the EGFR inhibitor, gefitinib, and fulvestrant was explored in an early phase clinical trial with 22 post-menopausal women.

Combination therapy with gefitinib and fulvestrant in this population was well tolerated and demonstrated disease activity. Based on these results, a phase II study combining erlotinib with fulvestrant is underway, and the research group is developing a dose escalation study of vandetanib, a multitargeted inhibitor with fulvestrant in lung cancer.

a) Relevant Statistics:

The following chart details the number of SPORE grants by organ site:

Organ Site Specific SPOREs

07 08 09

- **Bladder** 1 1 1
- **Brain** 4 4 3
- **Breast** 11 10 10
- **Cervical** 1 1 1
- **Endometrial** 1 0 2
- **GI** 5 5 6
- **Head and Neck** 5 5 5
- **Kidney** 1 1 1

07 08 09

- **Leukemia** 1 1 2
- **Lung** 7 7 7
- **Lymphoma** 4 4 5
- **Myeloma** 1 1 1
- **Ovary** 4 4 5
- **Pancreas** 3 2 3
- **Prostate** 10 9 10
- **Skin** 4 5 5

2. Future Programs:

a) Target Populations: In the future we expect to characterize tumors, including tumors of women, genotypically and phenotypically, which may allow sub classifying these cancers into groups that could be treated in different ways. SPOREs in the future will take advantage of these new findings to develop therapeutics that target different subclasses of cancers.

b) Benchmarks: SPOREs are grants that are peer-reviewed every 5 years. Successful studies will have reached a human endpoint and will have moved from the laboratory into clinical studies. In addition, the availability of tissues will allow the discovery and development of biomarkers that allow for personalized medicine.

A. Programs That Improve the Lives of America's Women and Girls

1. Program Description: The Cancer Diagnosis Program (CDP) in the Division of Cancer Treatment and Diagnosis, NCI, NIH administers a research grant portfolio that includes research project in breast, ovarian and cervical cancers. These projects cover the range of research from early cancer biomarker discovery and application of new technologies to asses molecular alterations in these cancers to development of clinical assays to identify patients who will benefit from therapies targeted to specific molecular alterations and the evaluation of those assays in clinical trials. CDP also supports cancer specimen repositories which contain tumor specimens from these cancers. Two of repositories are specifically for cancers from women;

one for breast cancer and one for ovarian cancer. These specimens are provided to researchers with meritorious projects. The remainder of the CDP research grant portfolio addresses cancers that affect both men and women. Developing the clinical tools for better patient management will improve outcomes for women and improve their quality of life.

a) **Relevant Statistics:** Approximately 20% of the CDP research grant portfolio addresses cancers in women.

2. Future Programs: CDP will continue to develop research opportunities for the cancer research community that address basic research and clinical needs in women's cancers.

a) **Target Populations:** There remains significant research needs in high risk breast cancer and in ovarian cancer.

b) **Benchmarks:** The primary benchmarks will be increased research funding in these target populations and improved outcomes for women with these diseases.

B. Overarching Recommendations:

For grant supported programs, the opportunity to make progress in women's cancer is dependent on the availability of adequate resources to fund all of the meritorious research competing for research dollars. This is especially critical for moving our research knowledge to clinical application where large, costly studies are often required to demonstrate clinical utility.

A. Programs That Improve the Lives of America's Women and Girls

1. Program description: The Radiation Research Program administers a basic and translational research grant portfolio that investigates the use of radiation therapy and other modalities to treat cancer. These include technical developments to improve treatment delivery by increasing the dose to the tumor and reducing normal tissue dose and by using biological modifiers to increase the efficacy of radiation therapy and reduce normal tissue injury. Our quality assurance programs support the clinical trials. The benefits derived from technological advances from NCI sponsored trials are usually rapidly incorporated in clinical practice with broad impact on the practice of medicine. Breast cancer:

There are currently 2 preclinical grants that would potentially enhance the efficacy of radiation for breast cancer. One is to study the role of the iodine transporter that is found in the thyroid but also in breast cancer so that radioactive iodine might be utilized as it is for thyroid cancer. Another is to study the role of B1 integrin to enhance radiation therapy for breast cancer. There are two clinical trials, one using a molecular targeted (multi-functional kinase) therapy and another to improve the technological delivery for women with node positive breast cancer using Intensity Modulated Radiation Therapy (IMRT).

A major Phase III trial with the Radiation Therapy Oncology Group and

National Surgical Adjuvant Breast and Bowel Project is in progress comparing whole breast irradiation and partial breast radiation. This is major study to see the validity of the newer partial breast techniques that have entered clinical practice.

2. Future programs

- a) **Target populations.** Breast cancer remains a major disease which is increasing in the developing world as well as in the developed world. We will continue efforts to improve the use of breast conserving therapy by reducing the burden of toxicity from the treatment and by increasing the efficacy of treatment. RRP supports cancer disparity research and we aim to increase this effort for both US and international investigators.
- b) **Benchmarks.** Basic research uses appropriate biological and statistical endpoints. Clinical trials compare the efficacy and toxicity against current standards in Phase II trials and between the arms of a Phase III trial. The partial breast irradiation trial should have results in a few years. Since recurrence can occur many years later, once a study is closed to patient entry there are still many years until a final result is known.
- c) **Other.** It is important to emphasize that breast and cervical cancers are diseases of health disparities populations. RRP has major interest in expanding the reach of our program to underserved in the US and worldwide.

B. Overarching recommendations.

- Continue to improve the technological approaches and subject them to careful clinical evaluation in both prospective trials but also using our advanced technology to help in comparative effectiveness studies (CER).
- Continue to explore biological approaches to enhancing tumor cell killing and reducing normal tissue toxicity. This will benefit from work being done to mitigate radiation injury from terrorist attacks (NIAID and HHS).
- Enhance the US effort for reaching health disparities populations through clinical investigation. Additionally, utilize the technology capabilities developed in the US that can enhance US collaboration with international partners to reach underserved populations as a matter of US policy.

A. Programs That Improve the Lives of America's Women and Girls

1. Program Description: The Cancer Imaging Program of the Division of Cancer Treatment and Diagnosis, NCI funds grants to study imaging techniques for breast, ovarian, endometrial, and cervical cancer. The techniques studied are for elucidation of basic biology of these cancers, to assist in development of therapies for these cancers, for screening patients for early detection, for diagnosis and staging, and for evaluation of response to therapy or monitoring for recurrence.

- a) Relevant Statistics: Cancer imaging program has the following grants

funded between 2005 and 2009:

- 79 grants relating to breast cancer, 11 with children represented (sex unknown)
- 5 grants relating to cervical cancer, 2 with children represented (sex unknown)
- 9 grants relating to ovarian cancer, 1 with children represented (sex unknown)

The grants are those that include a component for the specific cancers, but may not be exclusively focused on those cancers

Additionally, CIP funds a NCI sponsored imaging cooperative trials group that conducts phase 3 and large phase 2 clinical trials, several of which have addressed women's cancers including breast, ovarian, endometrial, and cervical cancers

2. Future Programs: We will continue to fund imaging related research for breast, ovarian, endometrial, and cervical cancers

a) Target Population(s): patients with or at risk of for breast, ovarian, endometrial, and cervical cancers

b) Benchmarks: Grants require progress reports on an annual basis. Successful research will be published for the medical community and will likely proceed to further development.

c) Other: The imaging cooperative group, ACRIN, conducted the national trial comparing conventional and digital mammography, which evaluated 50 thousand women and the results of which have changed screening practice. It also studied MRI evaluation of contralateral breast in patients with confirmed breast cancer, which has also changed practice.

A. Programs That Improve the Lives of America's Women and Girls

1. Program description: The Breast Cancer Risk Assessment Tool (BCRAT) has been the standard computational tool to estimate breast cancer risk in women; however, the tool was developed using data exclusively from white women. To adjust the BCRAT to more accurately predict risk of invasive breast cancer in African-American women, data from African-American women enrolled in the Women's Contraceptive and Reproductive Experiences (CARE) Study were used to calculate relative and attributable risks based on a number of known breast cancer risk factors. Data on actual breast cancer cases from the Women's Health Initiative validated the CARE model's predictions. The CARE model (available at <http://www.cancer.gov/bcrisktool/>) is recommended for counseling African-American women regarding their risk of breast cancer and determining their eligibility for breast cancer prevention trials.

2. Future programs: The tool continues to be updated and validated in other ethnic populations.

a) Target populations: Caucasian women, African-American women

b) Benchmarks: The BCRAT was previously validated for white women, and for African-American women in 2008.

A. Programs That Improve the Lives of America's Women and Girls

1. Program description: To investigate the hypothesis that hormonal exposures early in life, and particularly those *in-utero*, influence the risk of breast and other hormonally-related tumors in adults, NCI researchers reassembled and combined all of the United States-based cohorts of diethylstilbestrol (DES)-exposed daughters, sons, and mothers that had been previously studied in the 1970s and 1980s. A comparable group of young unexposed women was also assembled.

Data were ascertained from mothers' reports of cancers occurring in 8,216 sons and daughters, and pathology-confirmed cancers and benign diagnoses self-reported by 793 daughters. By comparing the cancer incidence of both groups from 1978 through 1994 to that expected based on the age- and time specific incidence rates in the general population, and to the experience of the unexposed groups, researchers found that only clear cell adenocarcinoma of the vagina and cervix was significantly excessive in the exposed women. Although clear-cell adenocarcinoma is an established long-term sequelae of *in-utero* exposure to DES, this was the first time that a direct measurement of the risk in a population of exposed women had been made possible. The incidence of ovarian cancer was also found to be higher than expected, and while preliminary, this finding supports continued monitoring of daughters of women exposed prenatally to DES.

2. Future programs: Research in this cohort is ongoing.

a) Target populations: Women among the general population who were exposed to DES.

A. Programs That Improve the Lives of America's Women and Girls

1. Program description: NCI research on cervical cancer natural history and screening has demonstrated that the detection of HPV DNA, particularly from HPV16 and HPV18 predicts greatly increased risk of cervical pre-cancers and cancers. A single positive test predicts elevated risk that lasts 16 years or more following testing. The magnitude of risk after persistent infection with carcinogenic types of HPV makes this one of the most powerful human carcinogens (e.g., more powerful than smoking for lung cancer). NCI scientists are strenuously exploring why persistent HPV infection is so carcinogenic by analyzing strains and variants that lead to cancer in cohort studies.

After screening, these same studies have shown that single colposcopic examination with biopsy, although previously considered the gold-standard for cervical diagnosis, detects only about two-thirds of pre-cancers. Work is ongoing to understand the natural history of HPV infection, improve diagnostic tools, and evaluate novel screening methods in low-resource areas. The ultimate goal is to extend the most effective screening and diagnostic strategies to regions with different resources, and to assure maximal access to effective screening and diagnosis.

2. Future programs: Research and collaboration in this area is ongoing

a) Target populations: Women and girls in the U.S.

b) Benchmarks: The American Cancer Society and Association of Clinical Obstetricians and Gynecologists issued updated guidelines incorporating NCI's research on the role of HPV testing in cervical cancer screening.

A. Programs That Improve the Lives of America's Women and Girls

1. Program description: Virtually all cervical cancer is caused by cervical infections by certain HPV types. Currently underway in Costa Rica and led by NCI, a multi-year effort is testing the ability of virus-like particle vaccines, originally developed at NCI, to protect against HPV16/18 infection. Since the trial began in 2003, the HPV vaccine has shown near complete protection against new infections and lesions caused by HPV types contained in the vaccine. A similar vaccine that targets HPV types 6, 11, 16, and 18, was approved by the FDA in 2006 and is now being used in the U.S. to prevent cervical cancer.

The NCI vaccine trial is evaluating the impact of vaccinating adolescents and young adult women against a subset of HPV types linked to cervical cancer. Since vaccination does not treat established infections and is not expected to protect against all types of HPV that can cause cancer and precancer, and since duration of protection and long-term vaccine effects are not fully understood, continued cervical cancer screening in vaccinated populations will be examined.

To understand the long-term impact of HPV vaccination and determine the most cost-effective, evidence-based screening strategies for vaccinated populations, studies are needed to prospectively evaluate longer-term vaccination effects and to track Pap cytology and HPV typing results linked to vaccination status. NCI is extending follow-up of women enrolled in the trial, which will provide important information on the long-term impact of HPV vaccination and on the effect of vaccination on cytologic and virologic screenings. Results from this trial will provide much needed data to inform changes in cervical cancer screening protocols and policies. To obtain data directly applicable to the United States, NCI is also participating in collaborations with extramural partners to create prospective, population based, cervical cancer screening registries that can fully monitor screening and prevention programs among vaccinated and unvaccinated individuals. Furthermore, NCI researchers are continuing collaborations with health decision analysts and economists to examine strategies for integrating the HPV vaccine into current screening algorithms.

2. Future programs: Research and collaboration in this area is ongoing.

a) Target populations: Women and girls in the U.S. and worldwide.

A. Programs That Improve the Lives of America's Women and Girls

1. Program description: In 1992, NIH established a policy to continually address and monitor the status of women scientists throughout the agency.

Since that time, Women Scientist Advisors have been elected in two year terms for each Institute and Center throughout the agency. WSAs are typically senior woman scientist of high standing who is familiar with the NIH. Each WSA is elected by the women scientists of her IC and serves a two-year term. WSAs hold regular meetings with her Scientific Director in order to advise him/her about issues relevant to women scientists and attend Lab/Branch Chief meetings to serve as a representative of women scientists. The WSAs also inform the Institute's women scientists on issues which will affect them (i.e., tenure track and staff scientist policy decisions) and solicit their opinions. They organize meetings for the women scientists, to discuss issues of general concern, or to present programs of general interest. Also, WSAs serve on tenure-track, tenured scientist, or lab/branch chief search committees. Attend WSA committee meetings (approx. every 2 months) where issues of concern to all NIH women scientists are discussed. In addition to the responsibilities above, NCI's Division of Cancer Epidemiology and Genetics appoints the WSAs to serve as voting members of the Senior Advisory Group, which discusses and makes decisions regarding administrative and scientific issues affecting the Division.

XII. NIH / National Center on Minority Health and Health Disparities (NCMHD)

B. Programs That Improve the Lives of America's Women and Girls

The National Center on Minority Health and Health Disparities (NCMHD) supports four programs which contribute to improving the lives of America's Women and Girls and to the NCMHD mission to lead, coordinate, and assess the National Institutes of Health (NIH) efforts to reduce and eliminate health disparities. Three of the NCMHD's principal programs: the Centers of Excellence (COE) program, the Loan Repayment Program (LRP), and the Community Based Participatory Research (CBPR) Initiative support basic, clinical, biomedical, and biobehavioral research projects; disseminate information; promote research infrastructure and training; foster emerging programs; and extend NCMHD's reach to minority and other health disparity communities. These three programs are based in the NCMHD Division of Extramural Activities and Scientific Programs (DEASP), one of the two divisions within the NCMHD. These programs in conjunction with the Small Business Innovation Research and Small Business Technology Transfer (SBIR/STTR) program located in the NCMHD Office of the Director/Office of Innovation and Program Coordination (OIPC) are leading NCMHD's research efforts to improve the lives of women and girls. All four programs provide opportunities for women to advance their scientific careers by serving as principal investigators of the grants supported through these programs. A brief description of each program is provided below.

Program Description: Community Based Participatory Research (CBPR)

1. The NCMHD Community Based Participatory Research (CBPR)

Initiative is designed to promote collaborative research between scientific researchers and members of their community through the joint design and implementation of intervention research projects targeting health disparities in underserved populations including racial and ethnic minorities, rural populations, and individuals of low socioeconomic status. The ultimate goal is to foster sustainable efforts at the community level that will accelerate the translation of research advances to health disparity populations and eliminate health disparities. The CBPR Initiative has three phases. It starts with a three year planning grant, followed by a competitive 5 year intervention grant and concludes with a competitive three year dissemination grant. This is a long term commitment by the NCMHD with potential funding for up to eleven years for an individual CBPR project. One example of a project supported under this program targeting women is the Partnerships for Improving Lifestyle Interventions (PILI) at the University of Hawaii. This is a partnership between five community groups, the medical school and the state department of health to focus on reducing and eliminating obesity health disparities. It is anticipated that women will constitute 80% of the participants in this study.⁵¹

a) Relevant Statistics: Current number of active CBPR awards: 40.

2. Centers of Excellence

The NCMHD Centers of Excellence (COE) were established to develop novel programs in the U.S. that would make significant advances and contributions to easing the health burden in underserved populations and in reducing and ultimately eliminating health disparities in several priority diseases and conditions. The COE program helps to increase the pool of investigators from health disparity populations through research training and faculty development. In addition, the collaborations with community organizations help disseminate health information to underserved populations and increase the participation of health disparity populations in clinical trials. Two examples of research on women's health that the program supports are:

- The Uniform Services University Center for Health Disparities Research, a partnership between the Uniform Services University of the Health Sciences and the University of Maryland,

⁵¹ Nacapoy AH, Kaholokula JK, West MR, Dillard AY, Leake A, Kekauoha BP, Palakiko DM, Siu A, Mosier SW, Marjorie KM; PILI 'Ohana Project. Partnerships to address obesity disparities in Hawai'i: the PILI 'Ohana Project. *Hawaii Med J.* 2008 Sep;67(9):237-41. PubMed PMID: 18853898; PubMed Central PMCID: PMC2585997.

Eastern Shore. This Center conducts research on long term behavioral modification aimed at reducing and preventing obesity among African American women. This project is increasing the research capacity of the partnership by laying a foundation for establishing a program on cardiovascular disease (CVD) and the metabolic syndrome, both of which disproportionately affect minority populations. Research includes issues related to lifestyle and health, health care access, health status and health disparities. The Healthy Lifestyles among African American Women through Weight Loss and Exercise project is exploring ways for women within faith-based communities to sustain weight reduction and maintenance efforts using different exercise regimes and different behavioral therapies.⁵²

- The Center of Excellence at the University of Texas, M.D. Anderson Cancer Center. Researchers at this Center evaluated the relationship between the weight status of mothers and their children, 5-18 years old, at baseline in a cohort study of Mexican origin, low-SES families residing in inner city Houston, TX. This is highly relevant given that obesity is a risk factor for several chronic conditions later in life, including cardiovascular disease, type II diabetes, and some cancers. The study found obese mothers were twice as likely to have an overweight and/or at-risk-for-overweight child compared with normal weight mothers. Women born in the U.S. were twice as likely to have an overweight and/or at-risk-for-overweight child compared with women born in Mexico. In addition, women with less than a high school education were twice as likely to have an overweight child compared with their more educated peers.⁵³

a) Relevant Statistics: The NCMHD has funded more than 90 institutions through this program since its inception in fiscal year 2002. Approximately 50 Centers are currently being funded.

3. Loan Repayment Program

The purpose of the NCMHD Loan Repayment Program (LRP) is to recruit and retain highly qualified health professionals to careers in health disparities or clinical research. The program offers an educational loan repayment of up to \$35,000 per year to qualified health professionals with doctorate degrees (e.g., M.D., Ph.D., Dr.PH.) who are employed in non-federal academic/research settings. This program offers two distinct extramural loan repayment opportunities:

- The NCMHD Loan Repayment Program for Health Disparities Research supports health professionals that engage in basic,

⁵² Sbrocco T, Hsiao C, Clark RD, Osborn R, Shivers A., Seibert, C. Family-centered weight loss program with African American women; Obesity Society, 27th Annual Mtg., Washington, DC 2009.

⁵³ Hernández-Valero MA, Wilkinson AV, Forman MR, Etzel CJ, Cao Y, Bárcenas CH, Strom SS, Spitz MR, Bondy ML. [Maternal BMI and country of birth as indicators of childhood obesity in children of Mexican origin](#); Obesity (Silver Spring) 2007 Oct;15(10):2512-9.PMID: 17925478.

clinical, behavioral, social sciences or health services research addressing health disparities; and

- The NCMHD Extramural Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds supports health professionals from financially disadvantaged backgrounds that engage in clinical research.

a) Relevant Statistics: More than 2000 individuals have been funded through the Loan Repayment Program since its inception in 2001.

4. The Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Program is a highly competitive federal program mandated by the Congress as a part of the Small Business Development Act. Each year designated federal departments and agencies award a reserved portion of their research and development funds to small businesses and to partnerships between small businesses and nonprofit research institutions to bring innovative technologies to market. The NCMHD SBIR/STTR Programs give high priority to research activities designed to empower health disparity communities to achieve health equity through health education, disease prevention, and partnering in community based, problem driven research.

a) Relevant Statistics: There are a total of 16 SBIR and STTR grants currently within NCMHD; 2 are STTR grants, and 11 are SBIR.

Future Programs: Under the American Recovery and Reinvestment Act, the NCMHD has established two research funding opportunities to jumpstart initiatives pertinent to women.

a) Target Population(s):

- **Women and Girls at Risk for Violence, especially domestic and intimate partner violence** - The NIH Challenge Grant topic area of Initiating Innovative Interventions to Prevent Family Violence includes domestic and intimate partner violence. Intimate partner violence is recognized as being a leading cause of death and disability among pregnant women.
- **Women not yet completing the dissertation for advanced degrees in the biomedical and related sciences** - the NCMHD Dissertation Research Award to Increase Diversity funding opportunity announcement is designed to increase the health disparities research workforce by supporting dissertation research for predoctoral students that have completed all other requirements for the degree. Based on the letters of intent for the Dissertation Research Award program, it is anticipated that approximately 80% of the applicants will be women.

B. Overarching Recommendations: The NCMHD is pleased with the results of a recent analysis that showed that nearly 50% of the principal investigators on the above four programs are women. This fact indicates that women scientists are critical to NCMHD programs and that they are making significant contributions to the NCMHD's efforts to eliminate health disparities. Nevertheless, while some progress is being made much more remains to be done to increase the number of women and other researchers interested in and dedicated to the challenge of eliminating health disparities. Specifically, focused efforts are needed to eliminate barriers to women scientists and researchers remaining in the sciences beyond the terminal research or professional degree, beyond the post-doctorate or residency stage and elect to pursue basic or clinical research as a career, and serving in leadership and decision making roles as members of scientific review panels or members of National Advisory Councils, for example. Thus far the NCMHD has been able to encourage future researchers through its programs, especially the highly competitive Loan Repayment Programs, yet each year the applicant pool become more competitive and challenge NCMHD's ability to keep pace with previous benchmarks. Fortunately, as the knowledge of and interest in health disparities expands, the number of applicants to all four of the above programs is expected to expand. NCMHD welcomes the challenges resulting from the increased interest in health disparities and is committed to developing creative solutions, for example, establishing new partnerships to meet these challenges. NCMHD actively seeks new partners and is committed to identifying and leveraging the resources of current and new partners for eliminating health disparities. NCMHD recommends that opportunities for establishing new partners within and among federal agencies be encouraged and created.

XIII. NIH / Institutes and Centers / National Center for Research Resources (NCRR)

A. Programs That Improve the Lives of America's Women and Girls

NCRR Overview

Transcending geographic boundaries and research disciplines, NCRR supports research, resources, tools, and training to help researchers funded by NIH transform basic discoveries into improved human health. NCRR's four integrated and complementary areas of focus (clinical research, biomedical technology, comparative medicine, and research infrastructure) accelerate and enhance research along the entire continuum of biomedical science. Through the Clinical and Translational Science Award (CTSA) consortium and other collaborations, NCRR supports all aspects of translational and clinical research, connecting researchers with each other and with patients and communities across the nation.

Although NCRR does not support initiatives dedicated to the area of women's health, it does contribute a significant portion of its budget to women's health and behavior research and continues to support initiatives developed by other components of NIH for

such efforts. In addition, the NCCR supports research on the prevention and treatment of various diseases, disorders, or conditions that are unique to women or may have a significant impact on women.

The following programs are supported by NCCR, a component of the NIH. Leadership for these programs is the responsibility of the corresponding Division Director with ultimate responsibility residing with the Director of NCCR. Many of these programs are collaborating with other agencies, including the Health Resources and Services Administration, the Indian Health Service, and the Food and Drug Administration.

Clinical and Translational Science Award (CTSA) Program

Led by NCCR, the CTSA program is a partnership between the NIH and a national consortium of 39 academic health centers and research institutions to build academic homes for clinical and translational research. By 2011, the NCCR expects to fund 60 CTSA institutions. The CTSA program is designed to translate more efficiently the rapidly evolving knowledge developed in basic biomedical research into treatments to improve human health. The CTSA programs are also training the next generation of clinical and translational researchers to excel in interdisciplinary team science. The CTSA programs are committed to supporting research in women's health.

Relevant Examples:

For example, the CTSA at the University of Colorado, Denver supports a child and maternal health core that is focused on lifespan issues, starting with pregnancy and birth through early childhood and extending into adolescence and adulthood. Similarly, the University of Pittsburgh, and the University of Ohio have established core activities in women's health. The CTSA program at the University of Pittsburgh is undertaking a number of clinical studies and research projects related to women's health, ranging from breast cancer therapeutic trials to genetic variation studies of pregnancy disorders.

Institutional Development Award (IDeA) Program

This program fosters health-related research and increases the competitiveness of investigators at institutions in 23 states and Puerto Rico with historically low NIH funding. The two major initiatives of the program are IDeA Networks of Biomedical Research Excellence (INBRE) and Centers of Biomedical Research Excellence (COBRE). INBREs establish a multi-disciplinary research network that strengthens the lead and partner institutions' biomedical research expertise and infrastructure while providing research support to faculty and students including those from community and tribal colleges. COBREs support thematic multidisciplinary centers that strengthen institutional research capacity by expanding and developing biomedical faculty capability and enhancing research infrastructure.

Relevant Examples:

An example of the research on women's health supported by the COBRE program is the Center of Biomedical Research Excellence for Perinatal Biology at the Women and Infants' Hospital of Rhode Island, which utilizes contemporary biological approaches to address important issues in the development of the mid-late gestation fetus and to develop strategies for new therapeutic interventions for fetal and newborn development. Their efforts are also focused the development of a transgenic mouse model to study

the mechanisms of pre-eclampsia, which affects five to seven percent of pregnancies. The IDeA Program also supports a COBRE program in Women's Health at the University of Kentucky. The center focuses on advancing our understanding of the unique role of gender and female reproductive hormones in the manifestation of health and disease, and builds a cadre of junior investigators in the field of women's reproductive health. A unique strength of the COBRE in Women's Health research is the multidisciplinary approach to investigate the fundamental mechanisms and impact of hormones and gender on heart disease, brain function, HIV/AIDS, reproductive tract physiology, and behavior.

Science Education Partnership Award (SEPA) Program. The goals of the SEPA program are to 1) increase the pipeline of future scientists and clinicians, especially from minority, underserved, and rural kindergarten to grade 12 (K-12) students and 2) to engage and educate the general public on the health-related advances made possible by NIH-funded research. By creating relationships among educators, museum curators, and medical researchers, SEPA encourages the development of hands-on, inquiry based curricula that inform participants about such timely issues as obesity, stem cells, and infectious diseases. The SEPA program continues its emphasis on rural and underserved populations with 18 out of the 23 IDeA states and Puerto Rico receiving SEPA funding.

NCCR Participation in the NIH Working Group on Women in Biomedical Careers NCCR continues to promote women in biomedical research through various training programs and workshops. NCCR organized and led a workshop on “**Women in Biomedical Research: Best Practices for Sustaining Career Success**” in collaboration with the Office of Research on Women's Health, and the NIH Working Group on Women in Biomedical Careers, which was held on March 4, 2008.

Relevant Statistics:

The workshop attracted over 500 registrants from government, academia, industry, and other organizations. The workshop featured speakers from academia, the private sector, professional organizations, the military, and NIH, who discussed their programs aimed at sustaining career success for women in biomedical careers.

NCCR Career Development Activities and Programs

NCCR supports a variety of training and career development programs that help advance the careers of women scientists. For example, Division of Comparative Medicine at NCCR participates in many NIH Career development programs. The K99/R00 Pathway to Independence Award allows promising postdoctoral scientists the opportunity to receive both mentored (K) and independent research support (R) from the same award. The K01 Special Emphasis Research Career Award (SERCA) in Pathology and Comparative Medicine, a Mentored Research Scientist Development Award, assists graduate veterinarians to become independent investigators in research related to comparative medicine. The K26 Mid-career Investigator Award in mouse pathobiology research provides support for established mid-career mouse pathobiologists, affording them protected time to devote to research involving mice and

to act as mentors for beginning investigators. The T32 and T35 Training Grants also provide opportunities for career development, providing long and short term support for training highly qualified veterinarians and veterinary students for research careers in biomedical areas related to comparative medicine, comparative pathology, or research related to applications that improve and extend healthy lives and prevent illness. Women are well represented in all programs both as mentors and trainees.

Relevant Statistics:

One hundred percent of the current Division of Comparative Medicine K99/R00 awards have both male and female Principal Investigators. In the K01 program, 45 percent of the Division of Comparative Medicine awards are made to women. Many of the top veterinary colleges have female principal investigators leading the T32 and T35 mentoring/ training programs. Women represent approximately 70 percent of the trainees in these programs.

XIV. NIH / Office of the Director / National Eye Institute (NEI)

A. Programs That Improve the Lives of America's Women and Girls

1. Program Descriptions:

National Eye Institute Extramural Grant Portfolio.

The NEI has a long history of investigator initiated research on normal visual function as well as disorders of vision. In 2008, the NEI awarded over \$12M in grants directly related to women's health. The corneal diseases portfolio of extramural grants includes a strong commitment to investigating a number of disparate diseases causing dry eye syndrome, a relatively common ocular disorder twice as prevalent in women. This effort includes a patient registry, funded in collaboration with the NIDCR, for Sjogren's Syndrome, an autoimmune disease leading to dry eye syndrome. A recently funded neuro-ophthalmology network was established to increase the patient recruitment and expertise for large scale studies of relatively rare diseases at the boundary of Neurology and Ophthalmology. The first protocol selected will examine intracranial hypertension, a disease that affects overweight women in childbearing age.

Relevant Statistics: Dry Eye is a syndrome that affects over 3 million women middle aged and older in the US. With an aging population, this number is expected to increase.

NEI Intramural Network for Women Scientists.

The NEI has established a program designed to support all female scientific and clinical staff in addressing the unique challenges faced by women scientists. The NEI deputy scientific director meets regularly in small groups with principal investigators, staff scientists, and clinicians to discuss various scientific and career topics. Women at all career stages are included from postdoctoral fellows to tenured staff. The exchanges are informal, often during lunch to enhance collaboration and shared experiences in order to build confidence and develop a social and scientific network.

Relevant Statistics: Women receive about 50% of the PhDs in biology awarded in the US. However, the number of women in academic positions significantly lags behind men.

XV. NIH / Office of the Director / National Human Genome Research Institute (NHGRI)

A. Programs That Improve the Lives of America's Women and Girls

1. Program Descriptions

Parent Communication of BRCA1/2 Test Results to Children.

Georgetown University, DC

One of the primary motivations for parents to participate in BRCA1/2 testing is to find out about their minor children's risk of developing breast and ovarian cancer. However, parents often report feeling distressed and conflicted about sharing this information with their youngsters once it is available. As few parents receive professional guidance in evaluating the potential risks and benefits of disclosure to children, parents may be prone to make ineffective decisions about communication that could lead to adverse psychosocial outcomes.

As clinical genetic testing becomes increasingly more common, this presents an ethical challenge that needs to be better understood so that interventions to promote positive outcomes can be implemented. This project is a prospective, longitudinal study to examine decision-making about disclosing a maternal BRCA1/2 test result to children and the psychosocial outcomes of parents' communication choices among tested mothers and non-tested fathers. The theoretical framework for this investigation is the Conflict Theory of Decision Making and data will be collected using qualitative and quantitative interview procedures.

Recent Publications

Beshkin, B. et al. Brief assessment of parents' attitudes toward testing minor children for hereditary breast/ovarian cancer genes: development and validation of the Pediatric BRCA1/2 Testing Attitudes Scale (P-TAS). *J Pediatr Psychol.* 2009 Jul; 34(6):627-38. Epub 2008 Apr 1.

DeMarco, T., et al. Role of Parenting Relationship Quality in Communicating about Maternal BRCA1/2 Genetic Test Results with Children. *J Genet Couns.* 2008 June; 17(3): 283–287. Published online 2008 February 21.

Tercyak K. et al. Information Needs of Mothers Regarding Communicating BRCA1/2 Cancer Genetic Test Results to their Children. *Genet Test.* 2007; 11(3): 249–255.

This research program is supported by the Ethical, Legal and Social Implications (ELSI) Research Program in the NHGRI Extramural Division.

a) Relevant Statistics:

Getting regular screening tests is very important for women who are at a higher risk of developing breast cancer. In general, a woman can be placed in the higher-risk category if she has either a single factor that greatly increases her risk or a combination of lesser factors that together increase risk.

Factors that can single-handedly increase a woman's risk a great deal include:

- Mutation in BRCA1 or BRCA2 genes.
- Very strong family history of breast cancer, such as mother and/or sister diagnosed at age 40 or younger.
- Personal history of breast cancer, LCIS or atypical hyperplasia.
- Radiation treatment to the chest area during childhood or young adulthood.⁵⁴

2. Future Programs:

a) Target Population(s): The subjects in this study are 250 intact mother-father parenting dyads with children ages 8-17 years, where mothers participate in a BRCA1/2 testing program and fathers are not tested

b) Benchmarks

c) Other: Follow-up interviews will be conducted 1- and 6-months after posttest counseling/receipt of test result to collect outcome data (disclosure of test result to child, decision satisfaction, psychosocial well-being).

1. Program Descriptions

Penn Center for ELSI Research in Emerging Genetic Technologies in Healthcare:
Longterm
behavioral impact of genetic counseling and testing for BRCA1/2 among African Americans.

University of Pennsylvania, PA

This Ethics Legal and Societal Implications (ELSI) of genomics center is an evaluation of the long-term psychological, social, and medical effects of genetic testing and counseling for breast cancer on African American women and their families. Subjects include African American and white women who have participated in genetic counseling for BRCA1/2 mutations from 2002-2006. Women who declined testing, as well as those who were tested and received positive, negative, or ambiguous test results are enrolled in the study. Subjects' understanding of test results, cancer screening and risk reduction behavior as well as psychological functioning are being evaluated through telephone interviews. Data are being collected on subjects' sociodemographic characteristics, medical history and risk perception, cultural beliefs and values, perceived risk and control, and coping efforts.

The project will produce new information about the longer-term consequences of BRCA1/2 counseling and testing among African Americans. The results may also inform the development of interventions to improve genetic counseling and clinical follow-up of African American women.

Recent Publications

Weathers, B., et al. Utilization of religious coping strategies among African American women at increased risk for hereditary breast and ovarian cancer. *Fam Community Health*. 2009 Jul-Sep; 32(3):218-27.

This research program is supported by the Ethical, Legal and Social Implications (ELSI) Research Program in the NHGRI Extramural Division.

a) Relevant Statistics:

In 1975 the incidence of breast cancer was 107 per 100,000 for white women and 94

⁵⁴ National Cancer Institute. "Breast Cancer Screening Modalities". 2009.
<http://www.cancer.gov/cancertopics/pdq/screening/breast/HealthProfessional/page5>.

per 100,000 for black women. Thirty years later in 2005, the number of new cases per year had risen to 126 per 100,000 for white women and 114 per 100,000 for black women.⁵⁵

2. Future Programs:

a) Target Population(s): Providers offering the test (results might inform their decision-making and sequencing of offering the tests); genetic counselors (to enable them to better counsel families about the tests); genetic professional organizations (provide input into guidelines for use).

b) Other programs: Comprehensive High-Throughput Mapping of Cancer Genomes
Baylor College of Medicine, TX

The study of highly rearranged genomes such as those found in breast cancer and other carcinomas will particularly benefit from an increase in resolution beyond currently available technologies. This project is developing a novel technology for identifying gene aberrations that are involved in the progression of breast cancer, the most common cancer among women, and in the progression of other solid tumors. NHGRI-funded researchers are developing comprehensive, rapid, and economical methods for detecting genomic changes in cancer. The methods will allow detection of recurrent chromosomal aberrations in hundreds of small specimens at the thousand base pair level of resolution. This development project employs next-generation technologies and methodologies essential for large-scale genome sequencing and mapping. To enable analyses of resulting data by basic scientists and clinicians who are not experts in genomics, the methods will be supported by a new informatics system developed in the context of genome mapping projects at the Baylor College of Medicine Human Genome Sequencing Center. Knowledge about specific gene aberrations gained through the application of these technologies will enable the development of novel highly targeted cancer therapies.

Recent Publications

Coarfa C., et al. Pash 2.0: scalable sequence anchoring for next-generation sequencing technologies. *Pac Symp Biocomput.* 2008:102-13.

This research program is supported by the NHGRI Division of Extramural, within the Cancer Genome Atlas (TCGA) program. TCGA is a collaboration between NHGRI and the NCI.

a) Relevant Statistics:

Breast cancer is characterized by genomic instability - tumor cells divide like mad and in that process their genomes are rarely transmitted faithfully. Breast cancer is no exception: any ten women with the disease will have ten different tumors-their cancers will be of different sizes, some will be more aggressive than others, and those tumors will each express their own peculiar set of genes (albeit with some overlap). Genome scientists and clinicians have begun to make use of breast cancer's heterogeneity to

⁵⁵ U.S. Cancer Statistics Working Group. *United States Cancer Statistics: 1999—2004 Incidence and Mortality Web-based Report.* Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute, 2007.

make predictions and guide treatment decisions. By examining the expression patterns of collections of genes that tend to be turned off or on together in an array of tumor samples and the clinical outcomes of patients who developed those tumors, researchers are now able to predict who is most likely to experience recurrent breast cancer and who is likely to remain cancer-free.⁵⁶ For more information: <http://www.genome.gov/25521889> or <http://cancergenome.nih.gov/>.

B. Overarching Recommendations

The NHGRI places high priority on enhancing the health of women by supporting the development of resources and technology that will accelerate genome research and its application to human health. A critical part of the NHGRI mission continues to be the study of the ethical, legal and social implications (ELSI) of genome research. NHGRI also supports the training of investigators and the dissemination of genome information to the public and to health professionals.

XVI. NIH / National Heart, Lung, and Blood Institute (NHLBI)

A. Programs that Improve the Lives of America's Women and Girls

1. The Women's Health Initiative: The NIH Women's Health Initiative (WHI) is administered by the National Heart, Lung, and Blood Institute (NHLBI). It is a major 15-year research program that was designed to address the most frequent causes of death, disability, and diminished quality of life in postmenopausal women—cardiovascular disease, cancer, and osteoporosis. It includes more than 160,000 women enrolled in clinical trials and an observational study, all of which have been completed. Follow-up studies and data analyses are now under way. In January 2007 the WHI entered a new phase, funding investigations using blood, DNA, and other biological samples and clinical data from WHI participants. Results of the studies will help explain the clinical trial findings and will investigate the impact of genetic and biological markers on common diseases affecting postmenopausal women. Twelve 2-year contracts were awarded that address the following topics:

- Adipolines (physiologically active proteins from body fat cells) and risk of obesity-related diseases.
- Physical activity, obesity, inflammation, and coronary heart disease in a multiethnic cohort of women.
- Endogenous estradiol and the effects of estrogen therapy on major outcomes of WHI.
- Identification and validation of circulating biomarkers for the early detection of breast cancer in preclinical specimens.
- Proteomics and the health effects of postmenopausal hormone therapy.
- High-dimensional genotype in relation to breast cancer and WHI clinical trial interventions.
- Genome-wide association study to identify genetic components of hip fracture.

⁵⁶ Duke Institute for Genome Sciences & Policy. "Breast Cancer Genomics". 2009. <http://www.genome.duke.edu/research/highlights/breastcancer/>.

- Predictive value of nutrient biomarkers for coronary heart disease death.
- Ancestry association analyses of WHI traits.
- Biochemical antecedents of fracture in minority women.
- Hormone therapy, estrogen metabolism, and risk of breast cancer or hip fracture in the WHI hormone trial.
- Interaction effects of genes in the inflammatory pathway and dietary, supplement, and medication exposures on general cancer risk.

A second round of contract proposals for studies using WHI biological specimens was solicited in October 2007 (BAA-NHLBI-WH-09-01). The NHLBI made 10 awards in FY 2009.

The NHLBI is investing substantial resources in activities to develop genotypic data on the participants in its large cohort studies. Such data can then be integrated with the wealth of already-available data about participant characteristics and health indicators to increase understanding of the genetic influences on disease risk and on disease manifestations and progression. This work includes a large genotyping effort of African American and Hispanic women from the WHI.

In 2008 the NHLBI initiated support for a 4-year renewal of the Women's Health Initiative Memory Study (WHIMS), an ancillary study to assess the relationship between postmenopausal hormone therapy and development of cognitive impairment and dementia.

a. Relevant Statistics: 161, 808 postmenopausal women were recruited into the WHI. The total funding to date (FY 1992-2008) is \$760,047,045.

2. The Heart Truth®: The Heart Truth is a national awareness campaign for women about heart disease sponsored by the National Heart, Lung, and Blood Institute (NHLBI), part of the National Institutes of Health. It has come to be recognized as a landmark heart health awareness movement that has been embraced by millions who share the common goal of better heart health for all women.

The Heart Truth campaign warns women about heart disease and provides tools to help them take action against its risk factors. It is primarily targeted to women ages 40 to 60, the time when a woman's risk of heart disease begins to increase. However, the campaign emphasizes that it is never too early—or too late—to take action to prevent and control risk factors since heart disease develops over time and can start at a young age—even in the teen years.

Millions of Americans recognize the issue of women's heart disease annually on National Wear Red Day®, which is celebrated on the first Friday in February.

a. Relevant Statistics: Since The Heart Truth began 7 years ago, millions of women have learned that heart disease is their #1 cause of death—a new survey conducted in March 2009 shows that 69 percent of women are aware that heart disease is the leading cause of death

among women, up from 34 percent in 2000.⁵⁷ Yet many American women—about one-third of them—still underestimate their own personal risk of getting heart disease. Heart disease deaths among American women continue to decrease – they decreased by more than 15 percent from 1999 to 2006.⁵⁸

More than 28 corporate partners are helping spread the campaign messages by featuring The Heart Truth and The Red Dress® symbol on grocery store displays, newspaper coupon inserts, corporate Web sites, and billions of product packages. Since 2003, The Heart Truth and The Red Dress Symbol have been promoted on nearly 9.5 billion product packages including those for Cheerios, Diet Coke, 8th Continent Soy Milk, Minute Maid orange juice, Celestial Seasons teas, Campbell’s soup, Snyder’s of Hanover, and Sara Lee products. The Heart Truth Road Show, launched in 2004, has traveled across the country to hold 25 heart health events that screened 16,456 individuals for heart disease risk factors and distributed more than 25,000 packets of heart health information.

Since the campaign’s inception in 2002, The Heart Truth has achieved nearly 3 billion media impressions (without multipliers or pass-along rates). The NHLBI has distributed more than 2.2 million Heart Truth educational materials and Red Dress pins.

Funded by the HHS Office on Women’s Health, The Heart Truth Champions program, initiated in 2006 to recruit health advocates and educators in local communities to increase awareness about women and heart disease, has trained more than 150 activists who are reaching out to women by organizing heart health activities in their communities.

Since the start of The Heart Truth Women of Color Initiative in early 2005, campaign messages have reached thousands of African American and Hispanic women throughout the United States. During 2007 and 2008, three leading organizations representing women of color—The Links, Inc., the National Coalition of Pastors’ Spouses, and the National Latina Health Network—were funded by the NHLBI to implement community events, including workshops and health screenings, which increased awareness of heart disease among African American women and Latinas across the country. In 2009, the Foundation for the National Institutes of Health awarded Heart Truth Community Action Grants to the National Latina Health

⁵⁷ National Center for Health Statistics, Deaths: Final Data for 2006 Heron M, et. al. Deaths: Final Data for 2006. Division of Vital Statistics. National Center for Health Statistics. *National Vital Statistics Reports: 2006:vol 57, no. 4, Table 7.*

⁵⁸ NHANES data, 1999-2006.

Network, The Links, Inc., and Cardiology Associates, Jonesboro, Arkansas, who will reach thousands of women of color and low income with heart health education programs and materials and risk factor screenings.

The First Ladies Red Dress Collection, which has been displayed at the Kennedy Center in Washington, DC, Reagan Presidential Library in California, and National First Library in Ohio, has drawn thousands of visitors and notable media coverage.

3. Guidelines for the Diagnosis, Evaluation, and Management of Von

Willebrand Disease: In February 2008, the NHLBI issued the first clinical guidelines ever published in the United States for the diagnosis and management of von Willebrand Disease (vWD), the most common inherited bleeding disorder. Although it affects equal numbers of men and women, it is more likely to cause serious symptoms in women during the childbearing years. The guidelines address the management of heavy menstrual bleeding in women who have vWD and the challenges that pregnancy and childbirth present for them. Recommendations for future research on these topics are also included.

4. Targeted Approach to Weight Control for Young Adults: This program was initiated by the NHLBI to support clinical studies to develop, refine, and test innovative behavioral and/or environmental approaches for weight control in young adults at high risk for weight gain. Interventions can address weight loss, maintenance of a healthy weight, or prevention of excessive weight gain during pregnancy.

a. Relevant Statistics: The NHLBI expects to fund 3-4 cooperative agreements for a total of \$18.85 million total costs over 5 years, starting in FY2009.

B. Overarching Recommendations

The NHLBI places high priority on enhancing the health of women by reducing the burdens of cardiovascular, lung, and blood diseases. As articulated in its Strategic Plan (<http://apps.nhlbi.nih.gov/strategicplan/Default.aspx>), the Institute's broad goals are to improve understanding of the molecular and physiological basis of health and disease and use that knowledge to develop better approaches to disease diagnosis, treatment, and prevention; to improve understanding of the clinical mechanisms of disease and thereby enable better prevention, diagnosis, and treatment; and to generate a clearer understanding of the processes involved in translating research into practice and use that understanding to enable improvements in public health and to stimulate further scientific discovery.

For many years the NHLBI has been diligent in ensuring that women are well represented in its clinical research projects and that its overall research portfolio addresses gaps in knowledge of how to diagnose, prevent, and treat disease in women. This effort has included not only careful monitoring of recruitment for clinical trials and other studies, but also support for certain studies conducted entirely in cohorts of women.

XVII. NIH / Office of the Director / National Institute on Aging (NIA)

A. Programs That Improve the Lives of America's Women and Girls

1. Program Descriptions: The *Study of Women's Health Across the Nation (SWAN)* is of high relevance to understanding healthy aging in midlife women and beyond. It is an ongoing cohort study evaluating longitudinal changes in biological, behavioral, and psychosocial parameters in women as they transition from pre- to post-menopause. The goal of SWAN is to characterize the biological processes, health effects, psychosocial influences, and sequelae of the pre- to peri- to post-menopausal transition in Caucasian, African American, Chinese, Japanese, and Hispanic women. Funded initially in 1994, SWAN is a cooperative agreement consisting of seven clinical field sites, a central reproductive hormone laboratory, a coordinating center, an advisory panel, and a repository of blood, urine, and DNA specimens. The study is supported by the National Institute on Aging, the National Institute of Nursing Research, and the NIH Office of Research on Women's Health.

a) Relevant Statistics: A total of 3,302 eligible women were enrolled into the longitudinal study population of SWAN and completed the baseline study. This group included 1,550 Caucasian, 935 African American, 286 Hispanic, 250 Chinese, and 281 Japanese women. Some 2,245 of these women completed the most recent data collection covering years 2006-2008.⁵⁹

The *MsFLASH (Menopause Strategies: Finding Lasting Answers for Symptoms and Health)* initiative is a multisite research network to conduct randomized clinical trials of promising treatments for the most common symptoms of the menopausal transition. Possible treatments to be studied during the five-year project period include antidepressants such as paroxetine (Paxil®) or escitalopram (Lexapro®), paced respiration (slow deep breathing; also known as relaxation breathing), yoga, low-dose estradiol patch and low-dose estradiol gel, and exercise. Women going through the menopause transition may experience a variety of symptoms, ranging from vasomotor symptoms (hot flashes and night sweats) to sleep disturbance, mood disorders, loss of sexual desire, and vaginal dryness. Until very recently, menopausal hormone therapy using estrogen has been the therapy of choice for relieving menopausal

⁵⁹ SWAN History. University of Pittsburgh; 2009 [cited 2009 Nov 6]. Available from: <http://www.edc.gsph.pitt.edu/swan/public/history.html>.

symptoms. But after 2002 and the release of findings from the Women's Health Initiative and other studies showing an increased risk of serious health problems, such as blood clots, stroke, heart disease, breast cancer and cognitive impairment, women and their health practitioners have been in search of alternative strategies to improve menopausal quality of life. Findings from this study will help practitioners identify interventions that will enable women to safely and effectively manage their menopausal symptoms.

a) Relevant Statistics:

As many as two-thirds of all women report vasomotor symptoms, and over 85% report at least one menopausal symptom as they transition through menopause. For the 25% of symptomatic women with who are severely burdened, the resulting discomfort greatly diminishes their quality of life.⁶⁰

ELITE: Early vs. Late Intervention Trial with Estradiol. Recent studies have demonstrated that with estrogen therapy, vasoreactivity improves in recently menopausal women with healthy endothelium but not in women remote from menopause with atherosclerotic plaques. If the hypothesis that estrogen therapy will reduce the progression of atherosclerosis when initiated soon after menopause when the vascular endothelium is relatively healthy versus later when the endothelium has lost its responsiveness to estrogen is correct, the results of ELITE will have significant implications for public health recommendations for the prevention of atherosclerosis and coronary heart disease in postmenopausal women. This study is testing the "timing hypothesis" that could explain the discordant results between observational studies and randomized controlled trials such as the Women's Health Study.

Experience Corps. NIA/NIH is funding a major community intervention designed to improve social, cognitive, and physical functioning among poor, inner-city elderly through the Experience Corps evaluation. Experience Corps recruits older people for cognitively challenging, meaningful roles as volunteers in inner-city elementary schools. The program is active in 19 cities nationwide, and the majority of volunteers are women. Target population is Americans ages 55 and over, and elementary school-aged children (male and female).

a) Relevant Statistics:

Over 2,000 Experience Corps volunteers work with some 20,000 students nationwide.⁶¹

The ***Women's Health Initiative Study of Cognitive Aging (WHISCA)*** investigates both on-trial and long-term post-trial effects of exposure to menopausal hormone therapy on cognitive aging within the context of the Women's Health Initiative Memory Study (WHIMS) and the Women's Health Initiative (WHI) more generally. While WHIMS

⁶⁰ Woods NF, Mitchell ES. Symptoms during the perimenopause: prevalence, severity, trajectory, and significance in women's lives. *American Journal of Medicine* 2005; 118:14S-24S.

⁶¹ Available from: http://www.experiencecorps.org/about_us/about_us.cfm.

focuses on the effects of menopausal hormone therapy on the risk and progression of Alzheimer's disease and other dementias, WHISCA assesses the effects of hormone treatment on memory, cognition, and mood in non-demented WHIMS volunteers age 65 and older who had been randomized to hormone therapy or placebo within the WHI trial. In addition to allowing assessment of hormonal effects on cognitive aging, this database also allows more general investigation of risk and protective factors for cognitive decline in older women. Since almost half of the women have also participated in the WHIMS-MRI study, this database also allows investigation of variation in brain volumes and brain lesion burden in relation to cognitive change.

A new study involving the WHISCA cohort has just begun to probe the complexity between genetic background and cognitive decline as an intermediate phenotype of dementia. The study will also examine how cognitive decline is modified by hormone therapy. The study will measure variations in candidate genes with known involvement in certain aspects of cognition, and will probe the relationship between these candidate genes and incidence of MCI and dementia.

Secondary analysis will examine the relationship between candidate gene variants and cognitive decline as a function of hormone therapy, and volumetric brain changes as an intermediate phenotype in the gene-to-behavior pathway.

a) Relevant Statistics: More than 12,000 longitudinal assessments have been performed for 2302 WHISCA participants.⁶²

NIH maintains a comprehensive program of health information aimed at older Americans. The *NIA/NIH Information Center* maintains a Web site and toll free telephone lines to provide information in English and Spanish aimed at maintaining and improving health. *Age Page* fact sheets offer comprehensive, easy-to-read information on nearly 50 topics. The research update *Spotlight on Aging Research (SOAR)* provides current information on health and NIA/NIH activities to the public, policymakers, and researchers.

The *NIH Senior Health Web Site* enables the growing number of “wired seniors” to find credible aging-related health information in an online format that is compatible with their cognitive and visual needs, as determined by NIH-supported research; it includes 42 health topics developed by 12 NIH Institutes and one topic contributed by the Centers for Medicaid and Medicare. NIH has also developed a senior-friendly

⁶² Resnick SM, Espeland MA, An Y, et al. Effects of conjugated equine estrogens on cognition and affect in postmenopausal women with prior hysterectomy. *J Clin Endocrin Metab.* 2009 Oct 22 [cited 2009 Nov 6]; 94(11): 4152-4161. Available from: <http://jcem.endojournals.org/cgi/content/abstract/94/11/4152>.

curriculum for people who train older adults to use computers. NIH also develops and disseminates publications aimed at older Americans, including a number dealing with topics of particular interest to women, including menopause, osteoporosis, and caregiving.

The *Alzheimer's Disease Education and Referral (ADEAR) Center* is the Federal government's primary source of information for patients, caregivers, health providers, policymakers, and the general public on Alzheimer's disease and age-related cognitive change. The Center maintains a national database of clinical trials and develops easy-to-read materials in English and Spanish.

In 2009, NIA/NIH collaborated with HBO Documentary Films, in association with the Alzheimer's Association, Fidelity Charitable Gift Fund, and Geoffrey Beene Gives Back Alzheimer's Initiative, on *The Alzheimer's Project*, which featured 4 documentary films, 33 supplemental films, a Web site, and a community-based information and outreach effort, with a companion book.

The KEEPS (Kronos Early Estrogen Prevention Study) Cognitive and Affective Study is the first multisite, randomized, placebo controlled, double-blind, parallel-group design clinical study to address major issues related to use of menopausal hormone therapy raised by the Women's Health Initiative and the Women's Health Initiative Memory Study. Specifically, this study evaluates the differential efficacy of conjugated equine estrogen (CEE – e.g., Premarin) and transdermal 17 p-estradiol (tE2) on comprehensive measures of cognition and mood in perimenopausal women over an extended therapy of four years. Study participants will also be treated with progesterone to counteract overproliferation of endometrial tissue, which can be a side effect of menopausal hormone therapy. The goals of the study are: 1) to characterize the potential differential efficacy and adverse effect profile of extended therapy with CEE and tE2 on cognitive function of perimenopausal women, 2) to identify the effects of micronized progesterone on the proposed battery of cognitive and affective tests in perimenopausal women, 3) to establish the relationship between estrogen-induced changes in markers of atherosclerosis, heart disease, and measures of mood and cognition, 4) to characterize the relationship between estrogen-related changes in proposed markers of inflammation, blood hypercoagulability, and tests of cognition and mood, and 5) to determine if ApoE genotype will influence cognitive responsiveness to menopausal hormone therapy. Most patients with Alzheimer's disease are cared for in the home setting, and a majority of caregivers are women.

Resources for Enhancing Alzheimer's Caregiver Health to Community Settings (REACH) was a multi-site randomized clinical trial for family caregivers

of patients with Alzheimer's disease or related disorders funded by NIA/NIH and the National Institute of Nursing Research. The intervention is designed to provide education, support, and skill building to help caregivers manage patient behaviors and their own stress. It includes 12 individual sessions in the home and by telephone and five telephone support groups over a six-month period. The Department of Veterans Affairs (VA) will provide nearly \$4.7 million for eight "caregiver assistance pilot programs" across the country to expand and improve health care education and provide needed training and resources for caregivers who assist disabled and aging veterans in their homes. One of these programs will be a translation of the REACH intervention. The VA Medical Center (VAMC) at Memphis/University of Tennessee, one of the participating sites for REACH, will serve as the Coordinating Center for this program, providing evaluation and training to the clinical sites, with the assistance of the REACH investigators. Across the country, 17 Home Based Primary Care (HBPC) programs for treating frail dementia patients and their caregivers in the home are providing the intervention to 200 caregivers. The VA Palo Alto Health Care System, which was also one of the REACH sites, will also participate, providing services to 150 caregivers.

Work, Family, and Health Network: Family-Responsive Workplace Policies and Practices in Small Businesses. This interdisciplinary research is identifying workplace practices and policies that impact the health of low-wage employees and their families from diverse racial/ethnic backgrounds. It is comparing employee health between three nursing homes with family friendly work policies and three nursing homes similar in size, location, and for-profit or not-for-profit status. The study is identifying family-related work policies; informal practices; and mitigating conditions, such as social support, care-giving responsibilities, and economic resources. The study is also speaking with managers to learn about the constraints of small businesses implementing worksite family policies. This study is looking at employee absenteeism, presenteeism, health behaviors linked to tobacco and alcohol, and psychological well-being. A small sub-study is objectively measuring physiological markers of stress based on salivary cortisol, ambulatory blood pressure, and sleep quantity and quality. This study is part of the larger NIH-supported Work, Family, and Health Network program.⁶³

a) Relevant Statistics: To date, recruitment is 80 percent complete on this program.

Cost-Effectiveness of Mammography Screening in Older Women.
As people age into their 80's and 90's they become more

⁶³ Internal (NIA) data.

heterogeneous in terms of their health and recommendations for health promotion must be individualized. More data on the benefits and risks of many health promotion measures for women aged 80 and older are necessary to help clinicians target use of these measures to those women most likely to benefit. In an ongoing study, an NIH investigator is exploring the benefits and burdens of mammography screening for women aged 80 or older. In a recent paper in the *Journal of Clinical Oncology*, the investigator reported that the majority of women 80 years and older are screened with mammography, yet relatively few benefit. Meanwhile, 12.5% experience a burden from screening. The data from this study can be used to inform elderly women's decision making and potentially lead to more rational use of screening. In 2006, women accounted for 68 percent of the population age 85 or older.⁶⁴

The *Study of Osteoporotic Fractures (SOF)* was established in 1986 to determine the long-term impact of physical activity on osteoporotic fractures and other more general health measures, including mortality. SOF is a prospective cohort study of a group of initially healthy women, 65 years or older, to determine what factors lead to the development of osteoporosis. This study identifies risk factors for hip and wrist fractures and changes in bone density. SOF began in 1986 with the recruitment and examination of more than 9,700 women 65 years or older. SOF is continuing to study this group of women. It examined how changes in bone density affect the risk of fractures, as well as what factors predict changes in bone density. In addition, the study is currently examining surviving SOF participants in their residences to assess several dimensions of cognitive function and determine why some women achieve exceptional cognitive function and mobility after age 85. SOF is funded by the National Institute of Musculoskeletal and Skin Diseases and the National Institute on Aging.

a) Relevant Statistics: In the United States today, 10 million individuals already have osteoporosis and 34 million more have low bone mass, placing them at increased risk for this disease.⁶⁵ (Source: NIA/NIHMS)

The *Alzheimer's Disease Centers (ADCs) program* provides an environment and core resources to enhance ongoing research by bringing together biomedical, behavioral, and clinical science investigators to study the etiology, progression, prevention, diagnosis,

⁶⁴ Federal Interagency Forum on Aging Related Statistics. Older Americans 2008: Key indicators of well-being. Washington, DC: U.S. Government Printing Office; 2008 March [cited 2009 Nov 6]. Available from: http://www.agingstats.gov/agingstatsdotnet/Main_Site/Data/2008_Documents/Population.aspx..

⁶⁵ Fact Sheet: Osteoporosis overview. Bethesda (MD): National Institute of Arthritis and Musculoskeletal and Skin Diseases; [cited 2009 Nov 6]. Available at http://www.niams.nih.gov/Health_Info/Bone/Osteoporosis/default.asp.

and treatment of Alzheimer's Disease (AD) and to improve health care delivery. ADCs also foster the development of new research approaches and provide suitable environments for research fellows and junior faculty to acquire the necessary skills and experience for interdisciplinary AD research.

There are currently 29 Alzheimer's Disease Centers, which conduct a wide array of activities focused on outreach, education and recruitment of diverse populations to research partnerships in local communities across the country.

a) Relevant Statistics: As many as 5 million Americans may have AD.⁶⁶

Future Programs: In 2009, the SWAN investigators applied for renewal of their research grants to ensure continuation of the program. New areas for SWAN include physical performance and osteoarthritis, history of major depression, and carotid wall thickness. SWAN will continue to monitor symptoms, cognition, cardiovascular risk factors, endocrinology, bone density, and fractures.

a) Target Population(s): The average age of participants at the beginning of SWAN IV will be 59 years (54 to 65), and they will be followed through the ages of 59 to 70.

b) Benchmarks: Undetermined at this point

Other: SWAN IV will advance our understanding of how modifiable risk factors related to the menopause transition are linked to sub-clinical disease measures and hard outcomes. This new understanding is necessary to develop improved strategies for the primary prevention of disease in aging women.

XVIII. NIH / Office of the Director / National Institute of Alcohol Abuse and Alcoholism (NIAAA)

A. Programs That Improve the Lives of America's Women and Girls:

Alcohol Use and Fetal Alcohol Spectrum Disorders

1. Prenatal Alcohol Exposure among High-risk Populations: Relationship to Sudden Infant Death Syndrome and Stillbirth. A cooperative agreement was established jointly between the NIAAA and the NICHD to conduct community linked studies on the underlying causes of sudden infant death syndrome (SIDS) and adverse pregnancy outcomes, such as stillbirth and fetal alcohol syndrome (FAS), and the role of prenatal alcohol exposure. The Prenatal Alcohol in SIDS and Stillbirth (PASS) Network consists of two comprehensive clinical sites in the Northern Plains and Western Cape of South Africa, a developmental biology and pathology center, a physiology assessment center, and a data coordinating and analysis center. The long-term goals of this initiative are to decrease fetal and infant mortality and improve child health in the affected communities.

a. Relevant Statistic: Since FY 2007, the PASS Network has enrolled nearly 2000 pregnant women (towards an enrollment goal of 12,000) in a comprehensive longitudinal cohort study in which their infants will be

⁶⁶ Plassman BL, Langa KM, Fisher GG, Heeringa SG, et al. Prevalence of dementia in the United States: The Aging, Demographics, and Memory Study. *Neuroepidemiology* 2007; 29:125–132.

followed for up to one year. In parallel, the network also is recruiting known cases of SIDS and stillbirth for a retrospective study. Additionally, embedded studies have been designed to explore the role of (under-) nutrition in exacerbating the effects of maternal alcohol exposure on fetal and offspring development.

b. Target Population: This study focuses on two populations with a high incidence of FASD including Native Americans of the Northern Plains region and Cape Coloureds of South Africa.

2. Collaborative Initiative on Fetal Alcohol Spectrum Disorders. Ongoing research within this consortium comprising multiple international sites with high incidence of FAS and fetal alcohol spectrum disorders (FASD) includes a cooperative agreement with the Moscow Region Ministry of Health to screen more than 26,000 pregnant women. A sample of heavy drinkers and controls will be selected for longitudinal follow-up of the offspring. An embedded study examines the effects of maternal micronutrient supplementation on the growth, neurobehavioral development, and alcohol-related physical features of the alcohol-exposed offspring. The long-term goals of this research consortium are to refine the diagnostic criteria for FAS/FASD, explore the underlying mechanisms of the disorder, and develop therapeutic interventions to provide relief to those affected with the most debilitating features of the disease.

Benchmarks: Some consortium members are developing animal models of FAS and FASD with aims of clarifying mechanisms, improving diagnostic methods, identifying genetic and molecular markers of these disorders, and testing potential interventions.

3. Maternal Risk Factors for Fetal Alcohol Syndrome: A Population-Based Study in South Africa. A comprehensive prevention study in five matched urban and rural communities in the Western Cape Province of South Africa that screened and diagnosed grade-school children for FASD and partial FASD found that mothers had a higher prevalence of current drinking and history of drinking during pregnancy when compared to control mothers. A significantly greater proportion of mothers of FASD children reported drinking before becoming pregnant than control mothers (92 percent and 25 percent, respectively), and more FASD mothers continued to drink throughout the first, second, and third trimesters of the index pregnancy.⁶⁷ Although differences in current drinking patterns were not significantly different, the mean number of drinks consumed per week during pregnancy was significantly higher among mothers of FASD children when compared with control mothers. Higher reported levels of drinks per day were associated with poorer IQ and verbal scores among the FASD children, and heavier drinking (e.g., three drinks or more per drinking occasion) during pregnancy was associated with behavioral problems among the women's

⁶⁷ May PA, Gossage JP, Marais AS, Hendricks LS, Snell CL, Tabachnick BG, Stellavato C, Buckley DG, Brooke LE, Viljoen DL. Maternal risk factors for fetal alcohol syndrome and partial fetal alcohol syndrome in South Africa: a third study. *Alcohol Clin Exp Res.* 2008 May; 32(5):738-53.

children. Characteristics of the mothers of FASD children included rural residence, farm worker status, lower height, weight, and head circumference, and body mass than control mothers. The predominant beverage of choice among these mothers was beer. This research program is administered by the NIAAA Division of Epidemiology and Prevention Research.

4. Prenatal drinking and knowledge of Fetal Alcohol Syndrome: a randomized trial in Russia. The overarching aim of the study is to reduce risk for alcohol exposed pregnancy (AEP) and Alcohol Related Neurodevelopmental Disorder /Fetal Alcohol Spectrum Disorder (ARND/FASD) by testing a prevention model specifically targeted to large numbers of women in OB/GYN clinics in Russia. The study will conduct a randomized trial to determine whether physicians, trained to conduct brief motivational intervention, can foster: 1) changes in childbearing-aged Russian women's health beliefs regarding risk for AEP; and 2) greater reduction of women's AEP risk behaviors (e.g., through abstinence from alcohol use and consistent contraception use) compared to standard OB-GYN care. Preliminary studies have suggested that while many Russian women reduce alcohol consumption after pregnancy recognition, prior to the diagnosis of pregnancy, few women recognize the risks of combining alcohol use with the potential to become pregnant. Therefore, substantial numbers of women of child bearing age may be at high risk for fetal alcohol exposure during the early weeks of pregnancy. Increasingly hazardous drinking in women indicates that prevention of alcohol-exposed pregnancies is an important public health issue in Russia. Effectiveness of this intervention across alcohol consumption levels will be explored and knowledge gained from the study can contribute to the FASD prevention research throughout the world. This research program is administered by the NIAAA Division of Epidemiology and Prevention Research.

Relevant Statistic: *The project has been approved to receive a supplemental award to recruit an additional 200 women who meet criteria as heavy drinkers and to conduct assessments of HIV/AIDS risk and treatment among this highrisk, understudied population. This would increase the number of subjects from 500 to 700.*

Target Population: Since American-based definitions of minority/ethnic group status are not comparable to Russian population subgroups, the research team will recruit minority participants specific to the Russian culture (i.e., Ukrainian, Tatar, Belarusian, etc). Thus, the sampling plan will include recruitment of participants from different socioeconomic classes and geographical regions of Russia (i.e., rural--Nizhniy Novgorod, Central; and urban--St. Petersburg, Northwest). These locations will provide diversity across the sample of women in Russia with regard to ethnic, cultural, and sociodemographic backgrounds.

Treatment of Women with Alcohol Use Disorders

1. Screening and Brief Intervention of Problem Drinking Women. Early identification and intervention among problem-drinking women may avert the more severe, adverse consequences of alcohol abuse and dependence.

Among nonpregnant women of childbearing age, the use of alcohol and, in particular, the riskier practices of frequent and binge drinking, have not changed since 1995. An ongoing randomized trial is evaluating the effectiveness of screening and brief intervention (BI) in reducing risk drinking (exceeding NIAAA sensible drinking limits of 7 drinks per week or 1-2 drinks per episode)⁶⁸ by nonpregnant women with four specific medical problems exacerbated by excessive alcohol consumption: diabetes; hypertension; infertility; and osteoporosis. The investigators predict that significantly more women who receive the medically oriented brief intervention than who receive medical treatment as usual will achieve NIAAA sensible drinking limits in the 12 months following study enrollment. It is also anticipated that clinical outcomes related to the targeted medical conditions will be better among women who achieve NIAAA sensible drinking limits. Preliminary findings indicate that women who had the highest number of drinks per drinking day and who had a positive screening test for problem drinking had the lowest scores on measures of physical and mental well-being. There were also statistically significant differences in baseline drinking behavior by disease and race, with alcohol screen positive women with diabetes consuming significantly more drinks per drinking day than those with infertility and osteoporosis. Preliminary results also indicate that African American women with a positive screening test for problem drinking consumed significantly more drinks per drinking day than Asian and Caucasian women with a positive alcohol screening test. There were no differences by race among women with a negative screening test for problem drinking. Findings from this study will inform future recommendations regarding alcohol screening and interventions in general medical settings. This research program is administered by the NIAAA Division of Treatment and Recovery Research.

a. Target Population: Alcohol-related health disparities in women have been recognized as an additional important factor in alcohol abuse and dependence. The findings from an ongoing randomized trial indicate that African American women with a positive screening test for problem drinking consumed significantly more drinks per drinking day than Asian and Caucasian women with a positive alcohol screening test. Biological basis of these differences is still poorly understood and need to be addressed further.

2. Behavioral Treatment for Alcohol Dependent Women with Co-Occurring Depression. Co-occurring alcohol dependence and major depression is a serious and common public health problem, yet one that, for the most part, has not been addressed. Among alcohol dependent individuals, co-occurring depression is associated with worse treatment outcomes, increased risk for relapse, worse long-term social and functional adjustment, and higher probability

⁶⁸ Chang G. Screening and Brief Intervention in Prenatal Care Settings. Available from: <http://pubs.niaaa.nih.gov/publications/arh28-2/80-84.htm>.

of dire outcomes such as suicide. In one ongoing study investigators are testing the feasibility and acceptability of Interpersonal Psychotherapy (IPT) as an adjunct to standard therapy for mentally ill chemical abusers (MICA) among alcohol dependent women with major depression and comparing its effects with those of treatment-as-usual individual therapy. IPT seeks to enhance interpersonal skills in four areas (interpersonal conflict; loss/grief; role transitions; interpersonal sensitivity) as a way to decrease symptoms and improve functioning. Compared to treatment-as-usual, investigators expect IPT to lead to greater reductions in women's drinking frequency, drinking intensity, and depressive symptoms, and to improved interpersonal functioning. Findings from this study may lead to the development of a novel therapy for women with co-occurring alcohol dependence and major depression that will expand and enhance the range of treatment options for women in this understudied but very vulnerable group. This research program is administered by the NIAAA Division of Treatment and Recovery Research.

Reducing Alcohol and Risks among Young Females

1. Interventions to Reduce Drinking-Related Harm in College Women. Heads UP! Women was a cooperative agreement project in NIAAA's Rapid Response to College Drinking Initiative that tested the efficacy of a multi-component motivational interviewing-based intervention for freshman women, females sanctioned by the university's Judicial Affairs, and general members of the college campus community. Findings from this cooperative agreement are notable as the intervention significantly reduced alcohol consumption, number of binge drinking episodes, and drinking-related consequences among all participant groups. In addition, the intervention effect was greatest among women with stronger social and enhancement motivations for drinking. This work has implications for designing effective interventions that target college women. Further, booster or maintenance sessions may promote more enduring effects. This research program is administered by the NIAAA Division of Epidemiology and Prevention Research.⁶⁹

2. Reducing Alcohol and Risks Among Young Females. An ongoing intervention study is examining and attempting to address the combined effect of early alcohol use and risky behavior within a population of urban African American and Latina adolescent females who are at high risk for HIV/AIDS and other infections. Past research by the investigative team has documented that nearly 10% of females in their target population are at risk in 7th grade and more than half by spring of 10th grade.⁷⁰ This study, involving parents and their 8th grade daughters, is examining the effectiveness of an audio-CD intervention in promoting attitudes and behaviors associated with reduced alcohol consumption and sexual risk taking among adolescent girls. Investigators are also seeking to determine whether changes in the girls' attitudes and behaviors are mediated by

⁶⁹ See <http://www.niaaa.nih.gov/AboutNIAAA/NIAAASponsoredPrograms/CollegeDrinkingMLDA.htm>.

⁷⁰ O'Donnell BL, O'Donnell CR, Stueve A. Early sexual initiation and subsequent sex-related risks among urban minority youth: the reach for health study. *Fam Plann Perspect*. 2001 Nov-Dec; 33(6):268-75.

changes in certain parenting mechanisms, including parental monitoring, household rule setting, and communication. Preliminary results from the study indicate that girls who received the intervention reported fewer sexual risks and less drinking at follow-up than those in the control group. In addition, their parents reported greater self-efficacy to address alcohol and sex and more communication on these topics. Findings from this study have advanced understanding of the link between early alcohol initiation and risky sexual behavior, and may have important implications for the design and implementation of school-based programs to reduce alcohol, drug, and HIV-related risks among adolescent girls. This research program is administered by the NIAAA Division of Treatment and Recovery Research. The program will target a population of urban African American and Latina adolescent females who are at high risk for HIV/AIDS and other infections.

HIV: Substance Abuse, Sexual Risk, and Gender Inequality

1. Brief HIV and Alcohol Combined Interventions for Women. A recent randomized clinical trial focused on reducing HIV risk behaviors among women seeking help for alcohol problems. This study is evaluating the relative effectiveness of Combined Behavioral Intervention (CBI), a state-of-the-art, empirically based treatment for addressing alcohol problems in dependent drinkers, followed by an HIV risk reduction intervention (HIV-RR) and CBI followed by an intervention limited to dissemination of HIV information (HIV-I). Investigators had predicted that women who responded favorably to alcohol treatment and who received the HIV-RR, an enhanced intervention including both HIV-related information and elements to increase motivation and behavioral skills necessary to reduce HIV risk behavior, would fare better than their counterparts in HIV-I. However, preliminary results indicate that by the last follow-up points, all participants, regardless of condition, improved across time on many sexual risk and substance use measures. The research team has hypothesized that, among other factors, these results may have been influenced by the severity of alcohol use disorders (high rate of alcohol dependence) among women in the study, the fact that women were seeking treatment for their alcohol and other drug use while not seeking to change sexual behavior, and the effect of reduced drinking on sexual risk. Thus, while it appears that there was a null result for the HIV risk reduction intervention, these results may add to a growing body of evidence that alcohol and other substance are the most important drivers of the high risk sexual behavior that is fueling the HIV epidemic, and that providing treatment for alcohol and substance use disorders is the key to reducing HIV risk related to both substance use and sexual behavior. This research program is administered by the NIAAA Division of Treatment and Recovery Research.

2. Alcohol and Psychiatric Comorbidity in HIV+ Women. Alcohol, depression, and anxiety independently affect HIV disease progression. Importantly, alcohol use frequently co-occurs with depression and anxiety, particularly among women. Despite the relative frequency of co-occurrence, the impact of co-occurring

alcohol use and depression/anxiety has not been evaluated among HIV+ women. An ongoing study is examining the effect of both co-occurring alcohol and depression and co-occurring alcohol and anxiety on HIV disease progression (i.e., HIV-RNA, adherence, quality of life, mortality) in HIV+ women and evaluating the effectiveness of brief alcohol interventions in HIV+ women with co-occurring disorders. In addition, the investigative team will conduct detailed psychological assessments of participants to examine the role of subthreshold psychiatric symptoms in alcohol use and HIV disease progression. This will mark the first time that subthreshold psychiatric symptoms have been explored within the contexts alcohol use or HIV disease. Study findings will advance understanding of the relationship between mental health, drinking, and HIV disease progression among women, and inform the development of innovative, women-focused interventions to reduce the impact of drinking among women with co-occurring HIV infection, alcohol use, and mental health disorders. This research program is administered by the NIAAA Division of Treatment and Recovery Research.

Gender Differences

1. Sex Differences in Alcohol Withdrawal (co-funded by ORWH). Clinical experience has shown that women alcoholics experience fewer alcohol withdrawal symptoms than men. NIAAA is supporting a research study, cofunded by ORWH through the REAP program, to establish mechanisms responsible for gender differences in the typical brain hyperexcitability that occurs during alcohol withdrawal. These neurochemical and behavioral studies are being conducted in an animal model of chronic alcohol exposure, with the objective of examining the role of specific synaptic proteins involved in the sex differences. The primary hypothesis is that sex differences in recovery from ethanol withdrawal involve sex-selective changes in inhibitory (GABAergic) and excitatory (glutamatergic) neurotransmission that occur as a result of the differing hormonal milieu between males and females. The project has identified significant sex differences in withdrawal recovery, in the effectiveness of GABAergic neuroactive steroids to moderate withdrawal seizure risk, and in chronic ethanol-induced alterations of GABA receptor subunit levels. This research program is administered by the NIAAA Division of Neuroscience and Behavior. Findings generated from this proposal have important clinical implications, by predicting neurobiological differences in the sequelae of withdrawal between men and women. This information will also enable tailoring of treatments of alcoholics according to gender and hormonal status.

2. Sex-Selective Effects of Ethanol. A growing body of evidence suggests that men and women exhibit significant differences in alcohol dependence and withdrawal. In fact, research has shown that females may recover more quickly from withdrawal-induced seizures than males. However, the neurobiological basis for this phenomenon remains unclear. Recent findings from an NIAAA funded research program demonstrate that differences between males and females in hormonal status as well as in brain structure contribute to the sex

differences in response to ethanol withdrawal. This research program is administered by the NIAAA Division of Neuroscience and Behavior.

Benchmarks: Several ongoing studies are examining sex differences in behavioral responses to ethanol withdrawal and hormonal treatments. They are also identifying sex differences in response to alcohol at the molecular level, including neuroadaptations of neurotransmitter systems, signaling molecules, and receptor expression. In addition to providing the neurobiological basis for sex selective effects of ethanol, the outcome of these studies suggests that treatment of alcohol withdrawal could be optimized by considering hormonal status.

3. Sex-specific differences in alcoholic gut and liver injury. Women are at a greater risk for alcohol-induced liver injury than men but underlying mechanisms are poorly understood. Many publications indicate that chronic alcohol consumption dramatically changes the hormonal milieu of both the blood and liver in both sexes. The liver is a key player in this scenario, because in addition to being the site of steroid hormone metabolism, the liver is responsive to sex hormones. One proposed link between female sex hormones and alcoholic liver injury is through gut-derived endotoxin, a component of the outer wall of Gram negative bacteria that causes hepatic tissue injury. Estrogen enhances liver sensitivity to endotoxin and may therefore worsen liver injury, especially in alcoholics that show elevated level of endotoxin. To understand the interactions among alcohol, gut-derived endotoxin, sex hormones and liver injury, this project investigates sex-specific differences in alcoholic gut and liver injury. Successful completion would add important information on how hormones and alcohol interact. This research program is administered by the NIAAA Division of Metabolism and Health Effects.

Benchmarks: The research findings of this project will provide new therapeutic possibilities that would be helpful in the regeneration or inhibition of tissue damage in alcoholic patients.

Overarching Recommendations:

NIAAA will co-sponsor, with NICHD, NCI, and NCCAM, an initiative for a multi-center international research network designed to conduct randomized clinical trials of interventions to reduce the major risks to maternal, neonatal, infant and early childhood health in resource-poor countries. NIAAA seeks to include alcohol screening and interventions in the health care of women in prenatal care and the screening of children from birth through early childhood for the disabilities that result from prenatal exposure to alcohol.

NIAAA will continue to support the meetings and work of the Interagency Coordinating Committee on Fetal Alcohol Spectrum Disorders (ICCFAS), which is developing a strategic plan with actions that involve the participation of alcohol researchers and research administrators. NIAAA and other

ICCFAS agencies will co-sponsor Research to Practice Meetings on diverse FASD issues. NIAAA will continue to work with the Substance Abuse and Mental Health Services Administration (SAMHSA) on the development of guidelines and training materials for criminal justice personnel.

NIAAA will partner with the Health Resources and Services Administration (HRSA) and the National Organization on Fetal Alcohol Syndrome (NOFAS) in an effort to include alcohol screening in maternal care programs and beyond and to identify research-based interventions that can be implemented in a cost effective manner in health care facilities.

XIX. NIH / Office of the Director / National Institute of Allergy and Infectious Diseases (NIAID)

A. Programs That Improve the Lives of America's Women and Girls:

1. Women Interagency HIV Study (WIHS): The WIHS is the largest observational study of HIV-infected women and includes participants living in six U.S. metropolitan areas. The size of the study, the number of recently diagnosed patients, and the availability of stored biospecimens allow the evaluation of clinical outcomes in the era of highly active antiretroviral therapy (HAART). Researchers are investigating factors such as the development of AIDS, drug resistance, co-infections, therapy use and treatment effects, metabolic abnormalities and toxicities, hormonal factors, aging, neurocognitive functioning, and physical impairment. This study has yielded major discoveries that have led to a better understanding of how HIV is spread, how HIV disease progresses and how it can best be treated. The study focuses on:

- The long term natural and treatment history of HIV infection in women; in particular, research that evaluates the impact of antiretroviral (ARV) therapy on the clinical course of HIV disease
- The effect of hormonal, endocrine, and local factors on HIV viral load and sexual transmission
- Studies of older populations of HIV-infected women to investigate what pathogenic processes are related to HIV, ARV therapy, and/or the aging process
- Characterization of acute clinical events and co-infections and their impact on HIV disease progression

• Studies of the female genital tract including the microenvironment, HIV virology, and immunology of the female genital tract as compared to blood

In addition to NIAID, WIHS is co-funded by the National Institute of Deafness and Communication Disorders (NIDCD), the National Cancer Institute (NCI), the National Institute of Child Health and Human Development (NICHD), and the National Institute on Drug Abuse (NIDA). The following NIH institutes are supporting training awards or research grants to investigators using WIHS participants, data, and/or specimens: the National Institute of Mental Health (NIMH), the National Institute of Dental and Craniofacial Research (NIDCR), the National Institute on Aging (NIA), and the National Heart, Lung and Blood Institute (NHLBI).

More information is available at: <http://statepiaps.jhsph.edu/wihs/>.

a) Relevant Statistics: The majority of the more than 3,500 women enrolled in the study are African American and Latina women living in urban areas.

Future WIHS studies will address:

- i. HIV Pathogenesis to determine the interactions between immunologic activation, inflammation, and long term health outcomes among women with HIV;
- ii. Antiretroviral therapy exposure, with longitudinal measures of therapeutic drug exposure to predict virologic and immunologic outcomes and adverse effects of subjects on HAART;
- iii. Metabolic and Cardiovascular Disorders to examine the role of chronic inflammation and immune function in the development of fat and metabolic changes and cardiovascular disease in subjects with HIV on or off HAART. (Secondary aims are to assess the association of HIV infection and ARV use with endothelial dysfunction and to study the prevalence and predictors of cardiac structural and functional abnormalities);
- iv. Neurocognition to study the relationship of inflammation, viral and host genetics, hepatitis C virus co-infection, menopause, and sex on the following: the incidence and prevalence of cognitive impairment and peripheral neuropathy and markers of structural changes in the brain as measured by Magnetic Resonance Imaging (MRI);
- v. Human Papillomavirus (HPV) and Cancer to study and compare the effects of immune status on the long term natural history of HPV by type and phylogenetic group. Other aims are to determine risk factors for cervical dysplasia among HIV-positive women and to study HPV vaccination in such women in collaboration with therapeutic clinical trial groups. Another aim is to collaborate with other cohorts to determine if there is increased incidence of specific types of cancer related to HIV exposure.

2. Microbicide Trials Network (MTN): The goal of the MTN is to reduce the sexual transmission of HIV through the development and evaluation of microbicide products. It is a global network that conducts scientifically rigorous and ethically sound clinical trials that will support licensure of topical microbicide products. An ideal topical microbicide would be one that prevents HIV infection and/or viral replication; is safe and non-inflammatory (causes no irritation to the vaginal/cervical/urethral/rectal epithelium); and reduces transmission and acquisition. An effective microbicide could provide women with an HIV prevention method they initiate. This would be particularly helpful in situations where it is difficult or impossible for women to refuse sex or negotiate condom use with their male partners. In February 2009 NIAID funded investigators reported that an investigational vaginal gel known as PRO2000 demonstrated encouraging signs

of success in a clinical trial. PRO 2000 was shown to be safe and approximately 30 percent effective. Though this was not statistically significant, it was the first human clinical study to suggest that a microbicide may prevent male-to-female sexual transmission of HIV infection. The clinical trial enrolled more than 3,000 women and was conducted at six sites in Africa and one in the United States.

Additional microbicide studies currently underway include:

- a phase II expanded safety and acceptability study of the vaginal microbicide 1% Tenofovir Gel (HPTN 059);
- a phase I study of the safety and acceptability of VivaGel™ applied vaginally in sexually active young women (MTN-004)
- a phase II adherence and pharmacokinetics study of oral and vaginal preparations of Tenofovir (MTN-001) –
- a phase IIB safety and effectiveness study of Tenofovir 1% Gel, Tenofovir Disoproxil Fumarate (DF) tablet and Tenofovir DF-Emtricitabine tablet for the prevention of HIV infection in women (MTN-003) - This is the first study to evaluate the effectiveness and acceptability of oral and vaginal forms of PrEP in the same study.

In FY 2008, more than 3,000 women were enrolled in ongoing MTN studies. For more information, visit: <http://www.mtnstopshiv.org/>.

3. HIV Prevention Trials Network (HPTN): The HPTN is a worldwide collaborative clinical trials network that develops and tests the safety and efficacy of primarily non-vaccine interventions designed to prevent the transmission of HIV. The HPTN research agenda is focused primarily on the use of antiretroviral therapy; treatment and prevention of sexually transmitted infections; treatment of substance abuse, particularly injection drug use; and behavioral risk reduction interventions. With regard to women, the HPTN is initiating a seroincidence study in women known as ISIS (or HPTN 064). ISIS is a multi-site, observational study that will estimate the overall HIV-1 incidence in women at high risk for HIV acquisition in the United States. Investigators will evaluate laboratory assays for HIV-1; estimate study recruitment and retention rates; describe sexual behaviors, alcohol and drug use, prevalence of domestic violence, and mental health indicators of women at risk for HIV; assess women's preferred recruitment and retention strategies for future studies; describe social, structural and contextual factors to inform future intervention studies; and explore facilitators and barriers to HIV testing among men residing in high-risk areas. In 2009, this HPTN study will begin enrollment of 2,000 women from ten geographically distinct high-risk areas of the United States. Investigators will follow all participants for six to twelve months. More information on this and other HPTN research is available at: http://www.hptn.org/research_studies.asp.

a) **Relevant Statistics:** In FY 2008, 44% (582) of those enrolled in HPTN studies were women.

4. HIV Vaccine Trials Network (HVTN): The HVTN is an international collaboration of scientists searching for an effective and safe HIV vaccine. The

HVTN's mission is to facilitate the process of testing preventive vaccines against HIV/AIDS, conducting all phases of clinical trials, from evaluating experimental vaccines for safety and the ability to stimulate immune responses, to testing vaccine efficacy. The NIAID-funded HVTN is planning two studies on the feasibility of recruiting and retaining women at high risk for HIV infection for participation in vaccine trials. HVTN 906 will enroll women who reside in areas of high HIV prevalence or who engage in high-risk behavior in New York, New York; Philadelphia, Pennsylvania; and Chicago, Illinois. Investigators will also enroll women who are partners of men from subgroups with a high prevalence of HIV. HVTN 907 will enroll women living in the Caribbean (Haiti, Dominican Republic, and Puerto Rico) and will focus on female commercial sex workers with demographic, behavioral, or other social factors associated with high prevalence of HIV. Investigators will also assess HIV prevalence in both studies. More information on HVTN research is available at: <http://www.hvtn.org/index.html>. In FY 2008 47% (756) of those enrolled in HVTN trials were women.

5. AIDS Clinical Trials Group (ACTG): The ACTG is a multi-center clinical trials network comprised of U.S. and international clinical trials units that conduct translational and therapeutic research. Its highest research priorities are translational research and drug development and optimization of clinical management, including co-infection and co-morbidities. In collaboration with other HIV/AIDS clinical trials networks, the ACTG also pursues therapeutic vaccine research and development, the treatment of pregnant women, and the prevention of HIV infection. The Women's Health Inter-Network Scientific Committee (WIHSC) of the ACTG and the International Maternal Pediatric Adolescent AIDS Clinical Trials Group (IMPAACT) is working on new data forms for gynecologic information. Also pregnancy outcomes forms, sexually transmitted disease forms are being updated and a new reproductive choices form is also being developed. In addition, the ACTG and IMPAACT have several studies in varying stages of development to address:

- pharmacokinetics of contraceptives, with newer antiretroviral drugs is in development.
- the pharmacokinetics of Efavirenz in the last trimester of pregnancy.
- gender differences in HAART responses evaluated in large naïve treatment trials;
- HPV co-infection, including 2 studies of HPV vaccine. An HPV vaccine trial in HIV infected girls >7 and <12 is open and enrolling (P1047) and a study of the safety and efficacy of an HPV vaccine in HIV infected women is enrolling (ACTG 5240).

a) Relevant Statistics: In 2008, 2% of those enrolled in ACTG trials were girls 18 years of age or younger and 30% were women over 18 years of age.

6. Transmission and Pathogenesis of HIV in Women: The goal of this program is to expand knowledge of the pathogenesis of HIV infection in women and to investigate gender-specific biologic factors that impact HIV-1 transmission, disease acquisition, and disease manifestations in women. Awards will be made

to applicants pursuing research that addresses gender differences in one or more of the following areas: 1) immunology, 2) pharmacology, 3) response to therapy, 4) complications of therapy, 5) immunology, virology, genetics, behavior of transmission, and 6) health care utilization. It is anticipated that three awards will be made in FY 2009.

7. Centers for AIDS Research (CFAR). The CFAR program is a unique infrastructure program to support a multidisciplinary peer-reviewed AIDS research environment that coordinates studies, promotes communication, provides shared services/expertise, and funds short-term feasibility studies that cannot be funded easily by other funding mechanisms. The CFAR has supported research in women as follows:

- “Pilot Study of HIV in Women Attending a Women's Health Clinic in Mumbai, India.” The purpose of this study is to gather pilot data on HIV seroprevalence, risk behavior, and knowledge, attitudes and beliefs about HIV infection among women at a women's health center in Mumbai, India.
- “HIV Prevention in Xhosa Women” - An HIV intervention tool was adapted to enhance its relevance for Xhosa speaking women in South Africa. Training is an ongoing part of this study as Emory University staff will spend the next year living in South Africa, continually providing technical assistance to local Black Xhosa speaking South African women to facilitate efficient delivery of this trial.
- "HIV prevention for women: Barriers, facilitators, and the media's role" - This pilot study will use an anonymous survey of African-American women ages 18-35. This study aims to identify the sociocultural context fueling the epidemic in this population in Boston, MA and the role the mass media will have in a prevention intervention to reduce the health disparity.
- "Genotypic resistance after pregnancy-limited combination antiretroviral therapy" - This study will determine rates of genotypic resistance and resistance patterns occurring among antiretroviral (ARV) naive women after pregnancy-limited use of combination ARV. Genotypic resistance and resistance patterns during repeat pregnancy in these women will also be investigated.
- “Exploring the Immunologic and Virologic Differences between Pre and Post Menopausal HIV-infected Women” - This study is examining immunologic and virologic parameters in pre and post-menopausal HIV-infected women. (University of North Carolina CFAR)

Other research supported through the CFARS includes an assessment of the situation of more than 200,000 women who are living in refugee camps in Western Tanzania. The study is obtaining important information about the sexual behaviors and reproductive health issues of women in these camps; the establishment of an HIV and menopause clinic that will help answer issues of osteoporosis/osteopenia, cardiovascular complications in the setting of HIV and menopause; and research on the role of family, domestic violence, poverty, menopause, gender roles, and other social conditions that surround women with HIV, as well as a particular focus on the pharmacology of antiretroviral therapy in

the genital tract of HIV-infected women.

8. Supplements to Promote Reentry into Biomedical and Behavioral Research

Careers- These supplements are awarded to Principal Investigators on funded NIAID grants so they may support scientists who wish to re-enter biomedical or behavioral research careers, and who have had to postpone their careers because of family or parental issues. This program is administered by the Office of Special Populations and Research Training (OSPRT), Division of Extramural Activities (DEA), NIAID. The Reentry program is an NIH-wide program.

a) Relevant Statistics: NIAID supports two to six reentry supplements per year. The program supports scientists of all ages.

9. Primary Caregiver Technical Assistance Supplements (PCTAS). These supplements provide technical support for one year to young postdocs who are primary caregivers of young children so they may maintain a high level of productivity in the laboratory. This unique program is also administered by OSPRT, DEA, NIAID

a) Relevant Statistics: NIAID supports 2-4 PCTAS per year. These are predominantly younger mothers who may be postdoctoral trainees.

10. Sexually Transmitted Infections. The goal of the Sexually Transmitted Infections Branch (STIB) in the Division of Microbiology and Infectious Diseases (DMID) at the National Institute of Allergy and Infectious Diseases (NIAID) is to support research on control and prevention strategies for STIs, a group of diseases and associated syndromes which disproportionately affect women and girls. STIB-supported research aims to understand the pathogenesis of these infections and the mechanisms by which the infections affect the reproductive health of women and girls. Studies also focus on the evaluation of diagnostics, treatment, and prevention strategies for STIs and associated syndromes. STIB supports approximately 88 research projects that focus on improving the health of women and girls, including

- One research project that addresses the needs of women is the Herpevac Trial. This trial is a clinical study designed to assess the efficacy of a promising investigational vaccine in the prevention of genital herpes disease in young women. Genital herpes is among one of the most common infectious diseases in the United States, but 90% of affected people are unaware of the infection. The herpes simplex virus remains dormant in the body for life and even people who do not have visible symptoms can spread herpes. NIAID has joined forces with GlaxoSmithKline Biologicals to study the investigational vaccine that may prevent this disease in women.

a) Relevant Statistics: There are about 8,000 women from the United States and Canada enrolled in the Herpevac study.

- The program also supports several research efforts focusing on the development vaginal microbicides. These topical antimicrobial products are designed to provide women with a safe and effective way to prevent acquisition of sexually transmitted pathogens.

- Research activities are also focused on the development of novel point-of-care (POC) diagnostic tests for STIs. These tests are designed to function in the local

setting, often in areas with limited public healthcare and harsh environmental conditions, in order to properly diagnose STIs and allow appropriate use of the limited supply of medicines. Ultimately, POC diagnostics will be an important part of improving the health of women and girls in resource-poor settings.

XX. NIH / Office of the Director / National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

A. Programs That Improve the Lives of America's Women and Girls Genetics of Autoimmune Diseases

1. Program Description: supports basic, translational, and clinical research, research training, and information programs on many of the more debilitating diseases affecting Americans. NIAMS funds studies on a number of diseases which affect women disproportionately, including: systemic lupus erythematosus (lupus), rheumatoid arthritis, scleroderma, osteoarthritis, osteoporosis, and fibromyalgia.

There have been significant advances in identifying disease risk genes for lupus in recent years. Genome-wide association, linkage analysis, and direct sequencing have revealed genetic variations in lupus patients, for molecules involved in immune mechanisms and regulation, and inflammation. These results are being replicated in distinct racial and ethnic populations. Long-term NIAMS support of disease registries and repositories of biological samples have been essential to successful projects. The numerous genes uncovered in these studies reflect the complex expression of lupus, which varies from patient to patient. Methods to analyze patients' blood samples are being developed to group disease-specific variations in gene expression according to pathogenic mechanisms. This system may be used to predict flares of lupus activity in the future, and guide individualized treatment. Lupus risk genes have also been discovered on the X- chromosome, and reproduced in animal models of the disease. These important findings shed light on the female predominance of lupus. Genome-wide association studies using patient samples from the ongoing North American Rheumatoid Arthritis Consortium (NARAC) have also provided information on genetic variations that may increase the risk for both lupus and rheumatoid arthritis. Further investigations of Swedish patients with rheumatoid arthritis and diabetes demonstrated that those with particular subsets of each disease (rheumatoid arthritis accompanied by particular blood markers and type 1 diabetes) have an increased risk for having both diseases. The possibility of shared pathogenic pathways in these autoimmune diseases offers important insights into prevention and treatment.

This research program is supported by the NIAMS Division of Skin and Rheumatic Diseases and the NIAMS Intramural Research Program.

Co-sponsors: NCI, NCCR, NHLBI, NIAID, NIDCR, and NINDS

a) Relevant Statistics

Female lupus patients outnumber males, nine to one. African American women are three times as likely to get lupus as Caucasian women, and it is also more common in Hispanic, Asian, and American Indian women.

Centers of Research Translation

1. Program Description: The NIAMS continues to support several Centers of Research Translation (CORTs), which are addressing diseases affecting women, such as lupus, osteoarthritis, and scleroderma. These CORTs are designed to bring together basic and clinical research in order to translate basic discoveries into new drugs, treatments, and diagnostics.

- The Center for Lupus Research investigates the role of different cell types in the origin and development of lupus, markers of disease activity and severity, and new targets for treatment.
- The Center for Genetic Dissection of SLE (Systemic Lupus Erythematosus) studies mouse models of lupus to identify the genetic background of developmental stages of the disease.
- The Center for New Approaches to Assess and Forestall Osteoarthritis in Injured Joints is developing new methods of forestalling post-traumatic osteoarthritis.
- The Center for Research Translation in Scleroderma is studying the molecular basis of scleroderma to understand its underlying causes, using functional genomics and gene networks.

This research program is supported by the NIAMS Division of Skin and Rheumatic Diseases and the NIAMS Division of Musculoskeletal Diseases.

The Osteoarthritis Initiative

The Osteoarthritis Initiative (OAI), a prospective, natural history cohort established to improve diagnosis and monitoring of osteoarthritis and foster development of new treatments, has collected biological specimens (blood, urine, and DNA); images (X rays and magnetic resonance scans); and clinical data such as dietary intake, medication use and pain, function, and general health assessments. This anonymous information is available to researchers worldwide, to expedite the pace of scientific studies and identification of biological and structural markers (biomarkers) for osteoarthritis. There are over 1,000 online users registered to obtain these clinical data. More than 2,500 datasets have been downloaded, and 135 imaging sets have been distributed. The OAI is a public-private partnership. Private sector funding from Merck Research Laboratories, Novartis Pharmaceuticals Corporation, GlaxoSmithKline, and Pfizer, Inc., is managed by the Foundation for the National Institutes of Health.

This research program is supported by the NIAMS Division of Musculoskeletal Diseases.

OAI co-sponsors: NIA, ORWH, NIDCR, NIBIB, NCMHD, and NCCAM.

a) Relevant Statistics

The OAI has collected data from nearly 5,000 participants, age 45 to 79, 58.5% female. Women constitute 50-59% of all groups, including minorities, so the cohort is well-powered for any analysis of gender differences in the onset and progression of osteoarthritis.

The Study of Osteoporotic Fractures

1. Program Description: The NIAMS also supports the Study of Osteoporotic Fractures (SOF) in women, which has been underway since 1986, and is providing insights into osteoporosis diagnosis, treatment, and prevention. It has identified specific characteristics associated with fracture risk in older Americans. Assessing risk is important because the devastating consequences of low bone mass can be prevented. For example, simple changes to a person's home (e.g., adding more lights, removing clutter) can prevent falls. A balanced diet and modest exercise build bone strength, and medications can slow disease progression. SOF and other studies have reinforced a notion, outlined in the Surgeon General's 2004 report on *Bone Health and Osteoporosis*, that older people who have a fracture should be tested for osteoporosis—even if the fracture occurred because of a traumatic injury (e.g., a fall off a ladder or an auto accident).

This research program is supported by the NIAMS Division of Musculoskeletal Diseases. SOF co-sponsor: NIA.

a) Relevant Statistics

The SOF followed 8,022 women for nine years.

Fibromyalgia Research

1. Program Description: Psychological processes are thought to contribute to the physical functioning, poor coping ability, and overt expressions of pain (“pain behaviors”) of fibromyalgia syndrome (FMS) patients. Psychological treatments, such as cognitive-behavioral therapy (CBT) and operant-behavioral therapy (OBT), have shown effectiveness in treating FMS patients. A clinical study of FMS patients receiving CBT, OBT, or “attention placebo” (AP) treatment (in which the control group participated in general, therapist-guided discussions about medical and psychosocial problems, with no intervention) indicated that more patients treated with CBT or OBT reported significant reduction of pain, as well as decreases in physical impairment, in comparison with the AP group. Many patients in the AP group had increased pain and physical impairment, suggesting that the discussions, without intervention, may have reinforced negative behaviors. Pretreatment patient characteristics, such as whether their reaction to pain is more or less overt, may serve as important predictors of response to psychological therapies, and allow matching of specific treatments to the appropriate person. With further outcomes research, it may be possible to tailor psychological and drug related treatments to the individual with FMS, which should lead to better, and more predictable, outcomes for FMS patients.

a) Relevant Statistics

Fibromyalgia affects 3 to 6 million Americans—as many as one in 50. Between 80 and 90 percent of those diagnosed are women; most people are diagnosed during middle age, although the symptoms often become

present earlier in life.

B. Overarching Recommendations

There are many diseases within the NIAMS mission areas that disproportionately affect women and are of great concern and interest to the Institute, such as lupus, rheumatoid arthritis, osteoarthritis, osteoporosis, and fibromyalgia. The diseases that are included in this report are those where the health disparity is clearly identified and research is under way or planned to address the disparity.

XXI. NIH / Office of the Director / National Institute of Biomedical Imaging and Bioengineering (NIBIB)

1. Dedicated Breast CT Scanner as an Alternative to Mammography

Early detection of breast cancer offers the best opportunity to find and treat small lesions before cancer spreads. However, the pinch that occurs when breasts are squeezed between two plates during a mammogram is enough to make some women avoid this potentially life-saving screening procedure.

A new approach to breast imaging – a dedicated breast scanner based on computed tomography (CT) – may someday offer women pain-free screening as well as more precise diagnosis and treatment options. Using x-rays taken from many different angles, breast CT provides a three-dimensional image of the breast using the same amount of radiation as that used for a mammogram. The scanner system, developed by researchers at the University of California, Davis (UC Davis), images the breast using cone beam geometry, a technique that radiates only the breast, protecting surrounding tissue in the lungs, heart, and back.

In order to be scanned, a woman lies face down on the special CT scanner table and places one breast through an opening in the table. The CT scanner and detector rotate 360 degrees around the pendant breast, gathering 500 images. Data are sent to a computer that compiles the cross-sectional slices into a single three-dimensional image. “We can look at the breast from any angle using the same data set,” says UC Davis Medical Physicist John Boone, principal investigator of the project.

As a potential screening tool, the breast CT scanner surpasses conventional mammography in several ways: it provides three-dimensional images of the breast compared with just two-dimensional images for mammography, eliminates compression of the breast between two plates, and eliminates image artifacts (suspicious areas that result from normal breast structures overlaying each other when the breast compresses). Women with dense breasts may particularly benefit from this more detailed imaging, since dense breast tissue can obstruct lesions.

In a recent clinical study, Boone, collaborator Dr. Karen Lindfors, Chief of Breast Imaging at UC Davis, and their team showed that CT scans are comparable to x-ray mammography in identifying cancerous lesions. Additionally, women in the study found the CT technique significantly more comfortable. “We can see masses better than with mammography because there is no overlapping tissue. This improved clarity could reduce the number of women called back for further evaluation,” says Lindfors.

The study also found that mammography was better at distinguishing microcalcifications, tiny clusters of calcium that indicate breast cell activity and can

sometimes be a sign of cancer. Imaging these clusters presents a challenge, but is a key to transforming the system into a viable clinical screening tool. “The third generation scanner will do better at identifying microcalcifications,” Boone says. “We’re hopeful the system can be used for screening, but the real niche may come in the area of diagnostics and therapy.”

Boone envisions a breast imaging suite where women could be screened and, if needed, receive care the same day. Currently, clinics may have 8 to 10 mammography systems and a stereotactic biopsy machine. Women with suspicious lesions are often sent for further evaluation at a magnetic resonance imaging (MRI) facility where they compete for appointment times with patients waiting to have their knees, heads, and other body parts imaged. Getting an appointment can take up to 2 weeks, and the imaging is performed by an MR technologist rather than a breast imaging technologist. “A dedicated breast CT scanner in the breast center would allow imaging to be performed by a technologist familiar with the breast, and the breast could be biopsied immediately if needed,” says Boone. Lindfors adds that with contrast injection (a dye that enhances images) CT results would be equivalent or superior to breast MRI for staging tumors and screening for high-risk patients.

A dedicated scanning system could be a workhorse in a breast imaging suite, Boone says, since it could provide breast imaging as well as robotic biopsy guidance and therapies such as tumor ablation (destruction). To perform a biopsy, a radiologist could use the CT images to guide a needle holder into place near a tumor. A hollow biopsy needle would then be inserted into the holder and a core sample of the tumor removed. For tumor ablation, the CT images would provide a more precise method to visualize tumor location and guide a needle into place to deliver radio waves that destroy the tumor. He also notes that CT scans would be less expensive and more easily available than breast MRI. CT’s open design would also permit the use of metal needles and would reduce claustrophobia (fear of enclosed spaces), an impediment to imaging sometimes associated with MRI scanners.

This work is supported by the NIBIB Division of Applied Science and Technology.

Extending their work, the researchers, in collaboration with UC Davis PET physicist Ramsey Badawi, have developed a hybrid CT/positron emission tomography (PET) scanner that could determine the extent or progression of tumors (staging), monitor response to chemotherapy, and provide interventional procedures such as biopsy and tumor ablation. As with the breast CT scanner, images from the hybrid system would guide a radiologist’s needle to the tumor site for core sample removal or delivery of radio waves to destroy a tumor. Boone and Lindfors imaged their first patient in December and are continuing to gather preliminary data on the system. “We’re really in our infancy with all of this,” says Lindfors. “We still need to have trials with multiple observers and equipment at multiple sites.” Only a handful of groups are working on similar systems, including researchers at M.D. Anderson, the University of Rochester, the University of Massachusetts, Worcester, and Duke University. Boone expects that within 3 to 5 years, the device could be available as a diagnostic tool. “This has the potential to replace the way we do breast imaging for cancer,” he says.

2. Biosensor Identification of Urinary Tract Infections

Urinary tract infections, or UTIs, are a serious health problem affecting millions of people each year. They result in more than 8 million office visits and over a million hospitalizations each year. The total cost for treatment reaches into the billions of dollars. A large share of that expense comes from waiting 48 hours for a urine sample to be cultured in the lab. That's why a new electrochemical sensor that detects and identifies bacterial DNA in 45 minutes is such welcome news.

"Present practice, which involves culturing urine for 48 hours, is so slow that doctors frequently over-prescribe broad-spectrum antibiotics to begin treatment promptly. This has led to unnecessary treatment in many patients and drug-resistance in the bacteria that cause UTIs," says Dr. Joseph C. Liao, a urologist at the UCLA School of Medicine in Los Angeles and co-principal investigator for the electrochemical sensor research. "Older antibiotics such as penicillins and trimethoprim-sulfamethoxazole (Bactrim) are frequently ineffective. Ciprofloxacin is now commonly used, but resistance to it has been on the rise." Liao adds that since there is no oral antibiotic to replace Ciprofloxacin the need to change the current approach for UTI treatment is critical.

To rapidly identify bacteria, the detector has an array of 16 electrochemical sensors customized with a library of DNA probes that target the most common urinary bacteria. The detection process works at the molecular level: when the RNA target from the bacteria is recognized by the probes on the sensor, an electric signal is generated. The signal is transformed by a computer chip on the unit into a digital readout. The sensor is able to give quantitative results since the more bacteria that bind to the detector's probes the stronger the signal.

The biosensor performed well in a recent clinical study trial: In tests of actual clinical urine samples, it identified the most common bacterial species found in UTIs with 98% accuracy. "This pilot generation of probes can identify the five most common bacteria that cause UTIs. Additional probes are being developed but the most clinically relevant bacteria are already on the list," says Liao.

The new detector represents a collaboration between medical researchers led by Liao, and GeneFluidics, Inc., a company started by Vincent Gau, whose UCLA PhD is in biomedical engineering. Gau began work on his detector in 1998 - with an eye toward detecting airborne biowarfare agents - but changed over to a diagnostic instrument in 2000. "The UCLA Urology Department and GeneFluidics received a \$5.6 million grant from the National Institute of Biomedical Imaging and Bioengineering (NIBIB) to develop a prototype device and conduct a clinical study, and the Urology Department at UCLA is a top-notch partner to work with on this UTI application," Gau says.

In addition to the species-specific probes used in the clinical tests, Liao's team has also developed "universal" probes that can, in theory, detect bacterial RNA from any organism as well as dead bacteria, leading to more precise diagnoses. "[In current practice] if a patient were to have a negative urine culture the physician assumes that

the patient does not have an infection," Liao says. "In reality the patient may harbor bacteria that does not grow well in an artificial laboratory setting for whatever reason. A rapid molecular approach such as ours that does not depend on the bacteria's ability to grow overcomes that problem."

This work is supported by the NIBIB Division of Discovery Science and Technology.

a. Relevant Statistics:

In the months since the clinical study ended GeneFluidics engineers have improved the biosensor so that, in preliminary tests, urinary bacteria can be identified in just 25 minutes, down from the 45 minutes it took during the clinical study.

Future Programs:

GeneFluidics is negotiating with several companies to commercialize the technology and expects to have a system ready for FDA approval in about 2 years. Gau expects the commercial design should be able to do much more than just find bacteria in urine: "It should be possible to develop detectors to analyze saliva, milk, serum, plasma and liquid culture media - and to detect bacteria, viruses and protein markers," he says. These results may be of interest to physicians studying infectious diseases in other organ systems or other non-infectious diseases processes.

Improved miniaturization and fabrication techniques will help create a "lab-on-a-chip" system that will permit all chemical analysis to occur within a single removable cartridge. "Eventually, though this will take several years, the design could lead to kits sold over the counter, for home use, like present-day pregnancy test kits," Gau says.

3. Magnetic Signals to Reveal Fetal Development

Most neurological damage occurs to fetuses prior to the onset of labor. Developing a screening tool to detect this damage is one of the goals of a new fetal monitoring system developed by researchers at the University of Arkansas for Medical Sciences in Little Rock. The high-tech device, nicknamed SARA (Squid Array for Reproductive Assessment), relies on an array of 151 sensors that detect and record extremely weak signals generated from naturally occurring magnetic fields in the body. The system provides a graph that shows the changes in fetal heart rate, brain activity, and other vital functions as well as changes in the mother's uterus.

Over the last two decades researchers have used SQUID arrays to assess adult brain activity. The technique of recording magnetic signals from the brain is called magnetoencephalography (MEG). Signals captured by the arrays are superimposed over images produced from imaging modalities such as computed tomography and magnetic resonance to give a complete picture of the adult brain and neuromuscular system.

In their research with SARA, Dr. Curtis Lowery, director, division of Maternal-Fetal Medicine, University of Arkansas for Medical Sciences and his colleague Hari Eswaran, director of the SARA Laboratory, University of Arkansas for Medical Sciences, found that the brain and heart signal patterns of healthy fetuses are far more complex than those of fetuses with problems. They have followed 70 patients since they began their fetal MEG research in 2005. "In theory high-risk fetuses produce less complex and more predictable signals than a healthy fetus," explains Lowery. "We now have some

evidence that healthy fetuses produce very complex signals."

NIBIB support has allowed the researchers to fine tune SARA's signal processing capabilities to produce a more complete picture of maternal/fetal heart/brain activity and their relation to uterine activity. "Normally [researchers] record brain and heart activity separately and then correlate it," says Lowery. "With SARA we record both activities on the same computer system so the correlation is easier."

SARA has the potential to provide an array of monitoring capabilities. For instance, the researchers have mapped fetal brain function in response to sound and light stimuli. Early results show that normal fetuses produce responses to these stimuli from a small area of the cortex while spontaneous brain activity involves the whole brain. The investigators also discovered that healthy fetuses can discriminate between two different sound frequencies while neurologically impaired fetuses cannot.

The system's ability to track heart function has enabled the researchers to study cardiac development as well as to monitor therapeutic drug interventions. A popular drug used to treat abnormal fetal heart rhythms is administered to the mother and crosses the placenta. One of the drug's drawbacks is widening of a critical heart interval. With SARA, clinicians can monitor the mother and fetus and, if the complication arises, quickly stop the drug.

Because SARA permits simultaneous monitoring of heart and brain activity, the researchers are developing a screening tool to detect early neurological damage in high-risk fetuses. Termed SARA Neurological Assessment Protocol or SNAP, the screening tool provides multiple observations of heart and brain activity including visual and auditory response with the hope that by cross correlating the information over time, a more complete picture of a fetus's condition will emerge.

"SNAP will help clinicians better predict how high-risk babies will do once they are delivered because it looks at the heart and brain with multiple parameters," explains Lowery. Early detection of impairment could also lead to interventions that may improve fetal survival.

In addition to monitoring fetal activity, SARA allows the researchers to track uterine activity. Other research groups have shown that close to term, electrical junctions form in the uterus. When contractions begin, the junctions synchronize and provide the energy to expel a fetus. Research with SARA may enable investigators to identify how cells are recruited when labor begins. These insights may help clinicians determine which mothers are at risk for pre-term labor before it occurs as well as to actually predict when term labor will begin. "If we can track the electrical signals related to labor, we can better treat labor," explains Eswaran.

The researchers have completed recording data on normal mothers and fetuses and have turned their attention to mothers at high risk including those with pre-eclampsia, diabetes, and those who smoke. A key goal of the project is to extract three-dimensional data for both mother and fetus using ultrasound and electrical signaling. "Ultimately we would like to combine both structural and functional information," says Eswaran. "It seems simple but it means mapping two different coordinate systems." To produce a 3D

image, the researchers must develop new algorithms or mathematical formulas so that the ultrasound and electrical signals can be combined in the same spatial dimension. *In addition to support from NIBIB Division of Applied Science and Technology, this research is supported by the National Institute of Neurological Diseases and Stroke.*

Future Programs:

Lowery notes that a SARA system will be installed in Tuebingen, Germany in 2007 and he anticipates more widespread use in the next three years as SARA gains attention in the research community. "This is a research tool with clinical applications but we need multiple applications for widespread use," he says. Other potential applications include noninvasive bladder and digestive tract studies as well as reproductive studies in nonpregnant women.

4. Point-of-Care Technologies Research for Sexually Transmitted Diseases

The need to develop acceptable, available Point-of-Care Tests (POCT) for identifying Sexually Transmitted Diseases (STDs) in at-risk populations is significant. In the U.S., five of the top ten reportable diseases are STDs and, per year, there are greater than 18 million new STDs that cost more than \$2 billion. Stigma, privacy, and confidentiality issues make STDs optimal for POCT at healthcare facilities and for over-the-counter (OTC) assays performed at home. The Center will conduct in-house clinical testing of POC devices, collaborate with scientists and engineers on exploratory technology development projects, complete a clinical needs assessment among STD healthcare professionals, provide training to technology developers on clinical issues pertaining to STD POCT, and provide an administrative structure to ensure that the Center achieves its goals. The Center will implement five Cores that complement each other and work with other Centers in the POCTRN to facilitate transitions from prototype development through inhouse pilot testing, by ensuring that such assays' specifications and qualifications have scientific merit that is sufficient for future clinical trials and FDA submission.

Core 1 will provide expert testing laboratory facilities for testing newly-developed POCT assays. It will also test unique methods of home-delivering OTC assays to end users *via* the Internet, as well as novel approaches for measuring acceptability and accuracy of OTC-type assays in primary care settings. Core 2 will provide grants to scientists to develop new assays, as well as utilize the molecular and basic scientific expertise of the Center's investigators in selecting appropriate applications. Cores 3 and 4 will work in an integrated fashion to provide the needs assessment, the results of which will reach scientists in the technology community and aid them in developing assays that will be meaningful, with regard to sensitivity and specificity, and positively influence public health. Core 5 will provide an effective management structure for a complex Center, the integration of all Core activities, responsiveness to members of the research community wishing to access the Center, and provide administrative services to the POCT Center.

This work is supported by the NIBIB Division of Discovery Science and Technology.

5. Trans-NIH Working Group on Women in Biomedical Careers

In addition to our active research program, NIBIB staff participates in a trans-NIH

Working Group on Women in Biomedical Careers. The Deputy Director of the Institute chairs a subcommittee of the Working Group called Integration of Women into Bioengineering Fields. In addition to the Deputy Director, staff in the Institute's Division of Discovery Science and Technology are active members of this Subcommittee. The goal of the Subcommittee is to ensure that the career challenges faced by women in bioengineering are addressed and that resources are developed to enable or eliminate any barriers to their career development and advancement. To date, the group has identified several issues facing women in bioengineering and has both developed and implemented solutions.

This program is supported by the NIBIB Division of Discovery Science and Technology.

a. Relevant Statistics:

o **The NIH Director's Wednesday Afternoon Lecture Series (WALS).** The Subcommittee has twice sponsored a women engineer for the prestigious WALS. Gordana Vunjak-Novakovic, Ph.D., Columbia University spoke on Tissue Engineering on October 17, 2007, and Martha Gray, Ph.D., Harvard/MIT spoke on January 21, 2009.

o **Engineering and Physical Sciences Special Interest Group (SIG).** This group was launched in the fall of 2008. The Engineering and Physical Sciences SIG aims to educate the NIH community about the role that engineers can play in the interdisciplinary biomedical fields.

o **K-12 Student Outreach and Education.** An award within the NCR Science Education Partnership Award (SEPA) Program, which funds grants for innovative educational programs, has been supplemented to include funding for increasing the interest of Native American girls in the physical sciences.

o **The Annual NIH Research Festival.** At the request of the Subcommittee, last years festival included a bioengineering theme and speakers included women engineers.

o **A Funding Initiative** was released by the Working Group entitled "Research on Causal Factors and Interventions that Promote and Support the Careers of Women in Biomedical and Behavioral Science and Engineering: The NIBIB is about to fund one of the grants focused on science, technology, engineering and mathematics.

Future Programs:

As we move forward in exploring and implementing ways to provide opportunities for career success, we recognize that we need to continue to work with the trans-NIH Women in Biomedical Careers Committee as well as partner with other organizations. The Subcommittee on Women in Bioengineering will continue to address pipeline

issues to help eliminate barriers to women at all levels of the educational and career pipeline who are interested and involved in bioengineering. We plan to do outreach at several levels. At the high school and college levels we will work to encourage participation of young women in research. The Subcommittee is considering the development of a brochure to highlight the bioengineering and imaging opportunities available within the NIH Summer Internship Program. The brochure would be designed to appeal to females. Discussions with Subcommittee members and communication contacts within relevant ICs are underway. The initial goal is to develop a draft by fall 2009. We also plan outreach to K-12 students. An educational video to counteract any gender bias in the quantitative sciences which will be called *Women are Bioengineers* is proposed. Initial partners are NIBIB and the ORWH. The hope is to broaden the participation by additional ICs. Finally, we plan outreach to graduate student, postdoctoral trainees, and medical residents. Members of the Subcommittee will continue to monitor data on women supported in the NIH Graduate Partnership Program (GPP), the NIH (NIBIB)-NIST Postdoctoral Fellowship Program, the Imaging Sciences Training Program (NIBIB-ISTP), and the NIBIB supported Biomedical Engineering Summer Internship Program (BESIP) with an eye towards encouraging medical and biomedical doctoral degree-holders to consider interdisciplinary research between the biological and physical sciences. Another long-term goal is to develop a high-quality database on women in bioengineering that could be used to identify mentors and role models as well as mentees. We will also continue to support the Institutes active research program focused on many women's and girl's health and disease-related issues. Over the next few years we will continue to support research programs to identify barriers to female participation in all aspects of the field of bioengineering through the NIH initiative on "Research on Causal Factors and Interventions that Promote and Support the Careers of Women in Biomedical and Behavioral Science and Engineering. We will also continue to profile outstanding women bioengineers in various venues such as lectureships and to enhance public awareness of the role of women bioengineers in helping improve the health of other women and families.

6. Women in Medical and Biological Engineering Committee (American Institute for Medical and Biological Engineering)

Outside of the NIH, the NIBIB participates in, and is supportive of, a new Committee that formed as part of the American Institute for Medical and Biological Engineering (AIMBE) called the Women in Medical and Biological Engineering Committee. The Committee celebrates women's contributions to both the field of bioengineering and to the health and well-being of our society through bioengineering technologies. The membership of the Committee spans corporate, academic, and government institutions. The Committee partners with the Association for Women in Science and the American Association of Engineering Societies. The Committee held their first-ever symposium in December 2008 called "It's Your Responsibility: How to Lead and Impact Policy: Enhancing the Role of Women in Medical and Biological Engineering.

This program is supported by the NIBIB Division of Discovery Science and Technology.

Relevant Statistics:

The Committee held their first-ever symposium in December 2008 called "It's Your Responsibility: How to Lead and Impact Policy: Enhancing the Role of Women in

Medical and Biological Engineering.

B. Overarching Recommendations:

The NIBIB is committed to eliminating any barriers to furthering the careers of women in the field of bioengineering. According to the American Society for Engineering Education Data Management System, the percent of women in bioengineering at the undergraduate level is about 50%. The bad news is that this percentage decreases gradually along the career pipeline to the point where only approximately 6% of full professors in bioengineering are women. To address this we will need to continue to develop opportunities and programs to support women in bioengineering along the entire educational and career pipeline. This will require partners in national coalitions such as AIMBE. Together all partners need to continue to confront those factors that keep girls and young women, especially minorities, from entering the field of biomedical engineering, sustaining a career, and reaching the top levels in the field.

XXII. NIH / Office of the Director / Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

Programs That Improve the Lives of America's Women and Girls

1. The National Children's Study (NCS)

The NCS promises to be one of the richest information resources available for answering questions related to children's health and development and will form the basis of child health guidance, interventions, and policy for generations to come. The landmark study will examine the effects of environmental influences on the health and development of more than 100,000 children across the United States, following them from before birth until age 21. This extensive research effort will examine factors ranging from those in the natural and man-made environment to basic biological, genetic, social, and cultural influences. By studying children through their different phases of growth and development, researchers will be better able to understand the role of these factors in both health and disease. Specifically, the NCS will identify factors underlying conditions ranging from prematurity to developmental disabilities, asthma, autism, obesity and more. The study is led by a consortium of federal agencies including the NICHD and the NIEHS at the NIH, the CDC, and the EPA.

(<http://www.nationalchildrensstudy.gov>)

2. Reproductive Health

Uterine Fibroids

The NICHD supports research to shed light on the development and treatment for uterine fibroids. In collaboration with the ORWH, researchers are creating a uterine fibroid tissue bank. Such a tissue bank will allow investigators funded by NIH to submit requests for fibroid tissue to conduct studies more rapidly, compared collecting tissues for each individual study.

The NICHD, with support from the National Institute of Environmental Health Sciences and the ORWH, are encouraging research with the goal of transforming advances in our understanding of the molecular basis of leiomyomata uteri (uterine fibroids) into new therapeutic options for prevention and treatment of this common gynecologic disorder.

(<http://grants.nih.gov/grants/guide/pa-files/PAR-08-102.html>)

Through the Cooperative Reproductive Science Research Centers at Minority

Institutions Program, the NICHD, in collaboration with ORWH and the National Center for Research Resources, is supporting a clinical research study on uterine fibroids at Meharry Medical College, which may help researchers find answers for the condition's increased prevalence rates in minority women. (<http://grants.nih.gov/grants/guide/rfafiles/RFA-HD-06-017.html>)

a) Relevant statistic: Uterine fibroids affect more than 1 out of 5 women under age 50. [<http://www.fda.gov/ForConsumers/ByAudience/ForWomen/ucm118522.htm>]

Research Training in Women's Health

In collaboration with ORWH, the NICHD is supporting an ongoing training and career development program for junior physician scientists--Women's Reproductive Health Research (WRHR) Career Development Program. The WRHR program addresses a continued need for bridging clinical training with an independent career in research addressing women's health concerns. Program sites provide departments of obstetrics and gynecology an opportunity to build a talented pool of junior investigators in women's health research.

Investigators with established research programs covering a broad range of basic and applied biomedical and biobehavioral science, in obstetrics and gynecology departments and collaborating departments, form an intellectual and technical research base for mentoring WRHR Scholars. The emphasis is on research relevant to obstetrics and gynecology and/or its subspecialties: maternal-fetal medicine, gynecologic oncology, and reproductive endocrinology and infertility. Related fields such as adolescent gynecology and urogynecology are also included. Mentors with established research programs, together with collaborating departments, form the intellectual and technical base for mentoring junior faculty accepted into the program.

(<http://www.nichd.nih.gov/research/supported/wrhr.cfm>).

Reproductive Medicine Clinical Trials Network

The NICHD continues to support this Network which is poised to conduct randomized clinical trials on novel therapeutic interventions to treat fibroids. The network is working with the NICHD intramural program to develop and use tissue samples from the fibroid tissue bank. (<http://www.nichd.nih.gov/research/supported/rmn.cfm>)

Specialized Cooperative Centers Program in Reproduction and Infertility Research (SCCPIR)

Since it began in 1998, the main objective of the SCCPIR was to establish a national network of centers aimed at improving human reproductive health through accelerated transfer of basic science findings into clinical practice. The SCCPIR is a research-based centers program designed to promote multidisciplinary interactions between basic and clinical scientists. Center investigators work with the NICHD staff in facilitating research collaborations and interactions within and between centers, as well as with private foundations and industry. (<http://grants.nih.gov/grants/guide/rfa-files/RFA-HD-08-001.html>).

Primary Ovarian Insufficiency

The Institute supports research on primary ovarian insufficiency—a menopause-like condition. Recently, scientists found that a delay in diagnosing primary ovarian insufficiency in young women is linked to low bone density. Without early treatment,

these women are at risk of developing osteoporosis. The study showed that minority patients were more likely to have low bone density than were white patients in the study. African-American women were less likely to consume sufficient calcium than were white women and more likely to have low vitamin D levels. Asian women were less likely than white women to take the replacement hormones prescribed as a treatment for the condition. These study findings explain why some women with the condition are more likely to develop low bone density. A comprehensive plan for diagnosing and treating the condition was recently developed and published. (<http://www.nichd.nih.gov/news/releases/020409-Evaluating-Menopause.cfm>) To conduct this research, the NICHD collaborates with researchers at the NIH Clinical Research Center and the National Institute of Diabetes and Digestive and Kidney Diseases.

The NICHD created a 28-page Spanish translation of the NICHD's "Do I have Premature Ovarian Failure" booklet—Tengo Falla Ovárica Prematura. The Spanish booklet explains the symptoms of POF, its possible causes, its associated conditions, and the latest NICHD research on the disorder. In addition, the booklet raises issues related to POF and infertility, lists possible options for women with POF who want to have children, and provides contacts for various POF support and information groups. (http://www.nichd.nih.gov/publications/pubs_details.cfm?from=&pubs_id=5638)
a) Relevant statistic: Overt primary ovarian insufficiency affects 1 in 100 women by age 40 years. [<http://emedicine.medscape.com/article/271046-overview>]

Polycystic Ovary Syndrome (PCOS)

PCOS is the leading cause of infertility in women, affecting 8 to 15 percent of American women of reproductive age. Along with infertility and cyst-like structures in the ovaries, women with PCOS are at higher risk for diabetes, heart disease, high blood pressure, excess hair growth, and acne. Obese women are more likely to develop the condition. Metformin is a new, promising drug treatment for some women with the condition and the drug is thought to increase fertility by increasing ovulation patterns. NICHD-supported

researchers discovered that women with PCOS are less likely to ovulate in response to metformin if they have a variation in the gene involved in controlling blood sugar levels, STK (serine-threonine kinase) 11. Researchers found that metformin lowers blood sugar levels and may be used as a treatment for PCOS; however, the study results also showed that women's response was dependent on how many copies of the variant gene they possessed. The next step for the researchers is to conduct a genetic analysis on a large sample of women, to try to find out how frequently the gene variant occurs in the population and to distinguish women who would be unlikely to ovulate in response to metformin from those likely to ovulate. Funding for the study was provided by the NICHD and the National Center for Research Resources.

(http://www.nichd.nih.gov/news/releases/gene_variation_040108.cfm)

For women with PCOS who are seeking to have children, treatments have been limited to metformin and clomiphene. Women with PCOS frequently experience insulin resistance, and metformin is thought to make the body more sensitive to insulin

therefore increasing ovulation. Clomiphene fosters ovulation by stimulating the release of hormones needed for ovulation resulting in multiple mature ovarian follicles. NICHD researchers conducted the largest, most comprehensive effort yet to compare metformin and clomiphene in helping women with PCOS achieve successful pregnancy. Researchers randomly assigned infertile women with PCOS for six months to one of three groups: 1) clomiphene and a placebo, 2) metformin and a placebo, and 3) both metformin and clomiphene. Researchers found that fewer women in the metformin-only group had given birth than had women in either of the clomiphene groups. Women in the combination therapy group ovulated more frequently than did the women in either the clomiphene-alone or the metformin-alone groups. However, the tendency to ovulate more frequently did not translate into a significantly greater number of pregnancies for the combination group. Women who ovulated while taking clomiphene were twice as likely to become pregnant than a woman ovulating on metformin. Women in the clomiphene groups had more occurrences of multiple pregnancies because of stimulation of multiple ovarian follicles. The study results support the use of clomiphene citrate alone as first-line therapy for infertility in women with PCOS. The NICHD and the National Center for Research Resources supported the study.

(http://www.nichd.nih.gov/news/releases/pcos_treatments.cfm)

The NICHD created a 32-page booklet describing the common symptoms, features, and other disorders associated with PCOS, the most common cause of infertility in the United States. The Polycystic Ovary Syndrome (PCOS): Beyond Infertility Booklet describes some of the ongoing research conducted and supported by the NICHD on PCOS and provides contact information for organizations that can provide additional information, services, and support to women affected by PCOS and their families.

(http://www.nichd.nih.gov/publications/pubs_details.cfm?from=&pubs_id=5699)

a) Relevant statistic: PCOS affects about 1 in 10 women in the United States.

[<http://www.mayoclinic.com/health/polycystic-ovary-syndrome/ds00423>]

Pelvic Floor Disorders

Pelvic floor disorders result when the muscles and connective tissue within the pelvic cavity weaken or are injured, leading to dysfunction of one or more pelvic organs. The Pelvic Floor Disorders Network, with seven sites throughout the country, supports research on the prevention and treatment of pelvic floor disorders. A recent study by the network revealed that a special two-step surgical procedure, compared to standard practice, reduced by half the incidence of urinary incontinence in women with pelvic organ prolapse. In addition, the Institute plans to enhance collaborative research among basic scientists and clinician researchers in female pelvic floor disorders, to promote research that has the greatest clinical applicability for addressing unknown aspects of physiology and pathophysiology of pelvic function.

(<http://www.pfdnetwork.org>; http://www.nichd.nih.gov/news/releases/sep091608_PFV.cfm; <http://grants.nih.gov/grants/guide/rfa-files/RFA-HD-08-008.html>) To conduct this research, the NICHD collaborates with the NIDDK and ORWH.

a) Relevant statistic: Nearly a quarter of women have a pelvic floor disorder.

[<http://www.webmd.com/urinary-incontinence-oab/news/20080916/one-fourth-womenhave-pelvic-floor-disorder>].

Vulvodynia

The NICHD, in partnership with the ORWH, is encouraging investigators to conduct systematic epidemiologic, etiologic, and therapeutic research on vulvodynia.

(<http://grants.nih.gov/grants/guide/pa-files/PA-07-182.html>) Moreover, the ORWH, with co-sponsorship from the NICHD and other organizations, launched the Vulvodynia Awareness Campaign. The ORWH and co-sponsors created the Vulvodynia: Research, Resources, Treatment, Hope (Packet) as a resource for women suffering from vulvodynia. The packet includes fact sheets and overview information about vulvodynia, resources for women who have been diagnosed with or who believe they have vulvodynia, and scientific journal articles about the latest research on the disorder.

a) Relevant statistic: Estimates of women with vulvodynia range from 200,000 to 6 million. [<http://women.webmd.com/vulvodynia>]

Contraception

Through its Contraception and Reproductive Health Branch, the NICHD develops and supports research and research training programs in reproductive health, epidemiology and contraceptive technology. Major research areas include studies of: new contraceptive methods; mechanisms of action and effects of contraceptive and reproductive hormones, drugs, devices, and procedures; optimal formulations and dosages of contraceptive agents, spermicidal microbicides, and hormone replacement therapies (in animals and humans); post-marketing surveillance of reproductive products, devices, and procedures; and health and fertility effects of reproductive drugs, devices, and procedures.

More than 100 million women worldwide use hormonal contraceptives and over 18 million women are infected with HIV (transmission occurs mostly during heterosexual intercourse). Studies to date had been inconclusive about the impact of hormonal contraceptives on HIV risk. Furthermore, despite significant advances in antiretroviral treatments for HIV/AIDS, very little information was known about how hormonal contraceptives and antiretroviral drugs interact in women with HIV. NICHD-supported researchers investigated the interactions between Depo Medroxyprogesterone (DMPA), a popular progesterone-based injectable contraceptive given every three months, and selected antiretroviral agents, tracking any changes in the metabolism of both the DMPA and antiretroviral drugs, and assessed the safety of the DMPA in women with HIV. The study results showed that DMPA remained at effective levels across groups for the 12 weeks after the injection without significant changes in HIV RNA levels or CD4+ cell counts. Side effects were similar to those in women without HIV and no pregnancies resulted after DMPA injection. These findings can reassure women with HIV, worldwide, who are of reproductive age and who are on antiretroviral therapy that there are effective hormonal contraceptive options for pregnancy prevention.

The NICHD commissioned a large study recruiting women without HIV seeking family planning services in Uganda, Zimbabwe, and Thailand to investigate the risk of HIV infection for women using the most commonly prescribed forms of hormonal contraception. Researchers found no evidence that the use of hormonal contraceptives increased a woman's chances of becoming infected with HIV. The study could not rule out an increased risk for HIV infection among "highly exposed" hormonal contraceptive users such as sex workers. Researchers, however, did find that in this study, women

using hormonal contraceptives with genital herpes had a lower risk of acquiring HIV when compared to women without genital herpes. The researchers agree that additional research is needed to confirm and explain why this was the case, since previous studies have found genital herpes to be a risk factor for acquiring HIV.

(http://www.nichd.nih.gov/news/releases/hormonal_contraception.cfm)

Preserving Fertility

In response to a growing need for technologies for fertility preservation, the NICHD is encouraging research that optimizes technologies designed to increase the fertility preservation options for individuals who are or may become infertile as a result of chronic disease or disease treatment, exposure to environmental or occupational hazards, advanced reproductive age, or genetic predisposition.

(<http://grants.nih.gov/grants/guide/pa-files/PA-08-104.html>)

Fertility

The NICHD is encouraging research to better understand the role of adipose tissue in the normal physiological regulation of reproduction, to discern its possible role in the etiology of diseases and disorders that impact human fertility, and to probe its potential importance in different racial/ethnic groups. (<http://grants.nih.gov/grants/guide/pafiles/PA-08-059.html>)

The Institute, in collaboration with the National Institute on Alcohol Abuse and Alcoholism, is promoting basic and/or clinical research on the short- and long-term epigenetic and genetic impact of adverse female health situations on the quality of human eggs prior to and around the time of fertilization and of preimplantation embryos. Such adverse health conditions may include poor nutrition, diabetes, polycystic ovary syndrome, endometriosis, aging, and alcohol consumption, as well as assisted reproductive technologies. (<http://grants.nih.gov/grants/guide/pa-files/PAR-07-350.html>)

While most children born through the help of assisted reproductive technologies (ART) appear to be healthy and developing normally, there are some reports of adverse outcomes and some concerns owing to the variety and type of ART protocols in use. To begin addressing these concerns, the NICHD is encouraging research to study the ways in which ART may affect eggs, sperm, and preimplantation embryos that could, in turn, lead to adverse outcomes during fetal development, the perinatal period, childhood, adulthood, or even subsequent generations.

(<http://grants.nih.gov/grants/guide/pa-files/PA-08-104.html>)

a) Relevant statistic: According to the CDC, the number of women in the United States ages 15-44 with impaired an impaired ability to have children is 7.3 million.

3. Healthy Pregnancy

The NICHD supports research on high risk pregnancies and poor pregnancy outcomes, including preterm labor and birth, fetal disorders, Sudden Infant Death Syndrome (SIDS), maternal health and stillbirth. Much of this research is conducted through centers and networks that bring together researchers from different disciplines and allow them to study larger numbers of patients. The Institute recently led the Surgeon General's Conference on the Prevention of Preterm Birth. To immediately implement

some key conference priorities, NIH launched a program to identify and address the factors contributing to prematurity among women having their first baby. For those infants born with an adverse pregnancy outcome, NIH plans to support research to develop safe and effective instruments and devices for infants in the neonatal intensive care unit to optimize their care and developmental outcomes. In addition, NIH commissioned an Institute of Medicine (IOM) study to review and update the 1990 IOM recommendations for weight gain during pregnancy. IOM's new pregnancy weight gain guidelines are similar to its 1990 guidelines, except there is now an upper limit on how much weight obese women should gain while pregnant, as gaining too much weight can be risky for both mother and infant.

(http://www.nichd.nih.gov/news/resources/spotlight/040908_preterm_prevention.cfm;
<http://grants.nih.gov/grants/guide/rfa-files/RFA-HD-08-029.html>;
<http://grants.nih.gov/grants/guide/rfa-files/RFA-HD-09-018.html>;
<http://www.ncbi.nlm.nih.gov/bookshelf/picrender.fcgi?book=napp&part=nap12584&blobtype=pdf&blobtype=pdf>)

a) Relevant statistic: According to the CDC, more than a half million babies in the United States—1 in every 8—are born premature each year.

NICHD-supported researchers have also found that maternal diabetes in a mouse model affects egg quality and can lead to developmental malformations. Diabetes is a chronic disease that can lead to complications throughout the body and its effects can even be seen in birth outcomes. The findings from the NICHD study were the first to show that acute exposure to a diabetic environment in vivo, limited only to the egg stage, can lead to abnormalities during fetal development. The findings raise the question, in humans, of what impact long-term maternal diabetes may have on egg quality, in addition to its effects on fetal development. Even more stringent control and management of diabetes over a longer period of time before pregnancy may be needed to lessen the effects that diabetes can have on egg quality. In another important study, researchers found that a mother's high, yet within the normal range, blood sugar level can place her unborn infant at risk for adverse health outcomes. Diabetes occurs in roughly 5 percent of all pregnancies in the United States. Babies born to mothers with diabetes are at higher risk of prenatal complications and for obesity, high blood pressure, and heart disease when they reach adulthood. Until now, physicians were not certain at which point elevated maternal blood sugar posed a risk for the baby. NICHD-supported researchers have conducted the first study to document that the higher the blood sugar levels (even if they are not high enough to be considered diabetes), the greater the risks for both mother and baby. Mothers with higher blood sugar levels were more likely to have infants with high insulin levels and low blood sugar levels at birth. Funding for this study was provided by the NICHD, National Institute of Diabetes and Digestive and Kidney Diseases, National Center for Research Resources, and the American Diabetes Association.

a) Relevant statistic: Diabetes occurs in roughly 5 percent of all pregnancies in the United States. [<http://www.nichd.nih.gov/news/releases/may072008-highBloodSugar.cfm>].

Obstetric Care

The NICHD Obstetric-Fetal Pharmacology Research Network was established, with

support from the ORWH, to provide the expert infrastructure needed to test therapeutic drugs during pregnancy. The network allows researchers to conduct a whole new generation of safe, technically sophisticated, and complex studies that will help clinicians protect the health of women, while improving birth outcomes and reducing infant mortality. (<http://grants.nih.gov/grants/guide/rfa-files/RFA-HD-07-019.html>)

The rate of cesarean delivery has risen dramatically over the past two decades; in fact, cesarean delivery currently ranks as the most commonly performed surgical procedure in the United States. More research is needed to determine how frequently cesarean deliveries are scheduled for women without medical indications for the procedure, and how these “maternal request” deliveries compare with vaginal delivery in terms of child and maternal health outcomes. Currently, NIH is supporting a Cesarean Registry through the Maternal-Fetal Medicine Units Network. Using data from the registry, researchers found that newborns are at greater risk for health complications after an early cesarean section delivery. Infants delivered by a repeat elective cesarean section at or after 37 weeks, and before 39 weeks, are at significantly increased risk of breathing problems, blood infection, low blood sugar, and admission to the neonatal intensive care unit, similar to those of infants born preterm. These findings continue to support recommendations that clinicians advise their patients to schedule an elective delivery no sooner than 39 weeks of pregnancy. A cesarean delivery that is not medically necessary before this time puts the infant at increased risk of respiratory problems and other adverse health outcomes.

a) Relevant statistic: According to the CDC, preliminary data show that the cesarean delivery rate rose 2 percent in 2007, to 31.8 percent of all births.

Researchers have also found that older mothers are more likely than younger mothers to deliver by cesarean section. The National Center for Health Statistics report that, between 1980 and 2004, the number of women in the United States giving birth at age 30 or older doubled, at age 35 and older tripled, and at age 40 or older nearly quadrupled. The risk of delivery complications increases with the mother’s age, as does the risk of premature birth and infant death. Such complications include excessive bleeding during labor, prolonged labor lasting more than 20 hours, and dysfunctional labor that does not advance to the next stage. It has long been speculated that older women undergo cesarean section at higher rates than younger women. NICHD-supported researchers examined over 8 million U.S. birth certificates and discovered that overall, pregnant women over age 35, despite race and smoking status, were at higher risk for complications during pregnancy and delivery and more likely to undergo cesarean delivery than were mothers who were younger. Whether or not the women had previously given birth also affected their risk of certain complications. Regardless of age, women giving birth for the first time were much more likely to deliver by cesarean section, even when their pregnancies were low risk (full-term, infants without birth defects, with a normal, head-down presentation, and in the absence of any bleeding complications). Women over 40 were also at greatest risk for excessive bleeding during labor, premature delivery, and cesarean delivery. Plus, women giving birth at age 45 or older were most likely to have high blood pressure and diabetes while pregnant. The researchers concluded that the chance of cesarean delivery in all pregnancies increased with the women’s age and include even pregnancies deemed low risk. (http://www.nichd.nih.gov/news/releases/caesarean_release_030807.cfm)

4. HIV/AIDS

The NICHD also supports research on HIV/AIDS and how it affects pediatric, adolescent, and maternal populations. Studies include domestic and international research into the epidemiology, natural history, pathogenesis, transmission, treatment, and prevention of HIV infection and its complications in infants, children, adolescents, pregnant women, mothers, women of childbearing age, and the family unit as a whole. Researchers have shown that a woman's response to anti-HIV therapy improved if she began treatment six months after an earlier preventive regimen to protect infant from HIV infection. In an earlier NICHD-supported study in Botswana, researchers showed that a single dose of nevirapine given during labor was effective at preventing mother-to-child transmission of HIV. Nevirapine is an inexpensive drug and is now commonly used in resource poor countries to reduce the number of children born with HIV. The drug is also one of several drugs used in combination antiretroviral therapies for adults with HIV in resource poor settings. Health professionals have questioned whether administration of the single dose of nevirapine during labor reduced the efficacy of antiretroviral therapy for the mother at a later time. To address this concern, researchers conducted a follow-up study and recruited 218 women who required antiretroviral therapy for their own health. After receiving antiretroviral therapy for at least six months, the level of HIV in the women's blood was assessed. Researchers found that the women who had received nevirapine during labor and who required antiretroviral therapy within six months after delivery still had detectable HIV levels. Conversely, the women who received a placebo during labor and who required antiretroviral therapy six months after delivery did not have detectable HIV levels. Plus, the researchers found that regardless of whether women received nevirapine or placebo, if the women received antiretroviral therapy six months or more after delivery, they did not have detectable levels of HIV. The findings indicate that nevirapine-based antiretroviral therapy is a viable option for women who require treatment six months or more after receiving single-dose nevirapine during labor. However, women given single dose nevirapine who require antiretroviral therapy treatment before six months should receive antiretroviral therapy that does not include nevirapine. NIH support for the study was provided by the NICHD and the John E. Fogarty International Center for Advanced Study in the Health Sciences.

(http://www.nichd.nih.gov/news/releases/nevirapine_therapy.cfm)

a) Relevant statistic: UNAIDS/WHO estimates that in 2007, 15.5 million women worldwide are living with HIV/AIDS.

5. Child Development

Bone Health

Because the risk for osteoporosis can start in childhood, the NICHD supports a public health campaign to help increase calcium consumption among children and teens, ages 11 to 15, a time of critical bone growth. The Milk Matters campaign is designed to educate parents, teachers, and health care providers about how most tweens and teens are not getting enough calcium their diets. The Milk Matters campaign stresses the need for calcium most especially for girls—unfortunately, fewer than one in ten girls ages 9 to 13 are at or above their adequate intake of calcium. The campaign features

materials and publications in English and Spanish.
(<http://www.nichd.nih.gov/milk/milk.cfm>).

NICHD-supported researchers have established reference curves for bone mineral content and density in children. The early findings are now available according to age, sex, and race, and can be used to help identify children with bone deficits and to monitor changes in bone in response to chronic diseases or therapies. Early study findings showed that bone minerals continue to accrue beyond the teenage years. In another study, NICHD scientists discovered two genes for osteogenesis imperfecta (OI), or brittle bone disease. The genes affect how collagen, an important building block for bone, is formed. Although there is no treatment for the disorder, the findings allow researchers to test families who have lost a child to OI for the presence of the defective genes.

a) Relevant statistic: Osteoporosis is a major public health threat for an estimated 44 million Americans. [<http://www.nof.org/osteoporosis/diseasefacts.htm>]

Fragile X Syndrome (FXS)

NIH-supported researchers are conducting a new study to design and prepare to implement a large multi-state study of infants with FXS and their families. The research project goal is to determine the incidence of FXS in the United States, develop screening procedures, address ethical and practical issues related to screening status, and conduct studies on infant development and family adaptation.

a) Relevant statistic: According to the CDC, the exact number of people who have FXS is unknown, but it is estimated that about 1 in 4000 males and 1 in 6000 to 8000 females have the disorder.

Violence

The NICHD also supports research concerning violence against women, especially in the area of women's reproductive health. Such studies include, among others:

- Identifying the factors related to violence against wives, by both husbands and other family members, which lead to pregnancy complications and adverse postpartum maternal and infant health. The findings may be used to develop recommendations for family and clinic-based intervention programs.
- Examining patterns of abuse against women before, during, and after pregnancy, and the subsequent effects of domestic violence and prenatal stress on the risk of preterm birth and slowed fetal growth. The findings will help determine if the risk for domestic violence increases during certain periods related to pregnancy and if prenatal stress, in conjunction with domestic violence, results in poor pregnancy outcomes.
- Analyzing the impact of women's relative earnings on the prevalence of abuse against women. The study is designed to examine the impact of domestic violence on maternal and child health and the potential mitigating effects of economic resources. A better understanding of both the causes and consequences of abuse against women will help to inform domestic violence policies.

Obesity

The NICHD is leading the way to develop and implement a multilevel public health

approach to address the issue of maternal as well as childhood obesity that encompasses new research directions, new training activities, and new partnerships and alliances with domestic and global organizations that share the same cause. As the maternal and childhood obesity epidemic widens, researchers are trying to understand the interaction among the many complex biological and behavioral factors that contribute to this rise, identify the long term impact on mother and child, and develop effective interventions to reverse these trends. NICHD obesity research, which includes a range of racial and ethnic groups, is examining such topics as:

- Basic research on the physiology, psychology, and genetics of obesity in children.
- Community-based partnerships to prevent and control childhood obesity.
- Applying computational and statistical methodologies to design and analyze multilevel studies on childhood obesity.

Multilevel studies include those that consider the range of biological, family, community, socio-cultural, environmental, policy, and macro-level economic factors that influence diet and physical activity in children. To conduct these research efforts, the Institute is collaborating with the NCI, NHLBI, and OBSSR. (<http://grants.nih.gov/grants/guide/pa-files/PA-09-140.html>; <http://grants.nih.gov/grants/guide/rfa-files/RFA-HD-08-023.html>)

a) Relevant statistic: According to the CDC, 34 percent of U.S. adults aged 20 and over are obese.

6. Health Communication

National Council of Negro Women Collaboration

The NICHD is collaborating with the National Council of Negro Women (NCNW) to help children maintain a healthy weight, particularly within NCNW clusters around the United States. The NCNW is a council of 39 affiliated national African American women's organizations and more than 240 clusters, which connect nearly 4 million women worldwide. NCNW cluster leaders will receive Media-Smart Youth: The Essentials, an adaptation of the NICHD's Media-Smart Youth: Eat, Think, and Be Active! curriculum, as well as Energize Our NCNW Families: Parent Program, an adaptation of the We Can!™ (Ways to Enhance Children's Activity and Nutrition) Energize Our Families Parent Curriculum with which they will conduct training sessions in their communities. The NIH and the NCNW have held several events to distribute the new programs and train NCNW cluster leaders, after which the cluster leaders will train fellow NCNW members to implement the training in a variety of community settings, including churches, schools, recreation and community centers. National Child and Maternal Health Education Program.

To develop a national maternal and child health education program with input from stakeholders, NIH created a program to effectively review and translate maternal and child health research findings into new knowledge that can be disseminated to clinicians and their patients--National Child and Maternal Health Education Program (NCMHEP). Forums have been created in which major stakeholders in maternal and child health can work together to review scientific findings and decide how to best communicate their findings to targeted audiences. NIH has identified four areas on which the NCMHEP will focus: prematurity and low birth weight, pediatric obesity, infant mortality, and

environmental influences on child health and development.

SIDS Outreach

Since 1994, when the NIH launched its campaign to reduce the risks of Sudden Infant Death Syndrome (SIDS), rates have declined significantly, yet the disparities in SIDS rates continue to exist. Today, babies in the American Indian and Alaska Native communities are twice as likely to die from SIDS as white infants. To help eliminate this disparity, NIH, in collaboration with Native American Management Services, Inc., developed adaptable, culturally appropriate SIDS risk reduction materials for use in five Indian Health Service Areas in the Northern Tier—Aberdeen, Billings, Bemidji, Portland, and Alaska. Under the guidance of a community-based work group, educational materials have been developed based on recommendations from the five Areas. The outreach project is called “Healthy Native Babies: Honoring the Past, Learning for the Future.” Project materials include a training manual and a CD ROM. The interactive CD ROM that has been developed includes templates for a variety of SIDS risk-reduction educational materials. It contains photographs of American Indian and Alaska Native families and infants from the five regions, taken by local photographers. These photographs can be incorporated into educational materials such as posters, flyers, brochures, and post cards.

a) Relevant statistic: According to the CDC, SIDS is the leading cause of death among infants aged 1–12 months, and is the third leading cause overall of infant mortality in the United States. Although the overall rate of SIDS in the United States has declined by more than 50% since 1990, rates have declined less among African American and American Indian/Alaska Native infants.

Future Programs:

Research efforts are vital to developing new interventions to prevent and treat health conditions that affect women and girls. The NICHD will continue to maintain our strong support for research in the areas of reproductive health, healthy pregnancy, pediatric and maternal AIDS, child development and growth, and health communications. Our major programs will be maintained, reissued and strengthened over the next several years. The NICHD views each of these programs as essential to supporting the health of women and girls in the United States.

Overarching Recommendations:

The NICHD was initially established to investigate the broad aspects of human development as a means of understanding developmental disabilities, including mental retardation, and the events that occur during pregnancy. Today, the Institute conducts and supports research on all stages of human development, from preconception to adulthood, to better understand the health of children, adults, families, and communities. The mission of the NICHD is to ensure that every person is born healthy and wanted, that women suffer no harmful effects from reproductive processes, and that all children have the chance to achieve their full potential for healthy and productive lives, free from disease or disability, and to ensure the health, productivity, independence, and well-being of all people through optimal rehabilitation.

The NICHD has made revolutionary progress toward achieving its goals. Since the Institute was founded:

- o Infant death rates in the United States have dropped more than 70 percent, with much of this decline resulting from NICHD-sponsored research.
- o Survival rates for respiratory distress syndrome have gone from 5 percent in the 1960s, to 95 percent today, due to advances in respirator technologies and the availability of replacement lung surfactant, resulting from the research efforts of the NICHD and other Institutes.
- o The rate of sudden infant death syndrome has dropped more than 50 percent, since the NICHD-led Back to Sleep education campaign to reduce the risk of SIDS began.
- o Transmission of HIV from infected mother to fetus and infant has dropped from 25 percent to less than 2 percent, as a result of NICHD's efforts in collaboration with other agencies and organizations.
- o The incidence of *Haemophilus influenzae* type B (Hib), once the leading cause of acquired mental retardation, has dropped more than 99 percent, because of development of the Hib vaccine by NICHD scientists, which has nearly eliminated this disease.
- o Congenital hypothyroidism, once responsible for many cases of mental retardation, no longer has an impact on cognitive development because of screening techniques used to detect the condition in all newborns in time to allow treatment to prevent its effects.
- o Phenylketonuria, a disorder that also caused mental retardation in many individuals, has been successfully eliminated as a factor in cognitive development through newborn screening and dietary therapy.
- o Infertility that at one time kept couples from having babies of their own often can be treated and reversed.
- o Sound scientific information about the safety and effectiveness of different contraceptive methods for women and men is now available.
- o Many social, physical, and behavioral rehabilitation treatments for people with mental, developmental, and physical disabilities are now available.

XXIII. NIH / Office of the Director / National Institute on Drug Abuse (NIDA)

A. Programs That Improve the Lives of America's Women and Girls

1. Program Description:

Basic and Clinical Neuroscience Research-- from Prenatal to Adolescence and Adulthood

Drug abuse and addiction are considered health issues that disproportionately affect males. This view is fueled in large part by the higher rates of use reported by males in national surveys, and the greater proportion of males compared to females in substance abuse treatment. However, there is growing evidence from both preclinical and clinical studies, as well as epidemiological research, that while males may have more opportunity to engage in drug use, females appear to be more vulnerable to the consequences of drugs use, including addiction and other adverse health effects. This is particularly true for stimulants, including nicotine and cocaine. . Adolescent girls appear particularly vulnerable, and in recent years have shown comparable rates to boys in illicit drug use—for all drugs except

marijuana—along with higher rates of non-medical use of prescription drugs, which could portend greater problems for this cohort in the future. Researchers are just beginning to explore the neurobiological basis for this greater vulnerability in females, using animal models to provide proxy measures for humans and clinical research, which together facilitate the dissection of biological and behavioral factors underlying sex differences in response to drugs and their consequences.

Basic Animal Model Research:

Sophisticated animal models of addiction are helping us to better understand the nature of the addiction process and factors that affect it. Animals will voluntarily self-administer nearly all drugs of abuse; and they “relapse” or engage in drug-seeking behavior when given access to drugs on which they previously were made dependent. However, animals show differences in sensitivity to various drugs based on age, genetics, sex, and environmental manipulation, with female rodents generally taking more, and showing greater responsiveness, particularly to stimulants. These differences may eventually inform the development of more responsive prevention and treatment approaches.

Clinical Neuroscience Research:

This program is similarly exploring sex differences in the biological and behavioral mechanisms underlying drug effects, both with respect to etiology and consequences. Studies are beginning to reveal gender-based genetic differences in outcomes of prenatal exposure to drugs; the role of reproductive hormones in the response to drugs in females, but not in males; and brain differences between male and female drug abusers, and between them and their non-drug using counterparts. Sex differences in the brains of drug dependent individuals point to differences in relapse factors, which can inform gender-specific treatment interventions.

[These programs reside within NIDA’s Division of Basic Neuroscience and Behavioral Research and Division of Clinical Neuroscience and Behavioral Research, with oversight responsibilities assigned to various program staff.]

a. Relevant Statistics

- National Survey on Drug Use and Health data from 2007 showed that while males 12 and older had rates of substance abuse twice that of females, among those 12 to 17 the gender gap has almost closed. Among youths aged 12 to 17, the rate of substance dependence or abuse among males was similar to the rate among females during a 6-year period (7.7 vs. 7.7 percent in 2007; 8.0 vs. 8.1 percent in 2006; and 9.3 vs. 8.6 percent in 2002). The survey has also found in a previous analysis (SAMHSA, Special NSDUH tabulations, 2002-2004 [In Press]) that compared to boys, girls use cocaine more frequently, use a greater quantity, and report more symptoms of dependence at lower use levels.⁷¹

⁷¹ Chen K, Kandel D. Relationship between extent of cocaine use and dependence among adolescents and adults in the United States. [Drug Alcohol Depend.](#) 2002 Sep 1;68(1):65-85.

2. Future Programs: NIDA has an ongoing call for research on women, gender differences, and drug abuse, which covers all areas of drug abuse–related research. Additionally, NIDA includes a focus on sex/gender differences in many of its specific funding announcements, and supports dissertation research in the area of women and sex/gender differences. Other prioritized funding areas in the coming years that include a focus on sex/gender research are:

- *Molecular Genetics of Drug Addiction and Related Comorbidities*—to identify genetic contributions to increased or decreased vulnerability to addiction, and/or response to treatment. This includes multiple classes of drugs, such as stimulants, opioids, and nicotine; multiple drugs of abuse; and/or associated mental co-morbidities, to include major depression, schizophrenia, and bipolar disorder. Research spans that from animal models to human beings, with NIMH a cosponsor of this program announcement.
 - *Prescription Drug Abuse*—to understand the factors contributing to prescription drug abuse; to characterize the adverse medical and social consequences; and to develop effective prevention, behavioral, and pharmacological treatments and service delivery approaches. Applications are encouraged across a broad range of experimental approaches including basic, clinical, and epidemiological studies.
 - *Behavioral and Integrative Treatment Development Program*—to improve behavioral treatment for substance abuse, with NIAAA and NCCAM as co-sponsors.
 - *Brain Imaging Studies of Negative Reinforcement in Humans*—to spur research on the brain processes underlying how aversive events control behavior, including the continuing compulsive use of drugs despite their potentially devastating consequences.
- a. **Target Population(s):** The intended goal of the basic research and clinical neuroscience research programs described above is to benefit all populations, and all ages.

B. Overarching Recommendations

NIDA has emphasized sex/gender analysis research for more than 10 years, and our research findings demonstrate that sex/gender often plays a pivotal role in the etiology, prevention, and treatment of drug abuse and its consequences. And while progress is being made in this understanding, the preponderance of research, particularly in the preclinical arena, still only includes male subjects for a variety of practical/cost considerations. This limits the generalizability of the findings and slows the pace of discovery into how the neurobiology of drug addiction differs in males and females and how drugs differentially impact their brains, which could directly translate to new prevention and treatment strategies. Thus, NIDA recommends continued efforts and research investment to actively promote the study of sex/gender differences in drug abuse in all areas of

research.

A. Programs That Improve the Lives of America's Women and Girls

1. Program Description:

Epidemiology and Prevention Research

NIDA is advancing field-based research focused on identifying gender differences in the trajectories and in the risk and protective factors for drug use. This research is yielding gender-based outcomes that can be useful in the development of prevention programs, which in turn often yield outcomes that vary by gender.

Epidemiology Research:

The epidemiology research program is aimed at understanding the nature, extent, consequences, and causes of drug abuse over the lifespan. This research includes multiple levels of investigation across individuals, families, communities, populations and, within those, more detailed investigations across gender, age, and other subgroups. Within this program, a recent focus is on *prescription drug abuse*. Unlike illicit drug use, which shows a continuing downward trend over the past decade, prescription drug abuse—particularly of stimulants and opioid pain medications—has seen a continual rise through the 1990s, and since 2002 has remained stubbornly steady among persons 12 or older. Because they can greatly benefit health as well as pose risks, prescription drugs present several challenges in how best to guard against their abuse.

A growing body of research shows gender differences in the type of prescription drug abused, use patterns, motivations for use, adverse effects, diversion rates, and symptoms of severity. Thus, NIDA will continue to test and evaluate prescription drug abuse prevention and treatment, tailoring interventions according to the medication being abused and the differing motivations behind the abuse—often biased by age and gender. NIDA-supported researchers will also continue to gather latest differential trend information on males and females through large-scale epidemiological studies investigating the patterns and sources of illicit use, particularly in high school and college students.

Prevention Research:

The goal of NIDA's prevention research program is to reduce risk and prevent the initiation of drug use and its progression to abuse and addiction. Within this program, studies focus on women and children as a sub-population of interest for targeted preventive interventions. These include early interventions for pregnant mothers, mother-daughter interventions for early adolescents, adolescent girls in the criminal justice system, post-rape interventions to reduce and prevent drug use, and HIV prevention for drug using female sex workers. Studies also focus on gender differences in the outcomes of interventions designed for families, schools, and communities. These programs reside within NIDA's Division of Epidemiology, Services and Prevention Research, with oversight responsibilities assigned to various program staff.

a. Relevant Statistics:

- In 2007, 7 of the top 11 drugs most commonly abused by high school seniors (excluding tobacco and alcohol) were either prescribed or over the counter medications (see figure below).
- Further, while data sources have historically reported that males, in general, abuse drugs at higher rates compared to females, a few key gender differences should be noted:
 - o NIDA's Monitoring the Future Survey found that in a number of drug categories, compared to 8th grade males, 8th grade females have higher rates of use (i.e., inhalants, Ecstasy, and past month use of alcohol) and that this pattern reverses in the 10th and 12th grades.
 - o In 2008 11% of female 8th graders reported abusing inhalants in the past year, compared to 7% of 8th grade males (2008 MTF).
 - o Among 12th graders a higher rate of females, compared to males, report past year abuse of amphetamines—6.5% of males vs., 6.8% of females in 2008 (2008 MTF).

2. Future Programs: NIDA has an ongoing call for research on women, gender differences, and drug abuse, which covers all areas of drug abuse-related research. Additionally, NIDA includes a focus on sex/gender differences in many of its specific funding announcements, and supports dissertation research in the area of women and sex/gender differences. Other prioritized funding areas in the coming years that include a focus on sex/gender research are:

- *Epidemiology of Drug Abuse*—to expand research focused on understanding the nature, extent, consequences, and etiology of drug abuse across individuals, families, age groups, gender, communities, and population groups.
- *Prescription Drug Abuse*—to understand the factors contributing to prescription drug abuse; to characterize the adverse medical and social consequences; and to develop effective prevention, behavioral, and pharmacological treatments and service delivery approaches. Applications are encouraged across a broad range of experimental approaches including basic, clinical, and epidemiological studies.
- *Drug Abuse Prevention Intervention Research*—to develop novel prevention approaches; to adapt interventions to special populations or delivery environments; and to understand how interventions are chosen, adapted, implemented, and funded.
- *Interactions between Physical Activity and Drug Abuse*—to stimulate investigations—using animal models or human subjects—of neurobiological and behavioral mechanisms that underlie the effects of physical activity on brain function across the lifespan; and to provide knowledge on the effects of exercise and physical activity as prevention and treatment strategies for drug abuse.

a. Target Population(s): Prevention programs focus mostly on children and

their families, and on adolescents. These are times when drug abuse usually begins, with earlier use associated with greater risk of later substance use and other problems. Moreover, early prevention has been shown to provide long-lasting benefits for a range of risk behaviors, including drug use.

B. Overarching Recommendations

There is growing epidemiological evidence that trajectories to drug abuse and addiction are different for boys and girls and that studies using gender-blind intervention approaches often yield results that occur only in one gender. Thus, continued surveillance and greater research is required to understand the reasons why such gender differences exist. Moreover, sub-populations at known high risk and in particular need of intervention include girls involved in the criminal justice system; females at risk for substance use *and* HIV, such as adolescent minority youth; and girls who suffer from physical/sexual abuse and neglect. Prevention programs are needed to address not just drug abuse and addiction, but also drug-related problems, including interpersonal violence, criminal involvement, and productivity loss. Prevention programs are also needed to address drug-related illnesses, such as comorbid mental health problems and infectious diseases, including HIV, hepatitis B and C.

A. Programs That Improve the Lives of America's Women and Girls

1. Program Description:

1. Drug Abuse Treatment and Services—“One Size” Approaches May Not Be Best

A constellation of factors contribute to the treatment of drug abuse and addiction, and these can vary by gender. Included are: how and when to intervene; the reasons and settings for seeking treatment; the treatments that are most effective; and the consequences of not receiving treatment.

Understanding these differences can help inform the tailoring of treatment approaches and increase the likelihood of positive outcomes.

NIDA supports a program of treatment and services research aimed at developing and testing behavioral and pharmacological interventions and their implementation and outcomes. Research is showing that women and men enter treatment with different treatment and services needs (e.g., medical, psychiatric and social functioning is usually much poorer in women than men).

Additionally, research is beginning to show that predictors of treatment retention, completion, and long-term outcomes often are different for women and men (e.g., among cocaine-dependent individuals, severity of childhood trauma is a predictor of cocaine relapse, but only for females, not males).

There is also evidence that tailoring drug abuse treatment to women's particular needs leads to more positive outcomes for women in treatment, and that certain subgroups of women may benefit from women-only programs (versus mixed-gender programs).

Historically, funding for research on gender differences in substance abuse

treatment has been limited. Most Phase 1 and 2 clinical trials do not have the statistical power to examine whether differences exist between men and women in terms of treatment response, or reasons for these differences. Many fundamental questions remain unanswered, such as whether women respond better to female therapists, and whether addiction treatments that also address comorbid conditions more prevalent in women are more efficacious in treating women's substance abuse.

Additionally, subgroups of women with drug abuse disorders need increased research attention, including the following: pregnant women and girls, older women, women and girls abusing prescription drugs, girls and women in the criminal justice system, and women who are in the military or part of military families.

These programs reside within NIDA's Division of Clinical Neuroscience and Behavioral Research, Division of Pharmacotherapies and Medical Consequences of Drug Abuse, Center for Clinical Trials Network, and Division of Epidemiology, Services and Prevention Research with oversight responsibilities assigned to various program staff.

Pregnant Women:

Pregnant women who abuse drugs are more likely to have poor obstetrical outcomes, including spontaneous abortion, placental abruption, premature labor, and intrauterine growth restriction. They are also less compliant with prenatal care and are more likely to have sexually transmitted diseases, HIV, tuberculosis, hepatitis. Children born to substance abusing mothers have impaired fetal growth, higher rates of prematurity, neurologic deficits, developmental delays, sudden infant death syndrome, and greater risk for child abuse. Thus, NIDA supports a variety of research projects to investigate the treatment of drug abuse in pregnant women. Examples follow. Pregnant girls and women who smoke cigarettes run an increased risk of miscarriage, stillborn or premature infants, or infants with low birth weight. Maternal smoking may also be associated with learning and behavioral problems in children. Smoking more than one pack of cigarettes per day during pregnancy nearly doubles the risk that the affected child will become addicted to tobacco if that child starts smoking. NIDA supports research to help pregnant women stop smoking through: treatment of comorbid mood disorders; use of voucher based incentives; and computer-assisted motivational treatments.

Treatment of pregnant women who are addicted to opiates (e.g. heroin, morphine) is critical for both mother and infant. *In utero* exposure to opiates can result in neonatal abstinence syndrome (NAS), which may require pharmacological treatment and extended hospitalization during the neonatal period. A five-site multi-center trial, Maternal Opioid Treatment: Human Experimental Research (MOTHER), has been funded to systematically compare the efficacy of methadone and buprenorphine in opioid-dependent pregnant women and their *in-utero* drug-exposed infants. Results of the study will provide needed evidence on the safety and efficacy of methadone vs. buprenorphine, and may be used to support a request for an FDA review of

labeling changes for both medications. Results from this and other studies can improve the care of pregnant women who are addicted to opiates and other drugs, as well as their drug-exposed newborns.

[These programs reside within NIDA's Division of Pharmacotherapies and Medical Consequences of Drug Abuse, and NIDA's Division of Clinical Neuroscience and Behavioral Research, with oversight responsibilities assigned to various program staff.]

Smoking Cessation Treatments for Women and Girls:

Cigarette smoking and nicotine addiction is one of the most common, and most difficult, substance abuse problems to treat. Although there has been a decline in smoking in the United States in recent years, the decline is far greater in males than in females. Nicotine replacement therapies are effective for both men and women, but unfortunately they are less effective for women. Particularly alarming is the rate of smoking among adolescent girls, including pregnant adolescent girls (see statistics below). Thus, NIDA supports a program of behavioral and combined behavioral and pharmacological research that includes adjunctive exercise interventions for women; treatment of tobacco use in drug-addicted and incarcerated women, motivation and skills training for high risk adolescents involved in the criminal justice system; use of technology to monitor smoking and cessation (e.g., ecological momentary assessment); and the treatment of young adult smokers who also abuse alcohol. This program resides within NIDA's Division of Clinical Neuroscience, Development, and Behavioral Treatment with oversight responsibilities assigned to various program staff.

NIDA's Clinical Trials Network (CTN):

NIDA's CTN is a national consortium of drug abuse investigators and community treatment providers (CTP), who cooperatively develop, validate, refine, and deliver new treatment options to patients in community-level clinical practice. Currently, the CTN comprises 16 regional centers at academic medical centers, affiliated with more than 240 CTPs throughout the United States and Puerto Rico. Results from three clinical trials specifically targeting women have recently been published: (1) Reducing HIV/STD Risk Behaviors: A Research Study for Women in Drug Abuse Treatment, (2) Women's Treatment for Trauma and Substance Use Disorders, and (3) Motivational Enhancement Therapy (MET) to Improve Treatment Utilization and Outcome in Pregnant Substance Users.

Currently, the trial data for 18 multi-site clinical trials are available for secondary analyses at www.ctndatashare.org. NIDA encourages investigators to take advantage of these data for addressing gender specific questions. In addition, as new trials are planned, NIDA invites scientists to work with the trial investigators to plan ancillary or platform studies that can provide needed information on issues that can affect women in drug abuse treatment.

[Program resides within NIDA's National Drug Abuse Treatment Clinical Trials

Network, with oversight responsibilities assigned to various program staff.]

a. Relevant Statistics:

- Even with fewer years of substance use, females at treatment entry average more medical, psychiatric, and adverse social consequences of their substance use disorders than males.
- Among pregnant women aged 15 to 44 years, 16.4 percent of the women in this age category reported cigarette smoking in the last month (vs. 28.4 percent of non-pregnant) (NSDUH 2007).
- Among pregnant youth aged 15-17, 24.3 percent of girls reported past month cigarette smoking (vs. 16.1 percent for non-pregnant), and 22.6 percent reported past month use of illicit drugs (vs. 13.3 percent of non-pregnant). Thus, among young women aged 15-17, there are *higher* rates of smoking among those who are pregnant compared to those who are not pregnant.
- Women constitute approximately 40 percent of the treatment-seeking adults seen in NIDA's CTN.

2. Future Programs: NIDA includes a focus on sex/gender differences in many of its specific funding announcements, and has an ongoing call for research on women, gender differences, and drug abuse, which covers all areas of drug abuse related research. Additionally, NIDA supports dissertation research in the area Women and Sex/Gender differences. Other prioritized funding areas in the coming years that include a focus on sex/gender research are:

- *Prescription Drug Abuse*—to understand the factors contributing to prescription drug abuse, to characterize the adverse medical and social consequences, and to develop effective prevention, behavioral and pharmacological treatments, and service delivery approaches. Applications are encouraged across a broad range of experimental approaches including basic, clinical, and epidemiological studies.
- *Interactions between Physical Activity and Drug Abuse*—to stimulate investigations—using animal models or human subjects—of neurobiological and behavioral mechanisms that underlie the effects of physical activity on brain function across the lifespan, and to provide knowledge on the effects of exercise and physical activity as prevention and treatment strategies for drug abuse.
- *Women's Mental Health in Pregnancy and the Postpartum Period*—to spur research on the effects of current or lifetime drug abuse, including treatment status and comorbid conditions, on onset and course of mental disorders during pregnancy or the perinatal period (co-sponsored by NIMH).
- *Health Services Research on the Prevention and Treatment of Drug and Alcohol Abuse*—to improve the quality of prevention and treatment services for drug and alcohol abuse, by way of: (1) clinical quality improvement; (2) organizational/managerial improvement; (3) systems of care and collaborative research; or (4) development or improvement of research methodology used in the study of drug and alcohol services

(co-sponsored by NIAAA).

- *Medications Development for the Treatment of Amphetamine and Amphetamine-Like Related Disorders*—to encourage preclinical and clinical research directed towards the identification, evaluation and development of safe and effective medications for the treatment of stimulant addiction.

- *Treatment and Prevention of Addiction for Military, Veterans and Their Families*—planned for release this summer as a combined NIDA/NIAAA/NCI/VA initiative.

a. **Target Population(s):** Pregnant women, women smokers, and adolescents, patients in community treatment settings; deployed families and women veterans with substance use and PTSD.

B. Overarching Recommendations

Women are underrepresented among individuals seeking drug abuse treatment, even when their lower drug abuse prevalence rates are taken into account. This disparity may stem from a constellation of cultural, economic, and health factors that could include stigma, lack of family support, need for child care, pregnancy, fears concerning child custody, comorbid psychiatric problems, and treatment access. In addition, women and men define their substance-related problems differently, bringing them to different healthcare settings and potentially contributing to different rates of drug abuse treatment entry. Moreover, predictors of treatment retention, completion, or outcomes (e.g., background characteristics) also vary by gender. Thus efforts are needed to develop new behavioral and pharmacotherapeutic options for women and girls, including a special focus on adolescents--to intervene early and prevent myriad adverse health and life outcomes, on pregnant women who risk harm to themselves and their unborn child; and on women with comorbid mental conditions, including depression, anxiety disorders, including PTSD, and eating disorders.

A. Programs That Improve the Lives of America's Women and Girls

1. Program Description:

HIV/AIDS-- Women, Infants, and Children

Among both males and females, few drug abuse consequences are more severe than HIV infection. Drug abuse heightens the risk of contracting HIV through shared injection equipment and altered decision-making, resulting in increased sexual risk-taking behaviors. And while all groups are affected by HIV/AIDS, not all are affected equally, with HIV/AIDS a growing issue for women, and particularly African American Women (see statistics below). To address these problems, NIDA's HIV/AIDS research program includes studies of gender-related differences in factors that contribute to and protect from HIV risk, including identification of high risk subpopulations. Other studies are pursuing gender-specific strategies to decrease injection drug use and high-risk sexual behaviors among women. Also, included in this program are studies that address the intertwined relationship between HIV/AIDS, other sexually transmitted diseases (e.g., HCV, HCB, TB), and drug use, especially among women and girls.

NIDA also supports research aimed at studying potential developmental effects of fetal and infant exposure to antiretroviral drugs (ARVs) used for the treatment of HIV, including infants also exposed to licit and illicit drugs of abuse, e.g., tobacco, marijuana, and alcohol. To this end, NIDA participates in the Pediatric HIV/AIDS Cohort Study (PHACS: <https://phacs.nichdclinicalstudies.org/overview.asp>), which has two main objectives (1) to investigate the long-term safety of fetal and infant exposure to ARVs and (2) examine the developmental outcomes of perinatally acquired HIV infection in adolescents and young adults.

[NIDA's program resides within NIDA's Office of AIDS Research, with oversight responsibilities assigned to various program staff in program divisions.]

a. Relevant Statistics:

- In 1990, women accounted for about 11 percent of all new reported AIDS cases, a percentage that increased to over 26 percent of cases in 2005.
- African American women are especially vulnerable:
 - o In 2007, 66 percent of the 10,977 HIV/AIDS diagnoses were among black women, compared to 18 percent among white women, and 14 percent among Hispanic women.
 - o In 2005, HIV was the third leading cause of death for black women aged 25-44 and the fourth leading cause of death for Hispanic women aged 35-44.

2. Future Programs: NIDA has an ongoing call for research on women, gender differences, and drug abuse, which covers all areas of drug abuse-related research. Additionally, NIDA includes a focus on sex/gender differences in many of its specific funding announcements, and supports dissertation research in the area women and sex/gender differences. Other prioritized funding areas in the coming years that include a focus on sex/gender research are:

- *Drug Abuse Aspects of HIV/AIDS*—to encourage drug abuse research to address the changing dynamics of the HIV/AIDS epidemic in the U.S., such as the increasing over-representation of minorities and women among new AIDS cases, and role of heterosexual sex as a transmission route. Studies are needed to develop novel preventive interventions that more effectively address the evolving epidemic. Internationally, studies are needed on how to translate and adapt interventions that have proven effective in the U.S. to other communities and cultures; and to learn from other countries' experiences about the causes, consequences, and differences in HIV-associated risks, morbidity, and mortality in diverse populations.

Overarching Recommendations

Because of the higher prevalence of HIV/AIDS in men than women, the issues

surrounding HIV/AIDS in women often are less recognized and receive less research attention. However, women have always been affected too, disproportionately so for women of color. Growing evidence suggests that issues surrounding HIV/AIDS among males and females are not the same, including the sub-population of drug users. Additional efforts are needed to develop interventions for drug abusing women with HIV/AIDS, those with HIV-risk behavior, and children who are born to HIV-positive, drug-using women. This should include populations with known risk factors (e.g., homeless youth and families, adolescent minority youth, low income females, sexual minority youth, and transgender youth). The goal would be to reduce, and hopefully eliminate, the transmission and harm of HIV/AIDS to women and their infants.

XXIV. NIH / Office of the Director / National Institute of Dental and Craniofacial Research (NIDCR)

The National Institute of Dental and Craniofacial Research (NIDCR) is one of 27 Institutes and Centers comprising the National Institutes of Health (NIH). Authorized by the Congress in 1948, it was the third NIH institute to be formed. The mission of the NIDCR is to improve oral, dental and craniofacial health through research, research training, and the dissemination of health information. This includes funding clinical and basic research to understand, prevent and treat oral and craniofacial diseases that disproportionately or solely affect women. These diseases include orofacial pain, diseases of the temporomandibular joint (TMJ), osteoporosis of the craniofacial complex, salivary gland diseases, autoimmune diseases, and oral diseases of pregnant women. NIDCR also makes a concerted effort to encourage young women to pursue scientific careers. In Fiscal Year 2008, the NIDCR reported \$36,266,502 funding spent to support research relevant to women's health issues.

A. Sex Differences in Pain and Temporomandibular joint disorders

1. Program Description

Program location: The National Institute of Dental and Craniofacial Research (NIDCR), National Institutes of Health, Department of Health and Human Services.

Leadership: This program is an overarching scientific research endeavor that spans the NIDCR organizational structure. It encompasses all four overarching goals of the NIDCR strategic plan. For that reason, general oversight for this program endeavor occurs at the highest levels of leadership, including Directors of the Divisions of Extramural and Intramural Research, and the Institute Director.

a) Relevant Statistics: Approximately 20% of all chronic pain is associated with the head and neck, and this pain disproportionately affects women. A recent survey found over 70% of individuals suffering chronic pain of the head and neck regions were female. The NIDCR supports several investigators examining sex differences in pain, including differences in sensitivity to pain stimuli and autonomic system tone. Results published to date suggest females are more sensitive to acute noxious stimuli than males. In addition, human females have more vasoconstriction due to a higher resting activation of the sympathetic

nervous system. These findings suggest that women should be more sensitive to noxious cold than males. Results from recent animal studies confirm these findings and highlight the importance of studying sex differences in pain research.

Temporomandibular joint disorders are important chronic pain conditions of the joint connecting the jaw to the skull, and are of particular interest to the NIDCR. The most common cause of facial pain is temporomandibular joint and muscle disorders (TMJD), which cause recurrent or chronic pain and dysfunction in the jaw joint and its associated muscles and supporting tissues. TMJD is the second most commonly occurring musculoskeletal condition resulting in pain and disability (after chronic low back pain), affecting approximately 5 to 12% of the population, with an annual cost estimated at \$4 billion. About half to two-thirds of those with TMJ disorders will seek treatment. Among these, approximately 15% will develop chronic TMJD. A recent study estimated the prevalence of myofascial temporomandibular joint disorder in community dwelling women to be 10.5 percent, and the prevalence appeared to be higher in younger women, women of lower socio economic status, Black women and non-Hispanic women.

b) Current Activities: NIDCR researchers developed a new, noninvasive way to measure TMJ pain in animals that is based upon an analysis of meal pattern duration. Results of experiments using the model suggest that both estrogen and progesterone may play an important role in regulating pain responses to noxious inflammatory insults. The NIDCR recently launched a seven-year clinical study that will accelerate research on our understanding of the biological and psychological risks for developing chronic TMJD and their treatments. The study, named Orofacial Pain: Prospective Evaluation and Risk Assessment or OPPERA, is the first large longitudinal prospective clinical study to identify risk factors for the onset and persistence of TMJD, and this multi-center study involves investigative units at: University of Florida in Gainesville, University of Buffalo-SUNY, University of Maryland at Baltimore, and the University of North Carolina Chapel Hill. Investigators are following 3,400 healthy volunteers from three to five years to see how many develop the disorders.

NIDCR is funding a multi-pronged approach to develop basic cellular and tissue-level knowledge, coupled with advances in tissue reengineering, to engineer *in vitro* TMJ disc prototypes that approximate natural disc structure and function for use in future clinical trials testing treatments of individuals with advanced TMJ destruction.

The NIDCR recently funded a study to determine if they could predict whether or not a patient with acute TMJD is likely to progress to chronic TMJD, and to determine the best therapy for those most likely to develop chronic TMJD. TMJD patients will be recruited from the community and

screened to determine the likelihood that their condition will become chronic. Those at highest risk for developing chronic TMJ disorders will be randomly assigned to one of two possible treatments.

TMJD Awareness Effort: NIDCR launched an initiative in spring 2008 to raise awareness about temporomandibular joint and muscle disorders and the availability of the Institute's patient education booklet on this topic, TMJ Disorders. The overall goal of this awareness effort is to help people with TMJ problems make prudent decisions about their care. The message "Less is Often Best in Treating TMJ" targets women ages 25-44, the group most commonly affected by this condition, and cautions against unnecessary and potentially harmful treatments. Media kits and email blasts sent to editors of national women's and health magazines highlight the issues addressed in the TMJ Disorders booklet and include "Less is Often Best" ready-for-print ads featuring women in the TMJD demographic. Links to the TMJ Disorders booklet, article for consumers, and advertisements suitable for use in newsletters, magazines and other publications are available on the TMJD page of the NIDCR website: <http://www.nidcr.nih.gov/OralHealth/Topics/TMJ/> .

2. Future Programs:

a) Target Populations: This program will continue to target women of all ages at risk for TMJD. Basic science findings defining sex differences in pain stimuli responses are relevant to all females, regardless of age.

b) Benchmarks: The program will continue to be evaluated primarily by 1) the generation of new knowledge in peer-reviewed publications about the mechanisms and genetics of sex differences in pain from researchers supported through this program and 2) the generation of evidence-based treatments for prevention or treatment of TMJD and 3) dissemination of evidence to the public and clinicians caring for patients

B. Osteonecrosis of the Jaw and Osteoporosis (ONJ)

1. Program Description

Program location: The National Institute of Dental and Craniofacial Research (NIDCR), National Institutes of Health, Department of Health and Human Services.

Leadership: This program is an overarching scientific research endeavor that spans the NIDCR organizational structure. It encompasses all four overarching goals of the NIDCR strategic plan. For that reason, general oversight for this program endeavor occurs at the highest levels of leadership, including Directors of the Divisions of Extramural and Intramural Research, and the Institute Director.

a) Relevant Statistics: According to the International Osteoporosis Foundation, over 200 million people worldwide suffer from osteoporosis, including approximately 30% of all postmenopausal women in the United States and in Europe. They estimate that at least 40% of these women and 15-30% of men sustain one or more fragility fractures in their

remaining lifetime. A major increase in incidence is expected due to aging of the population.

The exact incidence of bisphosphonate-associated ONJ is unknown but ranges from 0.03% to 10.5% in published reports. This is in part due to the lack of recognition of the condition and under-reporting, and lack of well characterized sufficiently powered cohorts for epidemiological studies. However, collectively, there is an extremely low incidence of ONJ for patients receiving bisphosphonate treatment for less than 12 months, suggesting that the cumulative effects of dose and time contribute to the manifestation of this adverse event.

b) Current Activities: Bone is living, growing tissue that constantly forms new bone while replacing older bone. When this process of bone resorption and new bone formation becomes unbalanced, the bone can become weakened, and diseases such as osteoporosis – *which women are four times more likely than men to develop* – can result. Osteoporosis is one of the diseases that affect mineralized tissues of the craniofacial complex, as well as periodontal disease and bisphosphonate-associated osteonecrosis, and thus is an area of intense study for NIDCR-supported researchers. Recent advances in this area include publication of a clinical trial testing treatments for periodontitis in osteopenic women, and clinical studies defining risk factors for osteonecrosis of the jaw.

Bisphosphonates are drugs that slow bone resorption and increase bone formation. Oral bisphosphonates are used to prevent bone loss and are prescribed for patients with osteoporosis or osteopenia, while intravenous bisphosphonates are primarily used to treat bone erosion and hypercalcemia associated with bone metastasis, Paget's disease and multiple myeloma. In 2003, reports appeared in the literature that suggested use of bisphosphonates could lead to development of ONJ. Patients with ONJ present with painful, exposed and necrotic bone, which may develop after invasive dental procedures or spontaneously. These lesions are non-healing or slow to heal, and can be complicated by secondary infection. Most cases of ONJ are related to intravenous bisphosphonate use in cancer patients, but several cases are associated with oral bisphosphonates. The NIDCR recognized the significance of the clinical problem and has funded studies examining the etiology and epidemiology of the problem.

One study used medical claims data from 714,217 people with osteoporosis or cancer to identify diagnostic codes or procedure codes for three outcomes: inflammatory conditions of the jaws, including osteonecrosis; major jaw surgery necessitated by necrosis or inflammation; and jaw surgeries necessitated by a malignant process. Their results indicate that oral administration of bisphosphonates decreases the risk of adverse bone outcomes, but intravenous (IV) administration strongly and significantly increases the risk of adverse jaw outcomes or surgery. Across both osteoporosis and cancer, patients receiving IV administration had a fourfold increased risk of having inflammatory jaw conditions and a greater than six fold increased risk of having undergone major surgical resection in the jaw. More clinical studies are needed to replicate and clarify these observed associations.

The three NIDCR funded Dental Practice-based Research Networks are completing a study to define risk factors for ONJ in patients (primarily women) treated with bisphosphonates. Preliminary data suggest that the risk of developing ONJ is low, but may be associated with particular dental procedures and aggravated by other systemic medical conditions.

Some antibiotics in the tetracycline family can inhibit processes that help mediate bone resorption. For example, minocycline can increase bone formation and decrease bone resorption, resulting in increased systemic bone density in rats whose ovaries have been removed. Estrogen deficiency in post-menopausal women can contribute to osteoporosis. The mechanism involves accelerated bone resorption and has been associated with increased tooth loss and oral bone loss. These findings provided the basis for a clinical trial to determine the efficacy of 2-year continuous low dose doxycycline on alveolar bone in postmenopausal osteopenic, estrogen-deficient women undergoing periodontal maintenance therapy. All received periodontal maintenance therapy. Although there was no statistically significant effect of doxycycline on the bone loss associated with periodontal disease of the entire group, subgroup analyses suggested some benefits. A significant clinical finding from the study was that conventional periodontal therapy controlled most periodontal disease of postmenopausal osteopenic women at risk for tooth loss.

a) Target Populations: This program will continue to target women of all ages at risk for osteoporosis and ONJ. Findings are most relevant to older women and women undergoing cancer therapy. Basic science findings defining mechanisms of bone loss or formation are relevant to all females, regardless of age.

b) Benchmarks: The program will continue to be evaluated primarily by 1) the generation of new knowledge in peer-reviewed publications about the mechanisms of osteoporosis and ONJ from researchers supported through this program and 2) the generation of evidence-based treatments for prevention or treatment of ONJ and 3) dissemination of evidence to the public and clinicians carrying for patients.

C. Sjögren's Syndrome and Salivary Hypofunction

1. Program Description

Program location: The National Institute of Dental and Craniofacial Research (NIDCR), National Institutes of Health, Department of Health and Human Services.

Leadership: This program is an overarching scientific research endeavor that spans the NIDCR organizational structure. It encompasses all four overarching goals of the NIDCR strategic plan. For that reason, general oversight for this program endeavor occurs at the highest levels of leadership, including Directors of the Divisions of Extramural and Intramural Research, and the Institute Director. Some portions of this research program area occur in partnership with colleagues at the National Eye Institute.

a) Relevant Statistics: Sjögren's syndrome (SS), an autoimmune disease that progressively destroys salivary and tear glands, is a high priority research area for the NIDCR. Saliva is a complex fluid that is central to maintenance of oral health. If insufficient quantities of saliva are made, severe impairments in oral health can develop. These include sometimes dramatic increases in dental caries, difficulty in swallowing, chewing, and speaking as well as loss of enjoyment of food, thrush (oral yeast infection), and reduced quality of life. Sjögren's syndrome is the second most common autoimmune disease in the United States, estimated to affect 1-2 million people, and nine out of ten Sjögren's patients are women. The most serious complication of SS is the greatly increased risk for developing malignant lymphoma, which is estimated to occur 40 times more frequently in these patients.

b) Current Activities: Recognizing that the lack of data and biospecimens was a significant roadblock for moving discoveries ahead in the field of Sjögren's syndrome, the NIDCR spearheaded an effort to establish Sjögren's patient registries at two extramural institutions as well as through our intramural program. These groups are working together to generate and share genome-wide genotyping data and clinical information from the cohorts enrolled through these efforts to the general research community. This resource should jump-start efforts to understand genetic contributions to Sjögren's syndrome and the etiologic overlap with related autoimmune conditions that also disproportionately affect women, such as Systemic Lupus Erythematosus and Rheumatoid Arthritis.

SS is a complex disease that can go undiagnosed for months to years. Early detection and diagnosis allow greater opportunity to slow, inhibit or even reverse disease progression. Investigators conducted comprehensive analysis of the composition of whole saliva from 10 primary Sjögren's patients and 10 matched control subjects. Out of hundreds of proteins and thousands of messenger RNA transcripts profiled, 16 peptides and 27 transcripts were found to be differentially expressed between Sjögren's patients and controls. This study is a significant first step toward defining a molecular profile for SS that could be garnered from a simple saliva sample. Significant effort is now

required for the validation of this panel of potential biomarkers. Intramural scientists continue to examine physiology, growth and development of salivary glands. These investigations help identify pathways that could be targeted by therapeutic medications, or define how salivary glands could be re-engineered to regain their function. Recent findings from intramural investigators include a genetic study demonstrating that certain genetic polymorphisms associated with rheumatoid arthritis and systemic lupus erythematosus also are associated with the primary form of SS. These intramural investigators also recently completed a clinical trial that tested the drug Raptiva for treatment of primary SS and are conducting an ongoing clinical study characterizing autonomic function in SS.

Several studies in animals suggest salivary glands can be used to make new proteins through gene therapy that have the potential for disease treatment. However, it is important to determine if this approach is equally successful in males and females. In one study, scientists compared male and female mice that received a protein expression vector directly into a salivary gland. A significant sex-related difference was found. Male mice had over two times the amount of vector expression in the salivary glands than did females, and vector expression lasted longer in males. These experiments demonstrate that sex may be a significant factor that influences the clinical application of gene therapy in salivary glands.

2. Future Programs:

a) Target Populations: This program will continue to target women of all ages at risk for Sjögren's syndrome. Findings are most relevant to adult women, as Sjögren's syndrome is rare in children.

b) Benchmarks: The program will continue to be evaluated primarily by 1) the generation of new knowledge in peer-reviewed publications about the mechanisms and genetics of Sjögren's syndrome from researchers supported through this program, 2) the development of better diagnostic methods to identify persons with SS, 3) the generation of evidence-based treatments for treatment of SS, and 4) dissemination of evidence to the public and clinicians carrying for patients.

D. Oral Health of Pregnant Women

1. Program Description

Program location: The National Institute of Dental and Craniofacial Research (NIDCR), National Institutes of Health, Department of Health and Human Services.

Leadership: This program is an overarching scientific research endeavor that spans the NIDCR organizational structure. It encompasses all four overarching goals of the NIDCR strategic plan. For that reason, general oversight for this program endeavor occurs at the highest levels of leadership, including Directors of the Divisions of Extramural and Intramural Research, and the Institute Director. No other agencies are involved.

a) Relevant Statistics: Pregnancy strains bodily systems, and the mouth is no

exception. For expectant and new mothers, maintaining good oral health is crucially important not only for their teeth, but also for the rest of their body. Medical researchers have only recently begun to understand the complexity of the relationship between poor oral health and its effects on other bodily systems. For example, the fluctuations of female sex hormones at various stages in a woman's life cause an exaggerated response by the gums to plaque. Previous studies suggest the infectious organisms causing periodontal disease and the inflammation associated with untreated periodontitis could have serious deleterious effects during pregnancy.

b) Current Activities: NIDCR sponsored two large randomized trials to determine if non-surgical treatment of periodontal disease during pregnancy reduced the incidence of preterm birth and associated growth restriction. Both the Obstetrics and Periodontal Therapy Trial (OPT Trial) and the Maternal Oral Therapy to Reduce Obstetric Risk Trial (MOTOR Trial) were designed to determine whether pregnant women having non-surgical periodontal therapy during the second trimester of pregnancy had fewer premature and/or low-birth weight infants as compared to women having periodontal therapy delayed until after delivery. Findings indicated that pregnant women who received nonsurgical treatment for their periodontal disease did not significantly lower their risk of delivering a premature or low-birth weight baby. This study also evaluated the safety of general dental care during pregnancy. It found that dental treatment through the second trimester - both general dental and periodontal care - did not increase the number of adverse events for women. The MOTOR study was completed in FY2008 and results should be available in the near future.

In previous cross-sectional or case-control studies, clinical periodontal disease has been associated with gestational diabetes mellitus. To test the potential possible association, investigators measured clinical, bacteriological (in plaque and cervico-vaginal samples), immunological, and inflammatory mediator parameters 7 weeks before the diagnosis of gestational diabetes mellitus in 265 predominantly Hispanic women in New York. Twenty-two cases of gestational diabetes mellitus emerged from the cohort (8.3%). When the cases were compared with healthy control individuals, higher pre-pregnancy body mass index, vaginal levels of the periodontal pathogen *Tannerella forsythia*, serum C reactive protein, and prior gestational diabetes mellitus emerged as risk factors, though clinical periodontal disease did not.

NIDCR also is supporting three studies investigating various approaches to health promotion interventions to improve the oral health of women and their infants. The studies include investigation of common barriers to oral health care in pregnancy and oral health advocates.

2. Future Programs:

a) Target Populations: This program targets women of child-bearing potential and their unborn children.

b) Benchmarks: The program is evaluated primarily by 1) the generation of new knowledge in peer-reviewed publications about the mechanisms of periodontal disease during pregnancy from researchers supported through this program 2) the generation of evidence-based treatments for treatment pregnant women with

periodontal disease and 3) dissemination of evidence to the public and clinicians carrying for patients.

Overarching Recommendations:

Consistent with our strategic plan, the NIDCR intends to continue to push forward the science related to these important women's health issues as quickly as scientific progress and available resources allow. Newer technologies, while holding great promise, also require great investment, as do large-scale clinical studies. In partnership with sister ICs, the NIDCR encourages applicants to submit study proposals through the announcement *Advancing Novel Science in Women's Health Research (ANSWHR)* through January 8, 2010.

We recognize the accomplishments that have been enabled by the systematic encouragement of research and interventions targeting women's health. We recommend continued attention to the importance of inclusiveness in research, including gender, age, and racial balance in assessment of the effectiveness of health interventions and disease prevention. We also urge additional efforts to encourage young people, and young women in particular, to consider a career in the sciences.

XXV. NIH / Office of the Director / National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Diabetes Prevention Program/Outcomes Study

1. Program Description

Diabetes prevention is crucial to improving the health of women and girls. Diabetes affects an estimated 23.6 million people in the United States, including at least 11.5 million women, and is the seventh leading cause of death. Another 57 million Americans are at risk for the disease. Diabetes lowers average life expectancy by up to 15 years, increases cardiovascular disease risk two-to four-fold, and is the leading cause of kidney failure, lower limb amputations, and adult onset blindness. Women are at a much greater risk of heart disease and stroke due to diabetes. Certain populations of minority women are affected disproportionately by end-stage renal disease as a result of diabetes. Ninety to ninety-five percent of diabetes cases are type 2 diabetes. Women who are obese, women who have had gestational diabetes, older women, and women who are members of racial/ethnic minorities in the United States are at significantly increased risk of developing type 2 diabetes.⁷²

The landmark Diabetes Prevention Program (DPP) clinical trial spearheaded by NIDDK compared the effect of intensive lifestyle modification, treatment with the drug metformin, and standard medical advice on preventing the development of type 2 diabetes in adults at high risk. Published in 2002, the DPP results showed that participants who received the lifestyle intervention had a dramatically reduced risk—by 58 percent—of developing type 2 diabetes. Metformin reduced diabetes risk by 31 percent. Sixty-eight percent of the DPP study participants were women; NIH ORWH support for the DPP facilitated recruitment and retention of women with a history of gestational diabetes (13 percent of all female participants). Currently, the NIDDK and other NIH and HHS components are supporting the Diabetes Prevention Program Outcomes Study (DPPOS), a comprehensive follow up study of participants in the DPP. The DPPOS is examining longer-term effects of the trial interventions on prevention of

⁷² National Institute of Diabetes and Digestive and Kidney Diseases. National Diabetes Statistics, 2007 fact sheet. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, 2008.

type 2 diabetes and its cardiovascular complications in DPP participants. The DPPOS will compare outcomes for women and men, and by age and ethnicity. The DPPOS will enable researchers to better determine the lasting benefits to diabetes prevention and/or the delay of onset.

This research program is supported by the NIDDK Division of Diabetes, Endocrinology, and Metabolic Diseases.

DPPOS co-sponsors: NIA, NEI, NHLBI, ORWH, NICHD, CDC, and IHS

a. Relevant Statistics: Sixty-eight percent of the DPP study participants were women; ORWH support for the DPP facilitated recruitment and retention of women with a history of gestational diabetes (13 percent of all female participants). The DPP group was also highly diverse (45 percent from minority ethnic and racial groups).⁷³

Gestational Diabetes and Diabetes Prevention

1. Program Description

NIDDK supports a program of research addressing the health challenges and risks posed by diabetes during pregnancy. Women can develop a form of diabetes during pregnancy called gestational diabetes (GDM). GDM affects about 7 percent of U.S. pregnancies annually, increasing risk of complications during pregnancy and birth for both mother and fetus. Women who have had GDM have a 20 to 50 percent chance of developing type 2 diabetes within the 5 to 10 years following pregnancy. GDM occurs more frequently among obese and women with a family history of diabetes, and among African American, Hispanic/Latina, and American Indian and Alaska Native women—women in minority groups already at disproportionately high risk for type 2 diabetes. The children of women with a history of GDM are also at an increased risk for obesity and diabetes compared to other children.⁷⁴ NIDDK is supporting basic and clinical research studies to better understand gestational diabetes and how to prevent it, including:

- Clinical studies in ethnically diverse women with a history of gestational diabetes on approaches to reduce future risk of type 2 diabetes in the women and their children.
- Fundamental research studies of how GDM develops on the molecular and cellular levels, in hopes of identifying therapeutic targets.
- An array of research studies to understand how a mother's diabetes affects the long-term health of children she carried while diabetic.

This research program is supported by the NIDDK Division of Diabetes, Endocrinology, and Metabolic Diseases.

⁷³ Knowler WC, Barrett-Connor E, Fowler SE, Hamman RF, Lachin JM, Walker EA, Nathan DM; Diabetes Prevention Program Research Group. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med.* 2002 Feb 7; 346(6):393-403.

⁷⁴ National Diabetes Education Program. Type 2 Diabetes Risk After Gestational Diabetes Fact Sheet. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health and Centers for Disease Control and Prevention, April 2006. *See also* National Institute of Diabetes and Digestive and Kidney Diseases. National Diabetes Statistics, 2007 fact sheet. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, 2008.

Research to Prevent Type 2 Diabetes in Youth

1. Program Description

An increasing number of girls and boys in the United States are being diagnosed with type 2 diabetes in youth, particularly children from ethnic and racial minorities.⁷⁵ For girls,

this also means that they are already diabetic during their childbearing years, with potential long-term health consequences for their own children. NIDDK supports a program of research to understand and prevent type 2 diabetes in youth and to potentially help break the vicious cycle of diabetes during pregnancy increasing risk of diabetes in the next generation. Studies include:

- The HEALTHY study, which is designed to target food service and physical education changes in schools and to promote healthy habits, in hopes of lowering risk factors for type 2 diabetes in middle school students. HEALTHY is being conducted in 42 middle schools across the country in which at least 50 percent of students are eligible for free or reduced-price lunch or belong to a ethnic/racial minority group.
- The SEARCH for Diabetes in Youth study, a large, population-based study of diabetes in racially and ethnically diverse youth. SEARCH is supported by NIDDK and the CDC.

This research program is supported by the NIDDK Division of Diabetes, Endocrinology, and Metabolic Diseases.

Sex/Gender Research on Irritable Bowel Syndrome

1. Program Description

Research supported by NIDDK is helping to improve the lives of women affected by digestive diseases and disorders. A key example is the functional gastrointestinal disorder irritable bowel syndrome (IBS). IBS causes pain and constipation or diarrhea and is especially common in women. While diet and stress contribute to this disorder, the underlying causes are unknown. Symptoms may be influenced by abnormal functioning of the intestinal nervous system and altered perception of intestinal stimuli by the brain. People with IBS have a colon that seems to respond strongly to stimuli that would not bother most individuals. A key goal for research is to understand the interplay of gut and brain pathways in these disorders, and to build upon this knowledge to design effective treatments. Researchers have also been examining sex and gender differences in this interplay. For example, investigators studying women with IBS have found that they perceive visceral pain associated with IBS differently than do healthy volunteers, and exhibit altered brain activity responses to both pain and the anticipation of pain. Pain responses are also heightened in women with IBS who have experienced physical abuse. Moreover, sex/gender-specific differences in brain activity in female and male IBS patients have been identified. These findings may lead to improved treatment strategies and outcomes for IBS-related pain. A key element of the research program is the Specialized Center of Research for Women's Health at UCLA, co-funded by NIDDK and ORWH, that is devoted to identifying sex-related differences in the visceral pain syndromes IBS and interstitial cystitis (a bladder disorder), which often

⁷⁵ National Institute of Diabetes and Digestive and Kidney Diseases. National Diabetes Statistics, 2007 fact sheet. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, 2008.

occur in the same individual.

This research program is supported by the NIDDK Division of Digestive Diseases and Nutrition.

Preventing Weight Gain in Women and Girls

1. Program Description

Adolescence, marriage, post-pregnancy, and menopause confer high risk for the development of obesity in susceptible individuals. Obesity, in turn, is a risk factor for type 2 diabetes and a host of other chronic illnesses. Studies have also demonstrated a link between overweight during pregnancy and early weight gain in offspring. The NIDDK is supporting studies to devise effective strategies for obesity prevention in women and children (particularly in minority racial and ethnic groups in the United States) addressing these vulnerabilities; ORWH is helping to foster this research.

Efforts include:

- Studies testing strategies to prevent obesity in adolescent girls, such as a randomized, controlled trial that will test the efficacy of an intervention that focuses on modifying diet, exercise, and other behaviors in college age girls with body image concerns
- Studies focused on strategies to increase physical activity in young girls from ethnic/racial minorities, who are at high risk for obesity later in life.
- A clinical trial testing a community-based strategy to prevent transition to obesity among middle aged overweight African American women by emphasizing current weight maintenance, rather than weight loss.

This research program is supported by the NIDDK Division of Diabetes, Endocrinology, and Metabolic Diseases and the Division of Digestive Diseases and Nutrition.

Look AHEAD (Action for Health in Diabetes)

1. Program Description

Cardiovascular disease is the leading cause of death in patients with diabetes. The risk of death due to heart disease is increased two-to-four fold in all patients with diabetes as compared to their age-matched non-diabetic counterparts. In women, the risk elevation is even greater--four-to-six fold. Moreover, while CVD mortality in men with diabetes has decreased, it has not decreased in diabetic women; the reasons for this sex difference may be due to biological, behavioral, or health care differences, or a combination of these factors.⁷⁶ An ongoing clinical trial addressing cardiovascular disease and diabetes that may prove especially beneficial for women is the Look AHEAD (Action for Health in Diabetes) clinical trial. This long-term multi-center trial in over 5,100 participants--nearly 60 percent women--is under way to determine if lifestyle intervention can improve cardiovascular outcomes in obese patients with type 2 diabetes. Encouragingly, first-year results of the trial have shown that while A1C, blood pressure and LDL cholesterol improved in both the lifestyle intervention and control groups, participants in the lifestyle intervention group saw greater improvement. Cosponsors include the NHLBI, NINR, ORWH, NCMHD, and the CDC.

⁷⁶ Steinberg HO, Paradisi G, Cronin J, Crowde K, Hempfling A, Hook G, Baron AD. Type II diabetes abrogates sex differences in endothelial function in premenopausal women. *Circulation*. 2000 May 2;101(17):2040-6.

This research program is supported by the NIDDK Division of Digestive Diseases and Nutrition.

Urinary Incontinence Treatment Network

1. Program Description

A conservative estimate is that approximately 13 million Americans, most of them women, suffer from urinary incontinence.⁷⁷ Urinary incontinence is a problem often associated with pregnancy, childbirth, and aging. Women can develop stress urinary incontinence (SUI), in which urine leaks under physical stress; urge urinary incontinence, in which involuntary urine leakage occurs after a sudden urge to urinate; or a mixture of both. Treatment options for urinary incontinence are currently limited to physical therapy to improve muscle tone and bladder control, medications, and surgical procedures. The NIDDK's Urinary Incontinence Treatment Network (UITN) is a multicenter research network conducting clinical trials in order to expand and improve these options for women. UITN efforts and accomplishments include:

- The Stress Incontinence Surgical Treatment Efficacy Trial (SISTER) finding that a procedure using a “sling” made from the patient’s own tissue to support the bladder neck and prevent urine leakage under stress helps more women with SUI achieve dryness than the Burch colposuspension technique.
- An economic study of the SISTER participants revealing the substantial personal economic costs of UI for these women prior to surgery.
- Another trial for SUI, TOMUS (Trial Of Mid-Urethral Slings). TOMUS will compare the outcomes of two minimally invasive surgical sling procedures FDA approved to treat this condition in women.
- Recent completion of a treatment trial for women suffering primarily from urge urinary incontinence (UUI).
- Recruitment for a new trial to evaluate strategies for treating women with mixed incontinence.

This research program is supported by the NIDDK Division of Kidney, Urologic, and Hematologic Diseases. The UITN is co-sponsored by NICHD and has also received support from ORWH.

Multi-disciplinary Approach to the Study of Chronic Pelvic Pain (MAPP) Research Network

1. Program Description

Interstitial cystitis (IC), also called painful bladder syndrome, is a chronic pelvic pain disorder whose cause is not yet known. PBS/IC causes recurring discomfort or pain in the bladder and the surrounding pelvic region. Although the number of American adults with PBS/IC is not known with certainty, recent estimates range from 700,000 to 1 million, mostly women (90 percent).⁷⁸ NIDDK supports a vigorous program of research

⁷⁷ Nygaard I, Thom DH, and Calhoun E. Urinary Incontinence in Women. In: Litwin MS, Saigal CS, editors. Urologic Diseases in America. US Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases. Washington, DC: US Government Printing Office, 2007; NIH Publication No. 07-5512, pp 159-191.

⁷⁸ Clemens JQ, Joyce GF, Wise M, Payne CK. Interstitial cystitis and painful bladder syndrome. In: Litwin MS, Saigal CS, editors. Urologic Diseases in America. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute of Diabetes and Digestive and

focused on elucidating the cause(s) of PBS/IC and on improving treatment and interventions. Recent studies suggest that clues to the etiology of PBS/IC may lie outside the bladder. The multi-center Multidisciplinary Approach to the Study of Chronic Pelvic Pain (MAPP) Research Network is conducting innovative, collaborative studies of chronic urologic pelvic pain disorders in women and men—focusing on PBS/IC and chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS), and the potential relationships between these conditions and other chronic pain disorders, such as fibromyalgia. NINDS, NICHD, and ORWH will contribute scientific expertise to help shape the Network’s research focus.

This research program is supported by the NIDDK Division of Kidney, Urologic, and Hematologic Diseases.

Sisters Together: Move More, Eat Better

1. Program Description

It is estimated that over 80 percent of adult non-Hispanic Black women in the United States are overweight or obese, using the body mass index (BMI) measurement—placing them at risk for many serious health complications. The NIDDK’s Weightcontrol Information Network (WIN) program, “Sisters Together: Move More, Eat Better,” is a national initiative that encourages African American women to maintain a healthy weight by becoming more physically active and eating more healthful foods. Among its publications are: “Celebrate the Beauty of Youth!,” “Fit and Fabulous as You Mature,” “Energize Yourself and Your Family,” and “Walking...A Step in the Right Direction.” WIN has also developed the “Sisters Together Program Guide.” The Program Guide walks community leaders through the steps of program planning, implementation and evaluation. <http://www.win.niddk.nih.gov/index.htm>

National Diabetes Education Program (NDEP)

1. Program Description

The National Diabetes Education Program (NDEP), jointly sponsored by the NIDDK and the CDC, works in partnership with public and private groups on efforts to improve the treatment and outcomes for people with diabetes, to promote early diagnosis, and, ultimately, to prevent the onset of diabetes. The NDEP runs a national multicultural type 2 diabetes prevention campaign—the first in the Nation—with tailored materials and messages for high-risk audiences. “Small Steps. Big Rewards. Prevent Type 2 Diabetes” campaign materials include motivational tip sheets, as well as print and radio public-service ads. The “It’s Never Too Early To Prevent Diabetes” component of this campaign is tailored to women with a history of gestational diabetes (GDM) and their offspring—especially women from racial and ethnic minority groups in the United States, who are at particularly high risk for GDM. Another key NDEP campaign, “Control Your Diabetes. For Life,” emphasizes the key elements of diabetes management to help prevent heart attack, stroke, and other diabetes complications. Materials for both campaigns are available in up to 15 different languages. Materials are also available to help children with diabetes, their families and school personnel deal with diabetes. New

consumer materials available from the NDEP include a CD/DVD called “Movimiento” for Hispanics and a CD/DVD called “Step by Step” for African Americans; both were created to encourage active lifestyles, and include a music video and original songs. An educational toolkit targeting American Indian and Alaska Native youth called “Move It! And Reduce Your Risk of Diabetes” encourages more physical activity in schools. The kit contains posters, fact sheets, resource lists, success stories, and a CD-ROM. Finally, the NDEP has developed a version of its web-based publications catalog in Spanish.⁷⁹ *NDEP is jointly sponsored by NIDDK and CDC.*

NDEP: <http://www.ndep.nih.gov/>

NDEP catalog in Spanish: <http://www.ndep.nih.gov/diabetes/pubs/spanishcatalog.htm>

NDEP youth materials: <http://www.ndep.nih.gov/diabetes/youth/youth.htm>.

XXVI. NIH / Office of the Director / National Institute of Environmental Health Sciences (NIEHS)

A. Programs which Improve the Lives of Women and Girls

1. Program Descriptions

The Sister Study: Environmental Risk Factors for Breast Cancer: The NIEHS Sister Study prospectively examines environmental and familial risk factors for breast cancer and other diseases in a cohort of sisters of women who have had breast cancer. Such sisters have about twice the risk of developing breast cancer as other women. The frequency of relevant genes and shared risk factors will be greater among sisters, increasing the statistical power of the study to detect risks. Studying sisters will enhance the researcher’s ability to assess the interplay of genes and environment in breast cancer risk and to identify potentially preventable risk factors. The prospective design will allow them to assess exposures before the onset of disease and avoid biases common to retrospective studies. The study—projected to last 10 or more years—will also allow them to examine a wide range of health outcomes of relevance to women, and to create a framework from which to test new hypotheses as they emerge. (*NIEHS Intramural, R&D Contracts; with co-funding from NCMHD*)

a) Relevant Statistics: Each year, more than 211,000 women learn that they have breast cancer. The Sister Study is just completing its targeted enrollment of 50,000 sisters of women who have had breast cancer.

The Breast Cancer and the Environment Research Centers: The BCERC is a network of four national centers created in September 2003 by the National Institute of Environmental Health Sciences and the National Cancer Institute to support transdisciplinary teams of scientists, clinicians, and breast cancer advocates to study the impact of prenatal-to-adult environmental exposures that may predispose a woman to breast cancer. The research at each Center includes a biology study, an epidemiology study, and a Community-based Outreach and Translation Core (COTC). The joint research being conducted by the Centers is based on the hypothesis that chemical, physical, and social factors in the environment interact with genetic factors to affect mammary gland development during puberty and across the lifespan in ways that can alter breast cancer risk in later life. The overall outcomes of BCERC will be used to develop public health messages designed to educate young girls and women who are

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at high risk of breast cancer about the role(s) of specific environmental stressors in breast cancer and how to reduce exposures to those stressors. (*NIEHS Extramural; in partnership with NCI and Avon*)

a) Relevant Statistics: Based on current rates, about 1 in 8 women born today will be diagnosed with breast cancer during their lifetime.

Agricultural Health Study: The Agricultural Health Study is a large epidemiological study of farm families to examine how their environmental exposures affect disease risk. Originally developed by the NCI to examine cancer risks, the scope of the project was expanded with funds from NIEHS to include a multitude of other health endpoints, including those with particular relevance to women. Women's health endpoints to be examined include premature ovarian failure, uterine fibroids, endometriosis, systemic lupus erythematosus (SLE), and menstrual function. Other disease risks to be studied are thyroid disease, Parkinson's disease, diabetes, childhood growth and development, asthma and altered lung function, immunologic response, degenerative eye diseases, and neurodegenerative and neurobehavioral effects. Additionally NIEHS is investigating other ways of enhancing this study such as (1) collecting blood and urine from the entire cohort to allow exposure assessment in future studies, (2) analyzing well-water samples for nitrates, and (3) monitoring exposure to pesticides and other agents in specific subsets of the cohort. (*NIEHS Intramural, R&D Contracts; in partnership with NCI*).

a) Relevant Statistics: Over 89,000 individuals are participating in the Agricultural Health Study. This includes private and commercial pesticide applicators as well as the spouses of these applicators.

Uterine Fibroid Study: Uterine leiomyomas (fibroids) are the leading indication for hysterectomy in the United States. Despite the morbidity and high medical costs associated with fibroids, there has been little epidemiologic study of this condition in the United States. To address the research needs in this field we have designed a large epidemiologic study, NIEHS Uterine Fibroid Study, designed to 1) estimate the age specific cumulative incidence of leiomyomas in black and white women, aged 35-49, 2) identify risk factors for the condition, 3) compare growth mediating factors in tumor and matching myometrial tissues collected at time of hysterectomy, and 4) to identify factors associated with development of fibroid symptoms including pelvic pain and uterine bleeding. (*NIEHS Intramural, R&D Contract*)

a) Relevant Statistics: Fibroids are one of the leading causes for hysterectomy in the United States. The NIEHS Uterine Fibroid Study found that by age 50 the cumulative incidence of uterine fibroids was over 80 percent for African American women and about 70 percent for white women. These numbers are much higher than reported from medical records.

Endocrine Disruptor Research: Endocrine disruptors are chemicals that may interfere with the body's endocrine system and produce a host of adverse effects. A wide range of substances, both natural and man-made, are thought to cause endocrine disruption, such as pesticides and plasticizers like bisphenol A. NIEHS supports a full portfolio of studies, from basic biology to toxicology to epidemiology, to determine whether

exposure to endocrine disruptors may result in human health effects including lowered fertility and an increased incidence of endometriosis and some cancers. Research shows that endocrine disruptors may pose the greatest risk during prenatal and early postnatal development when organ and neural systems are forming and may be related to development of disease later in life. The research effort includes a large body of research on estrogenic pathways and environmental estrogens, but other hormone pathways are also under study. (*NIEHS Extramural, Intramural*)

Statistics: Among the molecules identified as endocrine disruptors are industrial solvents/lubricants and their byproducts; polybrominated biphenyls; plastics; plasticizers; pesticides; and pharmaceutical agents.

NTP - Bisphenol A: The National Toxicology Program (NTP) is an interagency program of the Department of Health and Human Services established in 1978. The program was created as a cooperative effort to coordinate toxicology testing programs within the federal government, strengthen the science base in toxicology, develop and validate improved testing methods, and provide information about potentially toxic chemicals to health, regulatory, and research agencies, scientific and medical communities, and the public. Due to growing public concern and widespread use and exposure of bisphenol A (BPA) the NTP has taken an interest regarding human health effects. NTP concluded that there is potential risk for effects on the brain, behavior, and prostate gland in fetuses, infants, and children at current human exposures to bisphenol A. (*NIEHS/National Toxicology Program, an interagency program with NIEHS, CDC, and FDA*)

a) Relevant Statistics: BPA is found in the urine of over 90% of Americans.

The Superfund Research Program (SRP) – Arsenic: SRP is a network of university grants that are designed to seek solutions to the complex health and environmental issues associated with the nation's hazardous waste sites. The research conducted by the SRP is a coordinated effort with the Environmental Protection Agency. The SRP conducts a broad range of studies regarding environmental exposures. One study is examining arsenic as an endocrine disruptor and how it may cause or exacerbate various diseases such as reproductive and developmental problems. The goals of this study are to provide mechanistic insight into the basis of the endocrine disrupting effects of arsenic, to determine the biological consequences of such effects, and to identify potential biomarkers of exposure or effects that are useful in assessing the overall impact of arsenic exposure on human health. (*Extramural; NIEHS Superfund Research Program*)

A) Relevant Statistics: SRP-funded researchers at several universities played a vital role in the process leading to the revised drinking water standard for arsenic by contributing greatly to our knowledge of the risk and health effects of arsenic in drinking water.

Carolina Lupus Study: Systemic lupus erythematosus (SLE) is an autoimmune disease that can cause severe damage to the kidneys, joints, and other tissues. Mortality is also higher among blacks, compared to white, SLE patients. Reasons for the African-American excess risk are not known. NIEHS and the National Center for

Minority Health and Health Disparities (NCMHD) have joined to create The Carolina Lupus Study, a population-based, case-control study in eastern North Carolina and South Carolina designed to examine hormonal and environmental influences on the etiology of SLE. The Carolina Lupus Study offers the opportunity to examine occupational and environmental risk factors in a previously understudied population. These efforts may help illuminate etiologic pathways and develop prevention strategies for susceptible populations. Environmental exposures under study include silica dust, ultraviolet light, solvents, heavy metals, and pesticides. (*NIEHS Intramural, R&D Contracts; in partnership with NCMHD*)

a) Relevant Statistics: The study participants are 90 percent women and 55 percent African-American. Overall, ninety percent of SLE patients are women, and compared to whites, African-Americans are 3 to 4 times more likely to develop the disease.

Epidemiologic Study of Reproductive Outcomes and Environmental Exposures

The intense period of development between conception and delivery lays the foundation for future health of the individual. Factors that interfere with the capacity to conceive, or the healthy development of the fetus, are matters of public concern. NIEHS scientists are investigating factors that trigger the delivery of a baby. Despite intense interest in the causes of preterm delivery and delivery more generally, there is remarkably little information about the processes that initiate labor and delivery. Data from the Norwegian Medical Birth Registry was used to explore genetic components of this phenomenon. Associations were found between father and offspring (as well as with mother and offspring), suggesting that genetic factors transmitted through the fetus contribute to the onset of labor. This evidence for contributions of the fetus to onset of labor may suggest new biological pathways for those who are exploring the mechanisms of labor and delivery more directly. (*NIEHS Intramural, R&D Contracts; with the Norwegian Institute of Public Health*)

a) Relevant Statistics: The Norwegian Mother and Child Cohort Study is an ongoing pregnancy cohort enrolling 100,000 pregnancies.

Genomic and Proteomic Biomarkers of Biological Responses to Exposure

Substances like bisphenol A (BPA), butyl benzyl phthalate (BBP), di-2-ethylhexyl phthalate (DEHP) and genistein may affect human health by disrupting endocrine function. Their possible role in the occurrence of mammary gland and breast tumors later in life from exposure in prepubertal girls is unknown. NIEHS is supporting a project to develop genomic and proteomic technologies for identification of biomarkers of exposure in girls exposed to BPA, BBP, DEHP and genistein. Microarray technology will be used to measure genomic biomarkers of exposure from blood serum and buffy coat, and buccal swabs from prepubertal girls exposed to these chemicals. Sensitive and reproducible methods will be developed to measure protein biomarkers of exposure in blood plasma of prepubertal girls that are expressing high and low levels of these chemicals. An important aspect of this project is also using a rat model of exposure and a human cohort in similar biological conditions (puberty) exposed to the same compounds. From girls going through puberty whose urine identifies them as being exposed to high or low concentrations of specific environmental chemicals, differentially regulated genes and proteins will be measured in blood as biological indicators of

chemical exposure. In the rats, genes and proteins will also be assessed in the mammary glands as a function of exposure and puberty to gain insight into how environmental chemical exposure early in life predisposes for breast cancer later in life.

(NIEHS Extramural)

Future Programs:

a) Targeted Populations: While the basic research that is undertaken by NIEHS provides benefit to all subgroups, several of our human studies are specifically targeting recruitment of African American women and other underserved groups (e.g., the Sister Study and the Carolina Lupus Study).

b) Benchmarks: The BCERC is the subject of a GPRA goal for NIH. 2007 was Year 1 and the goal will conclude in 2011 as follows:

Year 1: Complete recruitment of 1,200 girls; complete pilot analysis of selected environmental exposures. [Completed]

Year 2: Over 85% of the current cohort was successfully contacted and completed questionnaires, with over 85% completing follow-up clinical exams. [Completed]

Conduct Year 3 follow-up clinical exams and data collection for 75% of the cohort to examine the presence of specific markers of exposure and correlate with signs of puberty.

Conduct year 4 follow-up clinical exams and data collection for at least 75% of the cohort to examine the presence of specific markers of exposure and correlate with signs of puberty. Perform chemical analyses of year 1 samples to assess levels of biomarkers in blood and urine.

Overarching Recommendations:

Environmental agents play a role in a number of female-predominant diseases. These are thought to include breast cancer, osteoporosis, ovarian dysfunction, uterine fibroids, and autoimmune diseases, among others. NIEHS approaches women's health research through defining underlying susceptibilities to these diseases, investigating the role of estrogenic and other endocrine-active compounds in their etiology, indentifying important environmental triggers for their development and important nutritional factors that can reduce risk, and determining the importance of timing of exposure to disease risk. As results of these studies become available, women can better determine how to alter lifestyle factors to reduce their risk for these diseases. Even more importantly, the medical and public health communities have a better understanding in preventing, diagnosing and treating these diseases, and regulators can better define standards that protect women from environmental exposures that are related to disease risk.

XXVII. NIH / Office of the Director / National Institute of Mental Health (NIMH)

B. Programs That Improve the Lives of America's Women and Girls

1. Program Description: Women's Mental Health in Pregnancy and the Postpartum Period - National Institute of Mental Health

Through two Program Announcements, the National Institute of Mental Health (NIMH), together with the National Institute on Drug Abuse, the Eunice Kennedy Shriver National Institute of Child Health and Human Development , and the Agency for Healthcare Research and Quality,

encourages and supports research on women's mental health in relation to pregnancy and the postpartum period. As illustrated by a few highly publicized cases, the consequences of severe untreated postpartum depression and psychosis can be devastating for individuals, families, and communities. In addition to the mood disorders, a subset of women enter the perinatal period with active and/or relapsing/recurring drug or alcohol use disorders as well as other mental illnesses (anxiety disorders, eating disorders, schizophrenia) and medical conditions such as infectious disease (HIV, HBV, HCV) that may be related to substance abuse or sexual risk behavior. Untreated perinatal mood and other disorders can have a range of poor maternal functional outcomes, from substance abuse, loss of employment, and divorce to suicidal behavior or death by suicide. Untreated perinatal depression also impairs a mother's ability to promote the infant's cognitive and emotional development. In extreme cases, such as postpartum psychosis, maternal depression has been associated with poorer neonatal outcomes, even infanticide.

NIMH and its partners are currently conducting numerous studies to address these disorders, including research on the clinical course, epidemiological work to determine risk factors, understanding the underlying neurobiology, and developing new interventions and services to screen for and treat these disorders. NIH is already making advances in this area, for example, NIMH-supported researchers have recently pinpointed a mechanism in the brains of mice that could explain why some human mothers become depressed following childbirth (Maguire J, Mody I. GABAAR plasticity during pregnancy: relevance to postpartum depression. *Neuron*. 2008 Jul 31; 59).

a) Relevant Statistics: It is estimated that 8-15 percent of women having children suffer from a clinically significant postpartum mood disorder; of these women, many experienced depressive symptoms during pregnancy. An estimated 0.5 to 1 percent of women will experience a postpartum psychosis.⁸⁰

b) Other: In order to ensure that NIMH research recognizes and incorporates the distinct characteristics, course and treatment needs of women's mental illness, NIMH established a Women's Program in the Office of the Director and Office for Special Populations, to oversee and coordinate research pertinent to women. With 2.5 dedicated federal and contract staff members devoted to coordinating the Program efforts and leading the trans-divisional NIMH Women's Team, the Program keeps senior leadership informed through reports and updates to the NIMH Steering Committee and the Senior Leadership Team. Other functions include serving as an organizational focal point for women's mental health

⁸⁰ Gaynes BN, Gavin N, Meltzer-Brody S, Lohr KN, Swinson T, Gartlehner G, Brody S, Miller WC (RTI-University of North Carolina Evidence-based Practice Center). Perinatal Depression: Prevalence, Screening Accuracy, and Screening Outcomes. Evidence Report/Technology Assessment No. 119. Rockville, MD: Agency for Healthcare Research and Quality; February 2005. AHRQ Publication No. 05-E006-2.

science communication, and liaising with NIMH's Intramural Research Program, the NIH Office of Research on Women's Health (ORWH) and other governmental and non-governmental organizations interested in women's issues.

Additional initiatives:

- NIMH co-funding of the NIH initiative, "Research on Causal Factors and Interventions that Promote and Support the Careers of Women in Biomedical and Behavioral Science and Engineering"
(R01) <http://grants.nih.gov/grants/guide/rfa-files/RFA-GM-09-012.html>
- NIMH participation in the ORWH "Re-Entry Supplements" program which provides training to individuals who have interrupted a science career for a family-related event, so they may resume their research career
PA-08-191 <http://grants.nih.gov/grants/guide/pa-files/PA-08-191.html>
- NIMH co-funding of the ORWH "Building Interdisciplinary Research Careers in Women's Health" (BIRCWH) and "Specialized Centers of Research on Sex/Gender Factors Affecting Women's Health" (SCOR) programs which provide cross-institute, interdisciplinary funding for training of researchers in women's health
- NIMH participation in the ORWH initiative "Advancing Novel Science in Women's Health Research" (ANSWHR) (R03)
<http://grants.nih.gov/grants/guide/pa-files/PAS-07-382.html>, (R21)
<http://grants.nih.gov/grants/guide/pa-files/PAS-07-381.html>

Overarching Recommendations:

NIMH recognizes the need to develop innovative, personalized interventions for mental disorders that incorporate knowledge about the unique biological, environmental, and social factors affecting women. The Institute's Strategic Plan details objectives and priorities that will direct and accelerate research to transform the diagnosis, treatment, and prevention of mental disorders. Through the Plan, NIMH seeks support for continued basic and clinical research to illuminate how the environment influences genes to control their function, and ensuring the participation of women (in addition to that of men) in such studies is essential. The Plan also highlights the need to examine how sex and gender can affect the developmental trajectory of mental disorders, such that the best times and methods for intervention may differ between women and men. Furthermore, NIMH urges researchers to consider sex and gender differences as they develop standard measures of functional outcome for psychosocial and biomedical interventions, as well as novel models of how best to implement mental health interventions. Overall, women need innovative approaches that will broaden the concept of intervention research to address how these interventions affect a person's ability to live a full life, and NIMH continues to work towards that goal.

A. Programs That Improve the Lives of America's Women and Girls

1. Program Description: Women's Mental Health and Sex/Gender Differences Research - National Institute of Mental Health

Through two Program Announcements, the National Institute of Mental

Health (NIMH), encourages and supports research on women's mental health and sex and/or gender differences research. There are differences in both the prevalence and clinical course of mental disorders between men and women. Starting in childhood, girls have higher rates of anxiety disorders than boys. Boys have higher rates of autism and attention deficit disorder. After puberty, women have higher rates than men of depression, eating disorders, and anxiety disorders, including post-traumatic stress disorder. For other serious mental disorders, such as schizophrenia and bipolar disorder, gender disparities in incidence are not found; however, significant differences in clinical course have been demonstrated. The NIMH funds numerous studies of these disorders in men, women and children, but also focuses on three major areas for research emphasis related to sex and gender differences: basic and clinical neuroscience; epidemiology and risk factors; and intervention and services research. The NIMH also devotes a considerable portion of its research portfolio to trauma research. Women are more likely than men to develop **Posttraumatic Stress Disorder (PTSD)** following trauma. Recent advances and outcomes in this area include an NIMH-funded study that has shown that prior exposure to interpersonal violence for women, as compared with men, predicts a higher rate of PTSD following a subsequent non-assaultive trauma, leading the way to future research on ways to circumvent this heightened sensitivity.⁸¹

Some of NIMH's ongoing trauma research on **Violence Against Women** intersects with its research portfolio on **HIV in Women**. For example, one study examines the relationship between HIV risk in women with a history of childhood sexual abuse, another looks at PTSD in HIV+ female adolescents, and another seeks to develop an intervention for adolescent girls that will prevent HIV and partner abuse. Not all women and children who are exposed to violence develop mental health disorders, so it is important to study risk factors, protective factors, personal and organizational responses to trauma, and the course of mental health disorders that follow trauma exposure. Funded research in this area includes studies of domestic violence and the relationship to child mental health, a study on preventing problems for girls in foster care, and a study of the genetic aspect of PTSD in women. Funded intervention research includes studies focused on systems of treatment and determining an effective approach or point of entry of intervention, such as a court-based mental health screening service for victims of intimate partner violence, and a longitudinal study which assesses whether very early home visit interventions in high-risk families prevents a myriad of later life behavioral and mental health problems, including violence.

In December, 2008, NIMH provided support for a meeting on ***Post-traumatic Stress Disorder (PTSD) in Women Returning from Combat***. The Society

⁸¹ Breslau N, Anthony JC. Gender differences in the sensitivity to posttraumatic stress disorder: An epidemiological study of urban young adults. *J Pediatr Psychol*. 2007 Apr;32(3):338-42. Epub 2006 May 22.

for Women's Health Research (SWHR) organized and co-sponsored the meeting in Washington, D.C. with support from the NIMH Women's Mental Health Team as well as DynCorp International, The Goodyear Tire & Rubber Company, and Magellan Health Services, Inc. Speakers discussed the neurobiology of sex and gender differences, as well as the trajectories of female and male PTSD over time, and the latest data on the differing incidence and prevalence of PTSD in males and females, in both civilian and military populations. Speakers also elucidated existing systems of care, including both private sector and military systems. Participants identified strategies for advancing research as well as practical knowledge needed by clinicians in the field. Dec., 2008.

In June, 2009, the NIMH Women's Team provided funding and support for a workshop on *Post-traumatic Stress Disorder in Rural Minority Women*. This plenary session at the National Association for Rural Mental Health's annual conference focused on the historical trauma of American Indian women who have higher prevalence rates for a number of mental health disorders, and the implications for treatment, as well as the issues of incarcerated, traumatized Latina and other women as they return to their communities.

a) Target Population(s): Immediate relevant research focus includes traumatized women and girls, women and adolescent girls at risk for HIV, and military women returning from combat.

b) Additional initiatives:

- NIMH co-funding of the NIH initiative, "Research on Causal Factors and Interventions that Promote and Support the Careers of Women in Biomedical and Behavioral Science and Engineering" (R01) <http://grants.nih.gov/grants/guide/rfa-files/RFA-GM-09-012.html>
- NIMH participation in the ORWH "Re-Entry Supplements" program which provides training to individuals who have interrupted a science career for a family-related event, so they may resume their research career PA-08-191 <http://grants.nih.gov/grants/guide/pa-files/PA-08-191.html>
- NIMH co-funding of the ORWH "Building Interdisciplinary Research Careers in Women's Health" (BIRCWH) and "Specialized Centers of Research on Sex/Gender Factors Affecting Women's Health" (SCOR) programs which provide cross-institute, interdisciplinary funding for training of researchers in women's health
- NIMH participation in the ORWH initiative "Advancing Novel Science in Women's Health Research" (ANSWHR) (R03) <http://grants.nih.gov/grants/guide/pa-files/PAS-07-382.html>, (R21) <http://grants.nih.gov/grants/guide/pa-files/PAS-07-381.html>

Overarching Recommendations:

NIMH recognizes the need to develop innovative, personalized interventions for mental disorders that incorporate knowledge about the unique biological, environmental, and social factors affecting women. The Institute's Strategic Plan

details objectives and priorities that will direct and accelerate research to transform the diagnosis, treatment, and prevention of mental disorders. Through the Plan, NIMH seeks support for continued basic and clinical research to illuminate how the environment influences genes to control their function, and ensuring the participation of women (in addition to that of men) in such studies is essential. The Plan also highlights the need to examine how sex and gender can affect the developmental trajectory of mental disorders, such that the best times and methods for intervention may differ between women and men. Furthermore, NIMH urges researchers to consider sex and gender differences as they develop standard measures of functional outcome for psychosocial and biomedical interventions, as well as novel models of how best to implement mental health interventions. Overall, women need innovative approaches that will broaden the concept of intervention research to address how these interventions affect a person's ability to live a full life, and NIMH continues to work towards that goal.

Programs That Improve the Lives of America's Women and Girls

1. Program Description: Eating Disorders - National Institute of Mental Health

Through its Request for Applications on *Innovative Trials for the Treatment of Anorexia Nervosa in Late Adolescence and Adulthood*, the National Institute of Mental Health (NIMH) continues to encourage and support research on eating disorders. Eating disorders frequently appear during adolescence or young adulthood, but some reports indicate that they can develop during childhood or later in adulthood. Women and girls are much more likely than males to develop an eating disorder. Men and boys account for an estimated 5 to 15 percent of patients with anorexia or bulimia and an estimated 35 percent of those with binge-eating disorder.⁸² Eating disorders are real, treatable medical illnesses with complex underlying psychological and biological causes. They frequently co-exist with other psychiatric disorders such as depression, substance abuse, or anxiety disorders. People with eating disorders also can suffer from numerous other physical health complications, such as heart conditions or kidney failure, which can lead to death. Researchers are studying behavioral questions, along with genetic and brain systems information, to understand risk factors, identify biological markers and develop medications that can target specific pathways that control eating behavior. Neuroimaging and genetic studies may also provide clues for how each person may respond to specific treatments.

Recent advances by NIMH-supported researchers include a brief school-based program for adolescents that uses a "dissonance based" approach.

Compared to young women receiving assessment only, young women who participated in the dissonance program showed significant effects 2- to 3-years after participation on measures of risk factors, eating disorder symptoms and psychosocial impairment.⁸³

⁸² Andersen AE. Eating disorders in males. In: Brownell KD, Fairburn CG, eds. *Eating disorders and obesity: a comprehensive handbook*. New York: Guilford Press, 1995; 177-187.

In order to ensure that NIMH research recognizes and incorporates the distinct characteristics, course and treatment needs of women's mental illness, NIMH established a Women's Program in the Office of the Director and Office for Special Populations, to oversee and coordinate research pertinent to women. With 2.5 dedicated federal and contract staff members devoted to coordinating the Program efforts and leading the trans-divisional NIMH Women's Team, the Program keeps senior leadership informed through reports and updates to the NIMH Steering Committee and the Senior Leadership Team. Other functions include serving as an organizational focal point for women's mental health science communication, and liaising with NIMH's Intramural Research Program, the NIH Office of Research on Women's Health (ORWH) and other governmental and non-governmental organizations interested in women's issues. Additional initiatives:

- NIMH co-funding of the NIH initiative, "Research on Causal Factors and Interventions that Promote and Support the Careers of Women in Biomedical and Behavioral Science and Engineering" (R01)
<http://grants.nih.gov/grants/guide/rfa-files/RFA-GM-09-012.html>
- NIMH participation in the ORWH "Re-Entry Supplements" program which provides training to individuals who have interrupted a science career for a family-related event, so they may resume their research career
PA-08-191 <http://grants.nih.gov/grants/guide/pa-files/PA-08-191.html>
- NIMH co-funding of the ORWH "Building Interdisciplinary Research Careers in Women's Health" (BIRCWH) and "Specialized Centers of Research on Sex/Gender Factors Affecting Women's Health" (SCOR) programs which provide cross-institute, interdisciplinary funding for training of researchers in women's health
- NIMH participation in the ORWH initiative "Advancing Novel Science in Women's Health Research" (ANSWHR) (R03)
<http://grants.nih.gov/grants/guide/pa-files/PAS-07-382.html>, (R21)
<http://grants.nih.gov/grants/guide/pa-files/PAS-07-381.html>

Overarching Recommendations:

NIMH recognizes the need to develop innovative, personalized interventions for mental disorders that incorporate knowledge about the unique biological, environmental, and social factors affecting women. The Institute's Strategic Plan details objectives and priorities that will direct and accelerate research to transform the diagnosis, treatment, and prevention of mental disorders. Through the Plan, NIMH seeks support for continued basic and clinical research to illuminate how the environment influences genes to control their function, and ensuring the participation of women (in addition to that of men) in such studies is essential. The Plan also highlights the need to examine how sex and gender can affect the developmental trajectory of mental disorders, such that the best times and methods for intervention may differ between women and men. Furthermore,

⁸³ Stice E, Marti CN, Spoor S, Presnell K, Shaw H. Dissonance and healthy weight eating disorder prevention programs: long term effect from a randomized efficacy trial. *J Consult Clin Psychol*. 2008 Apr; 76(2): 329-340.

NIMH urges researchers to consider sex and gender differences as they develop standard measures of functional outcome for psychosocial and biomedical interventions, as well as novel models of how best to implement mental health interventions. Overall, women need innovative approaches that will broaden the concept of intervention research to address how these interventions affect a person's ability to live a full life, and NIMH continues to work towards that goal.

Programs That Improve the Lives of America's Women and Girls

**1. Program Description: Work-Life Programs for NIMH Employees
- National Institute of Mental Health**

NIMH work/life programs are not targeted to female employees, but nearly all participants are women. Programs include NIMH workplace yoga courses, offered three days per week; one weekly tai chi course; a weekly onsite weight-management/pilates group; a weekly mindfulness meditation course; monthly stress-reduction seminars; and periodic 8-week healthful eating support groups, with a focus on modeling healthful behaviors for participants' children. NIMH also extends invitations to staff members at nearby ICs. NIMH also issues feedback questionnaires at the conclusion of all the above programs, which generally garner excellent ratings.

The NIMH Telework Program – which assists employees in balancing work/life demands by enabling them to work at home at least 1 day per month and up to 3 days per week – also draws disproportionately higher numbers of women (by a nearly 4:1 ratio).

a) Relevant Statistics:

There are approximately 50-60 staff members (99 percent female) who participate in the above NIMH wellness-programs during any given quarter (viz., yoga, tai-chi, mindfulness, etc), and 156 employees currently approved to telework on a regular basis (121 females, 35 males).⁸⁴

NIMH intends to continue its current offerings and develop new workplace wellness classes, support groups, and workshops, but both women and men will be invited to participate.

B. Overarching Recommendations:

In all its work/life programs, NIMH is primarily striving to provide employees with workplace opportunities to maximize personal health, and secondarily aims to help staff develop healthful behaviors they can model at home for children and spouses.

⁸⁴ NIMH Internal Document: Wellness-Class Registration List for First Quarter of the Calendar Year, compiled by the Management Analysis and Services Branch, National Institute of Mental Health, June, 2009. NIMH Internal Document: Telework Program Database, managed by the Management Analysis and Services Branch, National Institute of Mental Health, June, 2009.

XXVIII. NIH / National Institute of Neurological Disorders and Stroke (NINDS)
Programs That Improve the Lives of America's Women and Girls

1. Educating Women about Stroke: In 2001, NINDS developed “Know Stroke: Know the Signs. Act in Time”, a public awareness campaign to disseminate knowledge of the warning symptoms of stroke and the importance of seeking urgent treatment. NINDS partners with many national, regional and local organizations to expand the impact of the Know Stroke campaign. Since 2004, one such partner has been the General Federation of Women's Clubs (GFWC), the world’s oldest and largest women’s community service organization with some 1500 clubs nationwide. GFWC members host Know Stroke events, distribute campaign materials and feature the campaign in printed publications and on the GFWC web site. NINDS also strives to reach out to those communities that are at a higher risk for stroke. In 2004, NIH entered a partnership with the Centers for Disease Control and Prevention (CDC) to launch a grassroots education program called Know Stroke in the Community. The program identifies and enlists the aid of community leaders who work as “Stroke Champions” to educate their communities about the signs and symptoms of stroke and the need for immediate action. The program focuses on reaching African Americans, Hispanics and seniors in communities that have the health care systems in place to treat stroke. To date, the program has been implemented in twelve cities, educating 184 Stroke Champions who have conducted more than 600 community events. The program was expanded this year to Charleston, South Carolina and, as part of South Carolina efforts, materials will be developed for coastal communities with unique dialects. NINDS also recently expanded its public education programs by collaborating with the Brain Attack Coalition (BAC) to develop a new action-oriented message that all member organizations could use with their current stroke awareness efforts. The BAC is a group of organizations committed to stroke prevention and treatment chaired by NINDS. The new slogan—“Stroke strikes fast. You should too. Call 9-1-1”—was launched in May 2009 during Stroke Awareness Month. On occasion, NINDS staff make themselves available to participate in events and activities that educate targeted audiences about stroke. For example, in June 2008, Dr. John Lynch, program director in the NINDS Office of Minority Health and Research, was interviewed by Dr. Vivian Pinn, director of the NIH Office of Research on Women’s Health, for the podcast “Pinn Point on Women’s Health: Women and Strokes.” The program is available on the NIH web site and has an average of 300 downloads a week.

2. Investigator-initiated research on women’s health or gender-based differences in disease: Most of research on women’s health supported by NINDS comes from investigator-initiated proposals. For example, NINDS-funded researchers are studying the influence of the endocrine system on epilepsy seizure frequency and specific problems related to pregnancy and anti-epileptic drugs. Some forms of Multiple Sclerosis (MS) are more common in women and investigators supported by NINDS are studying the reasons for why

this is. Similarly, certain chronic pain conditions such as migraine headaches or fibromyalgia, tend to be diagnosed more often in women than in men and it is now widely believed that pain affects men and women differently. NINDS supports several research projects examining the differences between men and women in pain sensation and in analgesia and the biological mechanisms responsible for these differences. A number of NINDS-supported investigators are also studying several aspects of Rett syndrome, a childhood autism spectrum disorder associated with mutations on the X chromosome that is almost exclusively seen in females. Finally, NINDS supports a number of investigator-initiated studies on stroke in women. Stroke is the third leading cause of death in the U.S., and a major cause of disability in both women and men. Although women in general have a lower risk of stroke than men, because of their longer life expectancy they account for 60 percent of stroke fatalities.⁸⁵ NINDS recognizes the substantial burden of stroke on women as well as the importance of understanding gender differences in causation, treatment and prevention. To this end, it supports observational research to examine if there are any differences between men and women in stroke risk factors, the presentation of stroke symptoms, or on the eventual health care delivery; studies on the effects of hormones on cell death and repair pathways that are activated following stroke; and clinical studies on the risks of stroke in women with stenosis, or narrowing of the blood vessels.

3. The Role of Gender on Traumatic Brain Injury and Post-Traumatic Spectrum Disorders: In October 2008, the NINDS, the National Institute of Mental Health (NIMH), the National Institute of Child Health and Human Development (NICHD), the Office of Research on Women's Health (ORWH), the Department of Defense-Defense Centers of Excellence (DoD-DCoE), and the Department of Veterans Affairs (VA) co-sponsored a meeting entitled, Trauma Spectrum Disorders: The Role of Gender, Race, and Other Socioeconomic Factors on the NIH campus in Bethesda, MD. The meeting reviewed existing science on trauma spectrum disorders related to military deployment, such as post-traumatic stress disorder (PTSD) and traumatic brain injury (TBI). Speakers and discussants examined gender, race, and other socioeconomic factors as they relate to: a) psychological health needs of populations exposed to high stress, traumatic events, and deployment; b) TBI; and, c) treatment outcomes. The conference underscored the need for improved evidence-based strategies to better assess and treat TBI and associated psychological health issues and the need for more studies to collect data on the influence of gender, race, and socioeconomic factors on these conditions. Plans to continue this collaborative research effort among DoDDCoE, NIH, and VA are underway.

4. Research Supplements to Promote Re-Entry into Biomedical and

⁸⁵ Lloyd-Jones, D et al. *Heart Disease and Stroke Statistics—2009 Update. A Report From the American Heart Association Statistics Committee and Stroke Statistics Subcommittee.* December 15, 2008.

Behavioral Research Careers (PA-08-191)⁸⁶: NINDS is one of several Institutes and Centers that participates in a program to provide financial support for scientists to re-enter a research career after a qualifying work interruption for family or other responsibilities. The program provides administrative supplements to existing NIH research grants for the purpose of supporting fulltime or part-time research by these individuals. Examples of qualifying interruptions would include a complete or partial hiatus from research activities for child rearing; an incapacitating illness or injury of the candidate, spouse, partner, or a member of the immediate family; relocation to accommodate a spouse, partner, or other close family member; pursuit of non-research endeavors that would permit earlier retirement of debt incurred in obtaining a doctoral degree, and military service.

5. Advancing Novel Science in Women's Health Research

(ANSWHR) [PAS-07-381 and PAS-07-382]: Along with 22 other NIH Institutes and Centers, NINDS supports a research funding opportunity to promote innovative, interdisciplinary research that will advance new concepts in women's health research and the study of gender differences.⁸⁷

6. Mechanisms, Models, Measurement, & Management in Pain

Research (PA-07-282, PA-06-543, PA-06-542): Co-funded by NINDS and 11 other ICs in the Pain Consortium, this program seeks proposals to investigate the causes, costs, and societal effects of both acute and chronic pain and the relationships between the two, as well as proposals that link such understandings to the development of better approaches to therapeutic interventions. Interdisciplinary and multidisciplinary teams are strongly encouraged, as is research from underrepresented, minority, disabled, or women investigators.⁸⁸

7. Neurobiology of Migraine (PA-07-305, PA-07-306): Co-funded by NINDS, NIDCD, NIDCR, and NIEHS, this program seeks innovative research that will expand our current knowledge of susceptibility to migraine, pathophysiology of the disorder, neurobiological mechanisms underlying the phases of migraine, and the role of neuromodulators such as sex hormones, and genetic influences in migraine onset and duration.⁸⁹

Future Programs:

8. Advancing Novel Science in Women's Health Research

(ANSWHR) [PAS-07-381 and PAS-07-382]: This program is anticipated to

⁸⁶ <http://grants1.nih.gov/grants/guide/pa-files/PA-08-191.html>.

⁸⁷ PAS-07-381: <http://grants.nih.gov/grants/guide/pa-files/PAS-07-381.html>, PAS-07-382: <http://grants.nih.gov/grants/guide/pa-files/pas-07-382.html>.

⁸⁸ PA-07-282: <http://grants.nih.gov/grants/guide/pa-files/PA-07-282.html>, PA-06-543: <http://grants.nih.gov/grants/guide/pa-files/PA-06-543.html>, PA-06-54:2 <http://grants.nih.gov/grants/guide/pa-files/PA-06-542.html>

⁸⁹ PA-07-305: <http://grants.nih.gov/grants/guide/pa-files/pa-07-305.html>, PA-07-306 <http://grants.nih.gov/grants/guide/pa-files/pa-07-306.html>

continue receiving applications until July 2010.

9. Mechanisms, Models, Measurement, & Management in Pain

Research (PA-07-282, PA-06-543, PA-06-542): This program is anticipated to continue receiving applications until September 2009.

10. Neurobiology of Migraine (PA-07-305, PA-07-306): This program is anticipated to continue receiving applications until November 2009.

XXIX. NIH / Office of the Director / National Institute of Nursing Research (NINR)

A. Programs That Improve the Lives of America's Women and Girls

1. Program Description: Describe the program and include where the program is located in terms of agency organizational structure and which levels of leadership are responsible for the program. Also include whether there are other agencies/departments involved.

The National Institute of Nursing Research (NINR) supports clinical and basic research to build the scientific foundation for clinical practice, prevent disease and disability, manage and eliminate symptoms caused by illness, and enhance end-of-life and palliative care. The breadth and depth of NINR's research portfolio is ideally suited to explore some of the most important challenges affecting the health of women and girls, including:

- New challenges in improving and advancing perinatal care, including preventive care in disadvantaged populations;
- The emergence of new technologies driving biomedical discoveries in gender research and genetics research
- The growth of diverse, racial and cultural populations of women and the associated issues of health disparities in these at-risk, underserved populations;
- The need for accessible telecommunication and internet interventions for rural, low-income women, and;
- The growth of an aging female population faced with chronic diseases requiring complex, and;
- The need to build the next generation of scientists and practitioners in women's health.

In advancing the science of women's health, NINR funds and co-funds meritorious initiatives with specific attention to research that focuses on unique issues surrounding pain, aging, pregnancy, childcare, health disparities, and the participation and promotion of women in biomedical and behavioral research. Central to the themes within its strategic plan, NINR seeks to strengthen and enhance research dedicated to the study of diseases and disorders specific to women, whether as patients, caregivers, or as part of communities. The Institute actively ensures that diverse populations of women are represented in its studies and that disparities experienced by women in minority, rural, immigrant, and other underserved populations are addressed.

NINR's research program in women's health is managed through the Institute's Office of Extramural Programs in the Division of Extramural Research. Following the two-stage

NIH peer review process for grant applications, which includes review by a panel of outside experts and the National Advisory Council for Nursing Research, the NINR Director is responsible for final decisions on funding. As is the case with all NINR programs of research, the Institute seeks collaborations in women's health research with the other Institutes and Centers at the NIH and throughout HHS.

In FY 2008, NINR supported \$21,661,835 in research on women's health.⁹⁰ In future years, NINR will continue its commitment to supporting research in the area of women's health on topics consistent with its mission and strategic plan, as described above.

Across all of its scientific programs, NINR's research addresses, and will continue to address in future years, the special needs of at-risk and underserved populations with particular emphasis on reducing and eliminating health disparities. Progress in advancing science within NINR's Women's Health program is assessed regularly through a variety of mechanisms. For example, NINR extramural program directors and policy staff review scientific publications generated by NINR-supported investigators and assess their impact on future scientific inquiry and their potential for changing and improving clinical practice.

B. Overarching Recommendations:

Today's challenges in the field of women's health present unprecedented opportunities for the Institute to further expand its impact on the health of the Nation. NINR will continue to support innovative studies in research areas highlighted in its strategic plan, including: self-management, symptom management, and caregiving; health promotion and disease prevention; research capacity development; technology integration; and end-of-life science. Results from these studies will inform future strategies as NINR begins to consider its strategic plan beyond 2010.

XXX. NIH / Office of the Director / National Library of Medicine (NLM)

C. Programs That Improve the Lives of America's Women and Girls

1. Program Description: *Changing the Face of Medicine: Celebrating America's Women Physicians* is a multi-component project that included a 4000 square-foot exhibition installation at the National Library of Medicine, an ongoing comprehensive online exhibition including teaching and career resources, two copies of a traveling adaptation of the exhibition going to 60 libraries through 2010 and a third copy of the traveling version traveling to 22 medical school libraries over the course of the next three years.

The Exhibition Program, History of Medicine Division, Library Operations, National Library of Medicine developed the onsite exhibition and website. The Office of Research on Women's Health provided funding that helped create two copies of the traveling exhibition. The head of the Exhibition Program and the chief of the

⁹⁰ Research Portfolio Online Reporting Tool (RePORT) [Internet]. Bethesda (MD): National Institutes of Health; 2009 Jan 15 [updated 2009 May 7; cited 2009 Jun 30]. Available from: <http://report.nih.gov>.

History of Medicine were instrumental in shaping the exhibition experience, which was significantly supported by the director of the National Library of Medicine and the now deputy director of the Library. In addition, the director of the Office of Research on Women's Health supported the project.

The larger project was meant to raise awareness of the contributions of women physicians, to let young women know that they could be any kind of doctor that they wanted to be, and to encourage young people to consider careers in medicine. The online career resources target young people and para-professionals with an emphasis on resources for women. The 60 libraries that are hosting the travel exhibition (these are public, university, and medical libraries in rural and urban centers) are committed to hosting one public program that specifically targets young people and encourages them to consider careers in medicine. When the exhibition was available onsite at the National Library of Medicine, the Exhibition Program targeted community groups that catered to girls (e.g.: Girl Scouts) creating special tour programs.

a) Relevant Statistics:

Onsite visitor numbers:

The *Changing the Face of Medicine* exhibition was on display at the National Library of Medicine from October 2003 to December 2005. In 2004, there were over 7000 individuals in 265 scheduled groups who visited the exhibition. More than forty percent of these visitors were K-12 students (62 groups). In 2005, there were nearly 6000 people in 236 groups who visited the exhibition. Among them, nearly half were K-12 students (83 groups).

Young students came to the exhibition through trips organized by their schools, Girl Scout troops, summer camps, or community based youth programs in the Washington-DC metro area. High school students from all around the United States including participants of various pre-collegiate programs such as National Youth Leadership Forum, National Student Leadership Conference, People to People, Discovery Group, etc. visited the exhibition. These groups consisted of many female students, usually 50+%.

Web site page view numbers:

The *Changing the Face of Medicine* website maintains an audience of approximately 800,000 page views each year. About 10% of these page views are related to K-12 education resources such as lesson plans, career and other resource information, and online activities.

Traveling exhibition numbers:

The two copies of the exhibition traveling to 60 sites launched in 2005. Forty-eight sites have hosted the exhibition thus far. Over 100,000 people visited the exhibition in rural public libraries and university libraries set in urban centers. Libraries hosted over 100 public programs.

2. Future Programs:

a) Target Population(s): The Exhibition Program strives to create experiences that are meaningful to diverse audiences. Local school systems, community groups, and student leadership groups regularly sponsor visits to the exhibitions at the National Library of Medicine.

Online exhibitions include educator and student resources and larger projects, such as *Changing the Face of Medicine*, feature career resources for young people. Traveling exhibitions, whether hosted by rural public libraries or university libraries situated in large urban centers, are developed to appeal to local audiences of all ages and experiences.

Changing the Face of Medicine was an exhibition that focused specifically on the experiences of women physicians however all the projects developed by the Exhibition Program represent a full range of perspectives in its subject matter.

b) Benchmarks: Benchmarks for projects developed by the Exhibition Program are measured in terms of numbers of exhibition visitors, public programs and attendees, and page views. All projects were and will continue to be developed with informal formative and summative evaluations. As time and resources become available, more formal evaluations will be conducted.

Overarching Recommendations: America's libraries are often the intellectual and cultural centers around which communities interact. Serving as a place for raising awareness, educating the public, or beginning a dialogue, traveling exhibitions in libraries are an important and vital means by which to engage people in issues that matter. With its larger traveling shows or the more flexible banner traveling exhibitions, the Exhibition Program at the National Library of Medicine has established a foundation of traveling exhibition services that can reach whole communities across the country. Creating new exhibitions, expanding education and career resources, and enhancing community outreach support will reach more individuals.

Programs That Improve the Lives of America's Women and Girls

1. Program Description: Image Analysis in Cervical Cancer

The National Library of Medicine is working with the National Cancer Institute (NCI) and the American Society for Colposcopy and Cervical Pathology (ASCCP) in a collaborative effort to directly improve the lives of America's women and girls by the prevention of uterine cervix cancer. This program is located in the Communications Engineering Branch of NLM's Lister Hill National Center for Biomedical

Communications. Specifically, this NLM work supports research toward the prevention of uterine cervix cancer and assessment of proficiency of medical professionals in the field of colposcopy. NLM's effort is primarily in the design and development of the technology needed, and our research engineers work closely with medical experts from NCI and the ASCCP in the field of oncologic gynecology. Efforts to date have resulted in the creation of an archive of 100,000 digitized images of the cervix, using photographic data collected in the NCI multi-year Guanacaste and ALTS surveys; additionally, clinical data, including PAP test results, biopsy results, and HPV status for the women who participated in these surveys, has been archived along with the images. The tools that NLM has created in this collaborative work include:

- The Boundary Marking Tool, which allows the recording of graphical information on an image of the cervix, and the interpretation of the tissue that has been graphically annotated.
- The Multimedia Database Tool, which provides Web-based database access to all of the 100,000 uterine cervix images, plus the clinical data collected in the NCI Guanacaste and ALTS surveys.
- The Virtual Microscope, which allows viewing of biopsy images of the cervix over the Web.
- The Teaching Tool, which administers image-based professional competency testing in the field of colposcopy.

This work has resulted in publications in medical journals such as *Cancer Research*, *Obstetrics and Gynecology*, *the Journal of Lower Genital Tract Disease*, and the *American Journal of Obstetrics and Gynecology*, in addition to several in the engineering and computer science literature. The major impact of the work has been to provide the basis for an evidence-based analysis of practices in the field of colposcopy and to make colposcopic evaluation “more robust, reliable, and sensitive within a few years [1]”.

Data analysis to date suggests that about one-third of high-grade cervix pre-cancers may be missed by the common biopsy protocol of taking a single biopsy from the worst appearing visual lesion on the cervix. To determine a better and more sensitive protocol, NCI has begun a multi-year data collection, beginning at the University of Oklahoma Health Sciences Center. Data for 1,000 women will be collected in this study, over a two-year period. Each woman will undergo a colposcopic exam and multiple biopsies will be taken from the cervix; each biopsy site will be marked on a digital image of the cervix, using the NLM Boundary Marking Tool. For the first time, there will be a large-scale body of data that allows the correlation of biopsy outcomes with specific spatial locations on the cervix, and the analysis of this data will potentially allow the creation of new recommendations for a biopsy protocol which may be significantly more sensitive for the detection of high-grade pre-cancer. The data collected in this study will be put into a database in the NLM Multimedia Database Tool. The development of this new protocol could potentially affect the screening of millions of women in the U.S.

Also underway at the current time is the implementation of the NLM Teaching Tool to allow the assessment of professional knowledge of medical professionals in the field of

colposcopy. Two beta tests have been conducted, and NLM is working closely with experts from the ASCCP to bring the first exam, the Colposcopy Mentorship Program exam, online.

a) Relevant Statistics: Data are being collected in a clinical study

2. Future Programs:

a) Target Population(s): The target population is women who require uterine biopsies.

b) Benchmarks: This tool is being evaluated in a clinical research study and the outcomes of that study will be used to assess the efficacy of the BMT.

Overarching Recommendations: Recommendations for future work in this area include the development of analysis tools for the automated or computer-assisted interpretation of HPV linear array images, which are used to assess the specific types of HPV virus that a woman is carrying. A preliminary version of a tool to do this has been developed and has been reported in the *Journal of Clinical Microbiology*. Future work will also include the incorporation of advanced image-processing methods to allow the retrieval of significant biomedical information from cervix databases by combining searches based on both image and text characteristics. Other future work includes the expansion of the ongoing biopsy study with 1000 women in Oklahoma to larger cohorts in overseas populations. Also, a subproject within this overall effort is targeted to developing advanced tools to investigate the problems in inflammatory breast cancer.

This work is a strong example of the practical application of technological methods in an area which has already had substantial research impact, and can potentially contribute to clinical work. Support for this collaborative effort is critical, as it continues to be an opportunity and an example for engineering, computer scientists, and medical experts to work closely toward the common goal of better health care and disease prevention for America's women.

References:

1. Jeronimo J, Schiffman M. Colposcopy at a crossroads. *American Journal of Obstetrics and Gynecology*, August 2006; 195(2):349-53.
2. Gage JC, et. al. Number of cervical biopsies and sensitivity of colposcopy. *Obstetrics & Gynecology*, August 2006; 108(2); 264-272.

Programs That Improve the Lives of America's Women and Girls

1. Community Health Status Indicators (CHSI): The goal of CHSI (<http://communityhealth.hhs.gov>) is to provide an overview of key health indicators for local communities and to encourage dialogue about actions that can be taken to improve a community's health. The CHSI report was designed not only for public health professionals but also for members of the community who are interested in the health of their community. The CHSI report contains over 200 measures for each of the 3,141 United States counties. CHSI data is reported at the county-level, representing several areas of responsibility for public health such as access to and utilization of healthcare services, birth

and death measures, vulnerable populations, risk-factors for premature deaths, communicable diseases, and environmental health. The estimates are consistent across the CHSI reports. County measures of birth and death are included with statistics on birth weight and number of births to women under 18 and over 40 years of age, and unmarried women.

The National Library of Medicine, Library Operations, is one of the federal partners in a new partnership formed in 2006 that includes the Centers for Disease Control and Prevention (including NCHS and ATSDR), the Health Resources Services Administration, the Public Health Foundation, the Association of State and Territorial Health Officials (ASTHO), National Association of County and City Health Officials (NACCHO), National Association of Local Boards of Health (NALBOH), and Johns Hopkins University School of Public Health. The revised CHSI includes 3,141 county health status profiles representing each county in the United States excluding territories. CHSI now includes updated data and a website where the public can access and download the data and information.

Overarching Recommendations: The partnership would like to expand the data resources and add new data as they are released.

Programs That Improve the Lives of America's Women and Girls

1. Program Description: Online information resources on women's health – <http://sis.nlm.nih.gov/outreach/whrhealthtopics.html>

This resource was created in a partnership between the National Library of Medicine Outreach and Special Populations Branch and the National Institutes of Health Office of Research on Women's Health. The purpose of this page is to present topics pertaining to women's health collected by National Library of Medicine information products to support the mission of the Office of Research on Women's Health to promote research in the field. Using the 2009 National Institutes of Health (NIH) Priorities for Women's Health, health topics, research initiatives and overarching themes were identified. Within each section you will find a topic with links to resources which were selected based upon their relevance and authority for the specific topic. The content for this resource was selected primarily from Pubmed, MedlinePlus, and ClinicalTrials.gov.

a) Relevant Statistics: Current use is approximately 1500 visitors per month. NLM and ORWH will be promoting the web site over the next year, as more content is added.

2. Future Programs:

a) Target Population(s): NLM and ORWH will continue to develop and expand this resource with additional specific information from the other NIH institutes. This will enable the resource to include

specific targets. Currently, the resource covers a broad spectrum of women's health. The target populations include researchers in women's health issues and the general public interested in learning about the areas in which NIH is working and in the outcomes of that research.

b) Benchmarks: NLM will conduct evaluations including usability once the resource is more robust and widely promoted. This is done with all NLM web sites targeting special population groups.

Overarching Recommendations: It is essential that all the NIH institutes fully participate in the development of this site by contributing content from their portfolios. In addition the ICs will help promote the use of the resource to extramural scientists and the public through their own channels.

Programs That Improve the Lives of America's Women and Girls

1. Maternal, Infant and Child Health, Information

Access Project, Healthy People 2010: The purpose of this site is to make information and [evidence-based strategies](#) related to the Healthy People 2010 objectives easier to find. The National Library of Medicine and the Public Health Foundation staff have worked together to develop pre-formulated search strategies for selected [Healthy People 2010](#) focus areas. These one-click strategies search [PubMed](#), a database of the National Library of Medicine that provides access to over 11 million citations from MEDLINE and additional life science journals. PubMed includes links to many sites providing full text articles and other related resources. Click on the focus areas listed to link to specific search strategies. This project is funded by the [National Library of Medicine](#), with assistance from the [Public Health Foundation](#), Healthy People 2010 Work Group Coordinators and the [National Network of Libraries of Medicine](#). It resides on the Partners in Information Access for the Public Health Workforce (Partners) Web site (<http://PHPartners.org>). Partners is a collaboration of U.S. government agencies, public health organizations and health sciences libraries. The purpose of Partners is to help the public health workforce find and use information effectively to improve and protect the public's health.

a) Relevant Statistics: PHPartners.org recorded over 2 million pages views in FY08.

Future Programs:

a) Target Population(s): The specific HP2010 focus area and related PubMed searches and other Web links provided target the health of mothers, infants and children.

Overarching Recommendations: NLM is serving on several Healthy People 2020 groups and is planning on providing a similar service for the new set of focus groups when they are announced.

NLM does not have any extramural programs that specifically target women and girls. The Library has funded grants through our various grant programs from time to time that may be relevant. Review of NLM's recent awards for FY 08 and FY 09 shows one particular grant, titled "The History of Emergency Contraception", 1G13LM009242-01A2. This is a Scholarly Works grant awarded to principal investigator Heather Prescott to author a book focused on the history of emergency contraception, and was

co-funded by ORWH. NLM also participates in a current trans-NIH initiative (from ORWH) called “Advancing Novel Science in Women's Health Research (ANSWHR)”, although the Library has not received any assignment of applications so far.

Office of Public Health and Science (OPHS)

Office on Women's Health (OWH)

Programs That Improve the Lives of Women and Girls

Program Description: The Business Case for Breastfeeding

A critical challenge to Work/Life balance for women is having a baby and wanting to breastfeed them exclusively for six months. All major medical and nursing organizations recommend this for the health of the mother and baby. Yet, going back to work after delivery is a major deterrent to breastfeeding for American women, whose breastfeeding rates rank low compared to other nations. African-American women in the U.S. are also more likely to work in unsupportive work environments, and have the lowest rates of breastfeeding in the U.S. Two years ago, the HHS Office on Women's Health and HRSA's Maternal and Child Health Bureau partnered to release, promote, and disseminate the *Business Case for Breastfeeding*- a sophisticated toolkit for employers, HR personnel, breastfeeding advocates, and working mothers. The kit provides the ROI's and "How to's" for companies to provide lactation support in the way of rooms, daycare, pumps, time, and other benefits for breastfeeding working mothers. HHS OWH is providing technical support and training for 10 State Breastfeeding Coalitions a year to reach out to small and medium sized businesses in their states. In addition, we are supporting the National Business Group on Health in designing and disseminated their version of the kit for Fortune 500 companies. The latter will be released in August 2009.

Relevant Statistics:

20 State Breastfeeding Coalitions have been trained to date; with coalitions in such states as Alaska, Arizona, Iowa, Kansas, Michigan, New York, Pennsylvania, South Carolina, Vermont, and West Virginia. Hundreds of businesses have been approached and are now offering some type of lactation support to working mothers. Since the kit's availability on April 1, 2009, over 6,700 users have accessed the kit through OWH's website (www.womenshealth.gov). Additionally, 46,776 kits and individual publications have been ordered from HRSA in the last 18 months.

Future Programs

Target Population(s): 10 more state breastfeeding coalitions will be trained in 2009-2010, and another 10 in 2010-2011, resulting in at least 40 states reaching out to businesses employing women in this country.

Benchmarks: Expected benchmarks include a two fold increase in the percentage of businesses offering lactation services at the end of the project and/or evaluation mechanisms (yearly numbers of businesses offering comprehensive services).

Program Description: National Lupus Education and Awareness

Lupus is an autoimmune disease affecting approximately 322,000 Americans in the United States; nine out of ten affected are women. Lupus is two to three times as likely to affect minority women, specifically African-American, Asian, Latina and Native American/Alaska Native women. For these reasons, OWH piloted an innovative program on Lupus Education and Awareness. The program is aimed at women of childbearing age, 15-44, who are more likely to have this illness. The goal of the education and awareness programs are to educate women about Lupus and strategies they can use to improve their own health and well-being.

Program Description: OWH National Lupus Awareness Campaign

As part of the Lupus Education and Awareness programming, OWH launched a National Lupus Awareness Campaign on March 31, 2009 aimed at women of childbearing age 15-44. This campaign is designed to increase awareness and understanding of Lupus, recognizing that ignorance contributes to late diagnosis and increased complications. The campaign alerts the public to the symptoms of lupus, engaging the attention of a woman's family, friends, and employers, while helping them to better understand the physical and social effects of lupus. In addition, the campaign aims to help individuals who may have symptoms of Lupus to seek medical evaluation for early diagnosis and treatment.

Relevant Statistics:

- Affects more than 322,000 thousand Americans in the U.S.
- 90% of people with Lupus are women
- 8 out of 10 cases of Lupus develop among women of childbearing ages, 15-44
- 1 in every 77 households includes a person with Lupus
- 15% of Lupus cases are among young children
- Approximately 28% of people with Lupus are disabled from debilitating health effects of the disease

Future Programs: Eliminating Disparities in Lupus through Education and Training for Health Professionals (EDLET/HP)

Program Description:

This project is collaboration between The Office of the Secretary, Office on Public Health and Science, Office on Women's Health and the Office on Minority Health. The purpose of this program to increase the number of health professionals who are educated about Lupus resulting in improve early diagnosis, treatment, and management of Lupus for populations who are disproportionately affected by race, ethnicity and gender. The program will collaborate with medical and nursing schools, and medical professional associations to expand curricula to include a more comprehensive and inclusive coverage of Lupus and to educate a wide range of health care professionals in the diagnosis, treatment, and management of Lupus.

This project will develop a training program to educate and to strengthen health care professionals in the quality of diagnosis, treatment, and management of Lupus and this training will be accomplished through:

- The establishment of a consortium that will coordinate, manage and promote the expanded Lupus Curricula in medical and nursing schools, and schools of public health;
- The development of a multi-discipline curricula with an infusion/expansion of additional coursework on Lupus into medical schools and residency programs; and
- The delivery of courses through a variety of mechanisms including DVDs, webinars, professional and specialized seminars, and courses offered at satellite sites.

This program will launch in October 2009.

Relevant Statistics:

The National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health, US DHHS, reports that Lupus disproportionately affects African Americans, Asians, and American Indians. Lupus is two-three times more common in African Americans than other populations. The age range for individuals with Lupus varies widely, but is generally diagnosed between 15 and 44 years of age. In this age group, women with Lupus outnumber men 12 to 1.

Program Description: BodyWorks Program

OWH developed the BodyWorks program, in English and Spanish, to promote habits for maintaining a healthy weight and reducing obesity through healthy eating and increased physical activity among teens ages 8-17. BodyWorks focuses on helping parents and caregivers teach, facilitate, and support healthy eating and exercise habits for their family members. The approach for the program is based on research that describes parents/caregiver behavior and practices significantly influence healthy habits, which form in childhood.

The BodyWorks program features a series of 10 sessions, led by facilitators who have been trained in the BodyWorks curriculum. Each session has a core focus, including: tools for behavior change, goal setting, eating and emotions, choosing healthy foods, portion control, physical activity, meal planning, shopping, food labels, cooking, environmental barriers, and media influences. A formal evaluation of the program found that BodyWorks changed parent intentions, motivation, and immediate behavior. Examples include increased vegetable consumption to setting nutrition and physical activity goals. *BodyWorks* is disseminated using a train-the-trainer model through community-based organizations, state health agencies, non-profit organizations, social service organizations, health clinics, hospitals, healthcare systems, and schools and parent-teacher organizations. Currently there are over 1,700 trainers and 800 families throughout the country who have participated in the program.

Relevant Statistics:

- In the last 20 years: the prevalence of overweight among children aged 6 to 11 has more than doubled and the prevalence of overweight among adolescents' ages 12 to 19 has more than tripled.
- Overweight and obesity, influenced by poor diet and inactivity, are significantly associated with an increased risk of diabetes, high blood pressure, high cholesterol, asthma, joint problems, and poor health status.

OWH HIV/AIDS Programs for Women and Girls require and provide technical assistance to all grantees/contractors to ensure they employ holistic and gender-responsive programming which includes encouraging and supporting educational attainment, building skills related to financial literacy, work-life balance counseling and physical activity. Women participants are taught basic life skills such as financial literacy and work/life balance within a wellness curriculum for sustaining health and preventing HIV infection.

Program Description: HIV Prevention Program for Young Women Attending Minority Institutions

Gender specific prevention projects targeting college age minority women to increase their knowledge and self protective behaviors for preventing HIV/AIDS and other STDs; interventions include understanding how the female body works in relation to increased vulnerability for acquiring HIV/AIDS.

Program Description: Intergenerational Approaches to HIV/AIDS Prevention Education for Women Across The Lifespan Pilot Program

Reduce the incidence of minority adolescents and adults tested positive for HIV/AIDS by reaching two generations of minority females. Education is a critical component to this program.

Program Description: *Straight Talk* for Preventing HIV Program (Future Program)

The *Straight Talk* on Preventing HIV Program is to develop gender and age-specific, culturally, spiritually, and linguistically-appropriate HIV/AIDS prevention education. The program's aim is to teach sexual health as an integral part of health and to teach female members of the family that a healthy life includes physical health, emotional health, as well as sexual health.

Program Description: HIV/AIDS Prevention Education Services for Female Youth At-Greater Risk For Juvenile Delinquency

This initiative is a prevention education project focused on HIV/AIDS/STDs and juvenile delinquency for at-risk female adolescents/youths aged 9-16. This project specifically focuses on the intersection between sexually risky and juvenile delinquent behavior among female adolescents/youths. The program is evaluation intensive and will focus on building capacity within communities to service the needs of female adolescents/youths that are at-risk for HIV/STDs and juvenile delinquency. The program focuses on identifying and addressing the social and economic threats which contribute to the participation of female adolescents/youths in sexually risky and delinquent behavior. Additionally, the program focuses on building self-esteem and educating girls on how to cope with adverse situations. For FY 2008, all organizations expanded their focus to address issues related to the mental health and well-being of their young participants and provide supplement services to past program participants.

Program Description: In Community Spirit - HIV Prevention for Native/American Indian and Alaska Native Women Living in Rural and Frontier Indian Country

Prevention education integrating the strengths of traditions, values, culture and spirituality indigenous to the targeted communities.

Program Description: HIV Prevention for Women Living with HIV/AIDS in Puerto Rico

Prevention education projects targeting women living with HIV/AIDS to increase access to care, to increase knowledge of protective behaviors, and to reduce isolation of women living with HIV infection.

Program Description: HIV Prevention for Women Living in the U.S. Virgin Islands

Prevention education project providing accurate and comprehensive information on HIV/AIDS prevention and healthy behaviors for women living in the U.S. Virgin Islands.

Program Description: HIV/AIDS Prevention for Women Living in the Rural South Program

Demonstration projects to provide accurate and comprehensive HIV prevention education that addresses false information, stigma, self-protection behaviors and denial.

Program Description: HIV/AIDS Prevention and Support Services for Incarcerated and/or Newly Released Women

Demonstration projects to provide accurate and comprehensive HIV prevention education that addresses false information, stigma, self-protection behaviors and denial.

Program Description: Violence Against Women

OWH's Violence Against Women (VAW) Initiatives require and provide technical assistance to all contractors to ensure they employ holistic and gender-responsive programming which includes encouraging and supporting educational attainment, building skills related to financial literacy and achievement of work-life balance. The VAW initiatives focus on increasing the capacity of service providers assisting women in vulnerable situations and on educating, informing and raising the awareness level of college-aged women on issues related to VAW to encourage resiliency and self-sufficiency.

Program Description: End Violence Against Women on College/University Campuses

The newest OWH VAW initiative is a pilot program for college and universities. The program requires organizations to develop and implement programs to address Violence Against Women (VAW) on college/university campuses. The program targets female students of all ages and will train and educate faculty, staff and campus security and police concerning critical issues associated with VAW. The program will also lead to the development of an on-campus task force to enhance the sustainability and ensure the program adequately addresses the needs of the college/university.

Program Description: HIV/AIDS-Related Prevention Education Services for Survivors of Domestic Violence

Organizations develop and implement programs to address the intersection between domestic violence and the increased risk for contracting HIV/AIDS. The project primarily target female survivors/victims of domestic violence. The programs are designed to train domestic violence counselors to incorporate HIV/AIDS risk reduction strategies as a part of their service delivery. The project includes a cross-training component for HIV/AIDS service providers.

Program Description: Demonstration Projects for Tobacco Prevention and Cessation for Young, Low-SES Women

The OWH Tobacco Prevention and Cessation Demonstration Projects are funded and/or supported by the *Tobacco and Young, Low-SES Women: Federal Collaboration to Make a Difference* (Tobacco Collaborative). The Tobacco Collaborative is a group of Federal agencies working in partnership to address health issues related to tobacco use in young, low social-economic status women of child-bearing ages, their partners, and their children in underserved communities, and individuals at high-risk of tobacco use and/or exposure to second-hand smoke.

The Tobacco Collaborative members include the following HHS agencies: Office of the Secretary, Office on Women's Health (OPHS/OWH), Health Resources and Services Administration (HRSA), Indian Health Services (IHS), the Office of Research on Women's Health, National Cancer Institute (ORWH, NCI), Office of Women's Health, National Cancer Institute (OWH,NCI) Tobacco Control Research Branch, Division of Cancer and Population Sciences, National Cancer Institute, Centers for Disease Control, Office on Smoking and Health (OSH), Centers for Medicaid and Medicare (CMS) , and the Agency for Healthcare Research and Quality(AHRQ).

The interventions will be implemented through HRSA's Bureau of Primary Health Care Centers and through the IHS' urban or tribal clinics. This 18-months Demonstration Project will develop long-term and short-term efforts to reduce tobacco use in young, LSES women.

OWH, HRSA, and the IHS will also co-host a conference for the Demonstration Project launch in October 2009. The purpose of this conference will be to share best practices for tobacco prevention, cessation and elimination of second hand smoke exposure for LSES women of child bearing age. It will include all federal partners and other entities collaborating with the agencies implementing the program. Products from this conference will include training sessions for intervening partners, development of a toolkit of materials to be used during the interventions, identification of best practices for the tobacco prevention, cessation and elimination of second hand exposure, and meeting proceedings.

Relevant Statistics:

Twelve percent of all women reported smoking during their pregnancies, according to a report from the CDC. The greatest success in reducing smoking was for women in their late twenties and early thirties; where there was over a 40 percent drop since 1990. CDC also reports that the American Indian and Alaska Native Population have the highest smoking prevalence of the U.S. Adult Ethnic/Racial Groups.

Program Description: Realizing Women And Minority Faculty Potential In Academic Medicine: Data Analysis From A Five-School Partnership

Led by the OWH, a collaboration of 5 Federal agencies that are represented on the HHS Coordinating Committee on Women's Health (HRSA, ORWH, AHRQ, OMH, and CDC) provided supplemental funding for the multi-year C-Change initiative (to gain insight into the culture of academic medicine and document the experience of faculty in academic medicine and the organizational approach in the five participating C – Change medical schools – Duke University School of Medicine, George Washington University School of Medicine and Health Sciences, Tufts University School of Medicine, University of Minnesota Medical School, and University of New Mexico School of Medicine). The funds are supporting data analyses from both an in-depth qualitative interview study of faculty at the 5 medical schools, and a national survey at these schools and 21 others. Additional OWH support is being used to clarify relationships among faculty members' demographics, how they experience their medical school's culture, and their involvement, as researchers and clinicians, in improving the health of women and minority populations.

OWH provided additional support for examining under-represented minority faculty experiences in academic medicine. An article was submitted to the Journal of the American Medical Association (JAMA) entitled "Race, Social Disadvantage, and Faculty Experiences in Academic Medicine". The article documents predominant themes regarding the experience of under represented minority faculty members including, difficulty in cross-cultural relationships; isolation and feeling invisible, lack of mentoring, role models and social capital, etc. The article concludes that achieving real multiculturalism in medical school faculty would help meet the mission of academic medicine to train a physician and research workforce to meet the diverse needs of our multicultural society.

The OWH Regional Women's Health Offices are located in the ten HHS Regional Offices. Guidance is provided by the Regional Women's Health Coordinators (RWHCs).

Region I

The Office on Women's Health Region I, in partnership with the Employment, Benefits and Security Administration (EBSA) and the Women's Bureau of the U.S. Department of Labor, developed a conference program in Fiscal Year 2000 entitled, "*Healthy, Wealthy and Wise?*", focusing on current laws and regulations impacting women's healthcare coverage, financial security and employment rights. The conference has been held every year in one of the six states across New England and participation has generated from 75 to 250 registrations per conference, depending on the location of the conference.

While numerous laws exist to protect women's rights, they are administered by different agencies of the Federal government and obtaining information and identifying assistance is often challenging and confusing. "*Healthy, Wealthy and Wise?*" seeks to minimize such difficulties by being a 'one stop' information source for service providers to women. Experts on three panels will discuss real-life stories of women impacted by health care, retirement savings and employment issues. In turn, participants will receive comprehensive information on those topics, and be provided resource materials on services available to help women in the state address health, financial security and workplace challenges.

In hosting the conference, Federal organizers collaborate with key state partners in local government and community-based organizations to plan the event and prepare generic life stories about women experiencing job loss, illness, divorce, pregnancy, and caregiving. The stories are adapted as typical examples of women's lives for the state in which the conference is held.

Since 2000, the conference has provided information for community workers, case managers, human resource professionals, counselors, Employee Assistance Program specialists, health care providers and advocates, legal advocates, faith community representatives, state and local agencies, labor union staff, legislators and their staff, and other concerned women and men. It also provides an opportunity for attending service providers and program staff to network across programs and exchange resource information about their programs and additionally, supports outreach efforts for the three Federal partners of HHS and DOL.

In 2009, the Federal partners are working with the Maine Women's Health Campaign, a government/private sector collaboration on women's health in Maine, to host *Healthy, Wealthy and Wise?* in Auburn, Maine on September 11, 2009, and in Machias, Maine on September 25, 2009. The two locations, in both urban and rural areas, should draw up to 175 participants total. Federal partners expect that the current economic situation in Maine will generate a larger number of interested participants registering.

Region IV

OWH's Region IV, based in Atlanta, Georgia has collaborated with Historically Black College and University (HBCU), Spelman College to raise awareness about infant mortality within the African American community. Partner organizations were the Office of Minority Health, Centers for Disease Control, the Food and Drug Administration, and Pearce and Pearce Inc. The target population included girls ages 9-17 and women ages 18-85. A total of 150 women and 5 men were served.

OWH's Region IV has also collaboration with HBCU Tennessee State University to raise awareness regarding issues affecting the health and wellness of women. Awareness was raised through the incorporation of a week long series of workshops and lectures. Partnerships were inclusive of on campus student organizations such as Tennessee State University Health Center and Tennessee State University's Department of Residence Life. This project was under the direction of OPHS and Region IV OWH. A total target population of 259 individuals were served.

Another program within OWH's Region IV is the "Reviving Double Dutch in Communities Project", focused on motivation, education, and empowerment of youth to increase their free time, and physical activity through Double Dutch and to make healthy food choices. Community partnerships consisted of the local YMCA, McGruder Family Resource Center, Meharry Medical Center, Tennessee State University, Metro Nashville Health Department, Nashville Metro Parks, Metro Nashville Public Schools, and the Franklin HotShots. This project was under the direction of the Office of Public Health and Science and Region IV Office on Women's Health. Attendance at the first "mini" camp yielded 40 children in attendance.

Region IV – Education and/or careers in science

The proposed program will be entitled Adolescent Health in Schools Roundtable. A potential collaboration with local public schools, Parent Teacher Association (PTA) chapters to discuss childhood nutrition and physical fitness.

Future Programs:

Host two "obesity roundtable sessions" related to childhood obesity in the Fulton County and Dekalb County in the state of Georgia.

Target Population:

The target population would consist of representatives from local public schools, PTA's, and community based organizations that work with adolescent girls and boys (Example: Boys and Girls Club of America, C.H.O.I.C.E.S, GoGirlGo! Atlanta, etc.)

Benchmarks:

The percentage of schools that will adopt a new strategy to address childhood obesity and physical fitness during the academic year.

Region IV - Financial Literacy

Potential federal partnerships to include Social Security Administration, Centers for Medicare & Medicaid (CMS) and Office of the Regional Health Administrator (ORHA).

Future Programs: Collaborate with local financial institutions to conduct seminars and/or lunch-n-learn sessions regarding money management and financial planning.

Target Population: Adolescent girls and women.

Benchmarks: Annual surveys that assess how much more knowledgeable lunch n' learn participants are about how to improve their own financial planning.

Region IV - Work/Life Balance

A forum on Balancing Motherhood and the Workplace. Potential federal partnerships for the purposed program include Federal and Occupational Health (FOH), Employee Assistance Program (EAP) and Office of the Regional Health Administrator (ORHA). The reasoning behind the utilization of these particular organizations is because many working mothers have issues, either personally or professionally, that can affect their work productivity. Help with dealing with issues is vital in ascertaining a more focused and productive individual and the possible organization partnerships listed have the means to aide in this process.

Target Population: Working mothers

Benchmarks: A survey can be done to ensure that upon the conclusion of each forum the participants are able to incorporate what they have learned about balance into their daily lives.

Regions VI and IX

OWH Regions VI/IX offer a Border Women's Health Promotora Leadership Institute. This institute offers an educational program that fosters and enhances leadership and advocacy capabilities of women lay health workers or promotoras from among the 10 US and Mexico Border states. Currently, there have been forty-one promotoras trained in this program.

The OWH **Region VI** *Peer Educator Training for Woman to Woman: Inside and Out* curriculum and training program was developed for inmate peer educators using an OWH preventive health education model for care. The peer educators in the Texas Criminal Justice System and Oklahoma Criminal Justice System have adopted this training so the general population of incarcerated women have an opportunity to live healthier both inside corrections and outside in the free world. There have been over 100 peer educators trained, and the number of education contacts with the general population number in the thousands.

OWH **Region VI**, in partnership with the Federal Interagency Wellness Workgroup (OWH/OMH/FOH/EAP/Dallas Federal Employees Wellness Center, have worked together eight years to have special activity events during National Women's Health Week. Activities over the years have included walk/run events with Dallas City Hall, healthy scavenger hunt walk events coordinated with Dallas business community, and health screenings by FOH during the events. Other community health and social organizations have also been included, and they have held health presentations on stress in life, heart care, nutritional cooking programs, and special physical health activities such as yoga, tai-chi, zumba dancing, etc. Over 1800 Federal employees and contractors have participated in these events.

Region VII

OWH **Region VII**, located in Kansas City, held a Double Dutch Day Competition that addressed obesity in school age children by engaging them in jump rope physical activity on a regular basis. The event included over 180 students from the Kansas City Missouri School District and Kansas City Charter Schools. Double Dutch Jump Rope is now being incorporated into the Kansas City Missouri School District's before and after school programs.

For National Women's Health Week (NWHW), starting on Mother's Day of each year, OWH's Region VII partnered with Wal-Mart, grocery stores, restaurants, fitness centers, churches and a federal cafeteria to promote healthier choices. Wal-Mart included women's drugs in their prescription drugs program, offering a 30-day supply for \$4.00. The grocery stores offered discounted fruits and vegetables, the fitness center offered discounted prices to work out in the facility, the federal cafeteria offered low fat healthy meals during lunch, and the churches hosted educational programs highlighting women's health diseases and issues.

Gender Matters: Creating Services for Women and Girls in Correctional Settings. A special workshop, collaboratively arranged by OWH's Region VII, the University of Missouri – Kansas City, the Women's Bureau-Department of Labor and a variety of community and government partners, focused on the increasing number of women and girls in correctional, probation, and parole settings and how their needs differ from their male counterparts. Dr. Stephanie Covington, of the Institute for Relational Development and Center for Gender and Justice and a pioneer in the field of women's issues, lead the training. To build on the training provided Dr. Covington educational materials are available to community partners to check out from the regional office to continue to address issues in their communities.

Region VIII

OWH's **Region VIII** funds small contracts that have been used to support clinical conferences on specific women's health topics. OWH regional support helps defray costs so that more researchers, clinicians, and students are able to participate. An average of eight awards per year have been distributed relating to education/careers in science.

Region VIII OWH staff work closely with the Department of Labor on financial literacy activities for women primarily by assisting in the promotion of conferences and workshops sponsored by the DOL/Women's Bureau Region VIII, but also some small contract support and speaking engagements by the Regional Women's Health Coordinator. DOL materials are also used at women's health exhibits conducted by the Region VIII OWH staff.

Office of Disease Prevention and Health Promotion (ODPHP)

Office Overview

The Office of Disease Prevention and Health Promotion (ODPHP) accomplishes its mission by providing a prevention framework for the nation, leading the department's prevention communication efforts, contributing to the growing evidence base of science prevention, and conducting policy research and its dissemination. From these efforts, national policies and programs have been developed such as the *Healthy People, Dietary Guidelines for Americans*, the first-ever *Physical Activities Guidelines for Americans*, and *healthfinder.gov* among other disease prevention and health promotion initiative and programs.

Programs That Improve the Lives of Women and Girls

Program Description: Healthy People 2010

Healthy People 2010 is a set of health objectives for the Nation to achieve over the first decade of the 21st century. Under the auspices of the U.S. Department of Health and Human Services (HHS), Office of Disease Prevention and Health Promotion, Healthy People 2010 builds on initiatives pursued over nearly three decades. Healthy People's goals and objectives are the result of a collaborative process—over 350 national membership organizations, 250 State health, mental health, substance abuse, and environmental agencies participated in the process to develop of Healthy People 2010, and over 11,000 public comments on the draft objectives. The initiative's overarching goals call for increasing quality and years of healthy life and for eliminating health disparities, including gender-specific differences. Many of the objectives address the most significant preventable threats to women's health and establish targets for specific improvements.

Relevant Statistics:

OWH in partnership with ODPHP) tagged 226 objectives within *Health People 2010* that directly represent important indicators of women's health and gender-specific data.

Other:

Presently ODPHP is leading the development of the next iteration of national objectives – *Healthy People 2020*. The health agenda targeted for 2020 will continue to be evidence and science based, and data driven; it will include topic areas concerning the health of women and girls including: Maternal, Infant and Child Health, Adolescent Health, Family Planning.

Program Description: 2005 Dietary Guidelines for American

The *Dietary Guidelines for Americans* have been published jointly by the Department of Health and Human Services (HHS) and the Department of Agriculture (USDA) every five years since 1980. The Guidelines provide authoritative advice for people two years and older about how good dietary habits can promote health and reduce risk for major chronic diseases. They serve as the basis for Federal food and nutrition education programs. The 2005 *Dietary Guidelines for Americans* are based on the latest scientific evidence and intended to be a primary source of dietary health information for policymakers, nutrition educators, and health professionals. In addition to key recommendations pertaining specifically to women, general recommendations suggest that all healthy eating plans should:

- Emphasize fruits, vegetables, whole grains, and fat-free or low-fat milk and milk products.
- Include lean meats, poultry, fish, beans, eggs, and nuts.
- Be low in saturated fats, *trans* fats, cholesterol, salt (sodium), and added sugars.
- Stay within daily calorie needs.

Relevant Statistics:

Since the release of the *Dietary Guidelines for Americans* in January 2005, twelve sets of consumer education materials specifically targeted to women and girls have been developed by Federal agencies.

Future Programs: Dietary Guidelines

Target Population(s):

The Advisory Committee for the 2010 *Dietary Guidelines for Americans* is currently reviewing recent scientific and medical information in order to make updated recommendations for people ages two and older. As in the 2005 *Dietary Guidelines for Americans*, recommendations for specific populations groups, including women, will be made when necessary.

Other:

The complete 2005 *Dietary Guidelines for Americans* publication can be found at <http://www.healthierus.gov/dietaryguidelines>. Information about the development of the 2010 Guidelines is provided at <http://www.dietaryguidelines.gov>.

Program Description: 2005 Dietary Guidelines Key Recommendations Pertaining Specifically to Women (Text taken directly from 2005 *Dietary Guidelines for Americans* publication. Page numbers included after each excerpt.)

(A) Adequate Nutrients Within Calorie Needs

Women of childbearing age who may become pregnant. Eat foods high in heme-iron and/or consume iron-rich plant foods or iron-fortified foods with an enhancer of iron absorption, such as vitamin C-rich foods. (6)

Women of childbearing age who may become pregnant and those in the first trimester of pregnancy. Consume adequate synthetic folic acid daily (from fortified foods or supplements) in addition to food forms of folate from a varied diet. (6)

(B) Weight Management

Pregnant women. Ensure appropriate weight gain as specified by a healthcare provider. (14)

Breastfeeding women. Moderate weight reduction is safe and does not compromise weight gain of the nursing infant. (14)

(C) Physical Activity

Breastfeeding women. Be aware that neither acute nor regular exercise adversely affects the mother's ability to successfully breastfeed. (20)

(D) Alcoholic Beverages

Moderate consumption of alcoholic beverages is] defined as the consumption of up to one drink per day for *women...* (44)

Alcoholic beverages should not be consumed by...*women of childbearing age who may become pregnant, pregnant and lactating women...* (44)

Compared with women who do not drink, *women who consume one drink per day* appear to have a slightly higher risk of breast cancer. (44)

(E) Food Safety

.....*Pregnant women...* Do not eat or drink raw (unpasteurized) milk or any products made from unpasteurized milk, raw or partially cooked eggs or foods containing raw eggs, raw or undercooked meat and poultry, raw or undercooked fish or shellfish, unpasteurized juices, and raw sprouts. (48)

Pregnant women...: Only eat certain deli meats and frankfurters that have been reheated to steaming hot. (48)

The Food and Drug Administration (FDA) and the Environmental Protection Agency are advising *women of childbearing age who may become pregnant, pregnant women, nursing mothers,* and young children to avoid some types of fish and shellfish and eat fish and shellfish that are lower in mercury. (31)

Program Description: 2008 Physical Activity Guidelines for Americans

The HHS is responsible for producing the 2008 *Physical Activity Guidelines for Americans*, which are the first comprehensive guidelines on physical activity ever to be issued by the Federal government. This document is intended to be a primary source of information for policy makers, physical educators, health professionals and the public on the amount, types, and intensity of physical activity needed to achieve many health benefits by Americans across the life span. In addition to key recommendations pertaining specifically to women, general recommendations suggest that all adults should do at least:

- 2 hours and 30 minutes each week of aerobic physical activity at a moderate level OR
- 1 hour and 15 minutes each week of aerobic physical activity at a vigorous level OR
- An equivalent combination of moderate and vigorous level activity.

Relevant Statistics:

ODPHP coordinates a Supporter Network that currently consists of over 3,200 organizations that help promote the Guidelines.

Other:

The complete 2008 *Physical Activity Guidelines for Americans* publication can be found at <http://www.health.gov/paguidelines>.

Office of HIV/AIDS Policy (OHAP)

Programs That Improve the Lives of America's Women and Girls

Program Description: Minority Serving Institutions Demonstration Initiative and Capacity Building Activities

The Minority Serving Institutions Demonstration Initiative is a three year project focused on working collaboratively with colleges and universities that serve minority populations to increase capacity to address the sexual health needs of their student bodies. The other capacity building activities include collaborative efforts with various organizations including the YWCA as well as in-service trainings on various HIV/AIDS related topics including HIV/AIDS and women.

Future Programs

- a. Target Population: The target populations for this collection of capacity building activities will include college-age women, women currently enrolled in college, and women at increased risk or susceptibility for HIV/AIDS.
- b. Evaluation criteria are currently being developed and will include input from the participating colleges and universities.

Office of Population Affairs (OPA)

Office Overview

The **Office of Population Affairs (OPA)**, located in the Office of Public Health and Science (OPHS), has Title X Family Planning Services that authorize grants to assist in the establishment and operation of voluntary family planning projects which offer a broad range of acceptable and effective family planning methods and related preventive health services. Services include:

- § Natural family planning methods
- § Infertility services
- § Services for adolescents
- § Highly effective contraceptive methods
- § Breast and cervical cancer screening and prevention that corresponds with nationally recognized standards of care
- § Sexually transmitted disease (STD) and HIV prevention education, counseling, and testing
- § Activities that promote positive family relationships
- § Other preventive health services

Programs That Improve the Lives of America's Women and Girls

Currently, **OPA Title X** services are provided through a national network of more than 4,500 clinics. During 2008, services were provided to more than 4.7 million women, 55 percent of whom were under the age of 25. Priority for services is to individuals from low-income families. In 2008, more than 91 percent of individuals served had family incomes at or below 200 percent of the Federal Poverty Level. Family planning centers often serve as a woman's entry point into the health care system, and more than six in ten women who obtain care in a family planning center consider it their usual source of medical care.

The OPA Title X family planning providers must play a major role in HIV/AIDS prevention. Inadequate attention has been focused on prevention and clinical services for populations who are now at great risk—women (in particular, women of color and poor women) and adolescents, many of whom receive reproductive health services through the Title X program. Family planning clinics have the structure in place to provide HIV/AIDS prevention, counseling, testing, and referrals to populations at risk. However, family planning clinics have historically been viewed as low prevalence settings, and in many cases, the usual sources of funds have not been available to them for the provision of HIV counseling and testing services. All Title X-funded agencies are required to provide, at a minimum, HIV/AIDS prevention education, including education on risks and infection prevention and testing, either on-site or by referral. The extent of on-site HIV testing and counseling services in Title X clinics is based on the availability of financial resources, and many are not able to provide those services without specific sources of funding to do so.

Since 2001, the program has received funds through the Minority AIDS Initiative (MAI) to provide on-site HIV counseling and testing services in communities where racial and ethnic minorities are under-served or disproportionately impacted by HIV/AIDS. In FY 2008, OFP received \$7 million through the MAI, which was supplemented with \$3.8 million from the FY 2008 Title X appropriation. With this funding, OPA awarded 80 supplemental grant awards in 34 states or territories for the integration of HIV/AIDS testing and prevention services in Title X family planning service projects. Projects are required to implement CDC's Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings (September 2006). Since the project's inception in 2001, more than 565,000 clients have been tested and 1,727 HIV positive clients have been identified and referred for care and treatment, as reflected by data provided through 2007.

The OPA Title XX, Adolescent Family Life (AFL), program supports both demonstration and research grants. There are two basic types of demonstration projects: (1) Prevention projects which develop and evaluate educational and other intervention activities designed to encourage adolescents to postpone sexual activity, and (2) Care projects which develop interventions with pregnant and parenting teens, their infants, male partners, and family members in an effort to ameliorate the effects of too-early-childbearing for teen parents, their babies, and their families. AFL also funds grants to support research about the causes and consequences of adolescent premarital sexual relations, adolescent pregnancy, and parenting.

AFL is committed to improving its grantees' capacity to serve adolescents by providing intensive program and evaluation technical assistance. This is accomplished by using a variety of technical assistance efforts, including an annual conference, regional meetings, net conferences, e-learning modules and individual conference calls. Experts within the field of adolescent health and program evaluation are used to lead net conferences and regional meetings to direct service providers.

The AFL program currently funds 31 Care demonstration projects. AFL Care projects are unique because they provide comprehensive health, education and social services to pregnant and parenting adolescent girls, their infants, teen fathers, male partners and their families. Desired outcomes for care grantees include prevention of and reduction in repeat pregnancy, increased educational attainment among adolescents, and increased immunizations among their children. AFL also currently funds a variety of AFL Care projects, including several that are school-based.

Title XX currently funds 35 prevention demonstration projects which are developing, implementing and testing interventions, and using curricula and supportive activities in teen pregnancy prevention education. The purpose is to delay the onset of adolescent sexual activity and reduce the incidence of pregnancy and sexually transmitted infections (STIs). AFL prevention projects maximize the guidance and support available to adolescents from parents and other family members. Desired outcomes for prevention grantees include prevention of, and reduction in sexual activity, improved attitudes about abstinence, and increased parent-child communication among adolescents.

President's Council on Physical Fitness and Sports (PCPFS)

Council Overview

Through its Executive Order, the PCPFS is charged with promoting physical activity, fitness, and the benefits of sports participation to Americans of all abilities, aged 6 and up. The PCPFS is composed of twenty private citizens appointed by the President who serve as advisors to the President through the Secretary of the Department of Health and Human Services on issues associated with the promotion of physical activity and fitness, physical education, sports and sports medicine.

Programs That Improve the Lives of America's Women and Girls

President's Challenge Physical Activity and Fitness Awards Program. Each year over 5 million youth, ages 6-17, receive awards reflecting their level of physical fitness by participating in a series of activities that motivate youngsters to build aerobic endurance, muscular strength and endurance, flexibility and agility and promote regular physical activity. In 2003, the PCPFS launched a free, interactive website, www.presidentschallenge.org, which motivates youth and women and men to become and stay active as part of a healthy lifestyle. The Challenge encourages modified activities for physically challenged students/adults and recognizes all participants for their achievements.

Physical Activity and Sport in the Lives of Girls: Physical and Mental Health Dimensions from an Interdisciplinary Approach. This ground breaking report was created by the PCPFS in 1997, under the direction of the Center for Research on Girls and Women in Sport. It highlights the multiplicity of ways in which physical activity and sport have become an integral part of girls' lives. The report was also created to develop future research paths and policy recommendations as a guide for planning and programming. An update to the original was released in 2008 by the Tucker Center in Minneapolis, MN.

Healthy People 2010/2020: Physical Activity and Fitness Objectives. Physical Activity and Fitness is one of 28 focus areas in the nation's preventive health agenda. Specifically, 15 physical activity and fitness objectives have been established for significant improvement by 2010. Workgroups are in the process of developing science-based physical activity and fitness objectives for 2020. The PCPFS and CDC serve as co-leads on this national prevention initiative.

The President's Council on Physical Fitness and Sports Research Digest, a free, quarterly publication, synthesizes scientific information in the area of physical activity, fitness and sports for the lay practitioner. Several digests have dealt with young women and women's benefits from enhanced physical activity and fitness.

Commissioned Corps of the U.S. Public Health Service

Overview

The Commissioned Corps of the U.S. Public Health Service is an elite team of more than 6,000 full-time, well-trained, highly qualified public health professionals dedicated to delivering the Nation's public health promotion and disease prevention programs and advancing public health science. Driven by a passion for public service, these men and women serve on the frontlines in the Nation's fight against disease and poor health conditions. As one of America's seven uniformed services, the Commissioned Corps fills essential public health leadership and service roles within the Nation's Federal Government agencies and programs.

The mission of the Commissioned Corps of the U.S. Public Health Service is protect, promote, and advance the health and safety of our Nation. As America's uniformed service of public health professionals, the Commissioned Corps achieves its mission through:

- Rapid and effective response to public health needs
- Leadership and excellence in public health practices
- Advancement of public health science.

Commissioned Corps' approach to women and girls from a broad perspective: Commissioned Corps officers work in a variety of positions throughout the U.S. Department of Health and Human Services (HHS) and certain non-HHS Federal agencies and programs. Many of the agencies have programs or offices dedicated to women's issues.

Programs That Improve the Lives of the Federal Workforce

Alternate work schedules are available for Commissioned Corps personnel at the discretion of the supervisor.

Programs That Improve the Lives of America's Women and Girls

The Office of Commissioned Corps Force Management proposes to adopt a school in the local area with a focus on high school students.

Benchmarks: Expected Benchmarks and/or evaluation mechanisms

Expected benchmark is to track the number of students who eventually enter the Commissioned Corps of the U.S. Public Health Service. Potentially, students would enter the Junior or Senior Commissioned Officer Student Training and Extern Program (JRCOSTEP or SRCOSTEP) during undergraduate studies.

Other: Other ideas being considered:

- Participation by Commissioned Corps officers at a local high school's Career Day
- Commissioned Corps officers may serve as mentors to high school students who express interest in health professions

Substance Abuse and Mental Health Services Administration (SAMHSA)

Agency Overview

The Substance Abuse and Mental Health Services Administration's (SAMHSA) Women's Health Service activities are overseen by the Acting Associate Administrator for Women's Services. Moreover, the SAMHSA Women's Coordinating Committee (SWCC) is legislatively mandated under the Children's Act of 2000 to: 1) identify the need for women's services and make an estimate of funds needed for each fiscal year; 2) identify needs regarding the coordination of services for women; 3) encourage support from all agencies in the Administration for women's services; and 4) assure the unique needs of minority women are recognized and addressed within the Administration. Thus, the SWCC is charged with addressing the health issues of women and girls with mental and addictive disorders by integrating programs and policies across SAMHSA's three Centers, as well as nationally.

SAMHSA's Advisory Committee on Women's Services (ACWS)

Members of SAMHSA's Advisory Committee for Women's Services (ACWS) advise SAMHSA's Associate Administrator for Women's Services on appropriate activities to be undertaken by the agency with respect to women's substance abuse and mental health services, collect and review data, and improve the collection of data on women's health. ACWS members include physicians, practitioners, treatment providers, other health professionals and consumers. They have clinical practices, specializations, or professional expertise that include a significant focus on women's substance use and mental health conditions.

In the past two years, the ACWS agenda has reflected the members' interests and priorities as well as the realities of the field. Members are engaged in conversations with national, State and local experts on advancing behavioral health of women and girls in the health care reform environment, and plan to continue that discussion in the future. Recently, the ACWS reviewed and commented on SAMHSA's "Substance Abuse Treatment Improvement Protocol for Women" that will be published in the summer of 2009. Members attended the Third National Conference on Women, Addiction, and Recovery where they held a listening session with a national audience representing different facets of the communities served by SAMHSA. SAMHSA's ACWS has developed a strategic plan outlining national substance abuse and mental health treatment and prevention priorities for women and girls.

The Committee's strategic plan includes the following priorities:

- Consumer/Peer-led Services
- Criminal and juvenile justice
- Cultural competence/Eliminating disparities
- Evidence-based practices/Science and Service

- Models for integration of care (mental health and substance abuse with primary care)
- Suicide prevention
- Trauma
- Wellness
- Data

SAMHSA's women's health programs, for the most part, are managed through SAMHSA's three Centers: the Center for Substance Abuse Prevention (CSAP), the Center for Substance Abuse Treatment (CSAT), and the Center for Mental Health Services (CMHS). Program measures are conducted in SAMHSA's three Centers to ensure that the Agency is reaching those in need of services; providing adequate resources; and developing culturally-appropriate, evidence-based interventions. Under its statutory mandate, SAMHSA must provide national data on mental health and substance abuse treatment services and on persons with mental and substance use disorders. This mandate includes the determination of the national incidence and prevalence of the various forms of mental illness and substance abuse, and characteristics of treatment programs. Conducting services-related assessments, including evaluations of mental health and substance abuse prevention and service systems and the organization and financing of care, is also part of SAMHSA's mission.

SAMHSA is also required to collect performance data and analyze the effectiveness of its programs. In particular, SAMHSA must meet the requirements of the Government Performance and Results Act (GPRA). Under GPRA, agencies must develop long-term strategic plans defining goals and objectives for their programs, develop annual performance plans specifying measurable performance goals for all of the program activities in their budgets, and publish an annual performance report showing actual results compared with each annual performance goal.

Related to GPRA is the Program Assessment Rating Tool (PART). The Office of Management and Budget (OMB) developed PART to assess the effectiveness of Federal programs and help ensure that management actions, budget requests, and legislative proposals are focused on results. PART examines various factors that contribute to the effectiveness of a program and places great emphasis on performance measurement and program results, including improved outcomes and efficiencies. PART also assesses if and how program evaluation is used to guide program planning and to corroborate program results. Increasingly, information from GPRA and PART assessments is being factored into Federal budget requests.

SAMHSA has responded to these requirements in various ways, including the development of a set of National Outcome Measures (NOMs). NOMs data cover 10 domains for all discretionary and block/formula grant programs with client-level outcomes (<http://www.nationaloutcomemeasures.samhsa.gov>.) A primary function of NOMs is the creation of a basic national data set to measure the performance of systems administered by State substance abuse and mental health agencies.

Programs That Improve the Lives of the Federal Workforce

SAMHSA has incorporated a number of employee focused initiatives to the Agency's mission and policy workforce to address women and all of its employees.

The Partnership for Public Service released its Best Places to Work in Federal Government index earlier this year and the Substance Abuse and Mental Health Services Administration (SAMHSA) was noted as one of the "Biggest Movers" in 2009 (<http://bestplacetowork.org/BPTW/analysis/toprends.php>). SAMHSA enjoyed a 45% increase from its score in 2007 and moved up 68 places in the rankings!

In fact, according to the 2008 OPM Federal Human Capital Survey:

- Employees' sense of empowerment has increased from 27% to 41% (52% improvement)
- High levels of respect for Senior Leaders increased from 32 % in 2006 to 53 % in 2008 (66% improvement)
- SAMHSA employees' overall satisfaction with their jobs has increased from 54% to 68% (26% improvement)
- Employees' overall satisfaction with SAMHSA, as an organization, has increased from 38 % to 60 % (58% improvement)

Agency leadership attributes much of this success to SAMHSA's employee-driven, work/life balance, human capital initiative, called "**PeopleFirst.**" Flying in the face of typical governmental human capital improvement efforts, SAMHSA eschewed external consultants who would assess and direct change from the top down. Instead, the union and senior management partnered to enlist the help of people who knew the agency (and its problems) best – the employees. The selected 14-member team reflected the diverse SAMHSA workforce.

The PeopleFirst Team then conducted a multi-faceted in-reach campaign to request comments, summarize feedback, and provide updates on progress toward the collective goal of making the agency a stimulating and supportive place to work. Employees identified problems ranging from poor work/life balance, opportunities for community development, and a lack of clear agency values. From 300+ suggestions received, the Team created a roadmap based on the PeopleFirst Vision (*Shared Values. Shared Goals. Shared Knowledge. One Community.*) and invited all of SAMHSA to join the transformation.

Thanks to the hard work of 150+ employees over the past two years, PeopleFirst has launched numerous activities to support increased work/life balance and an improved organizational culture. To date, PeopleFirst has increased employee engagement and work/life balance through the following employee developed and led activities:

- ***SAMHSA In-Motion.*** 13 employee-organized, physical fitness activities ranging from the "Sammies" softball team to a walk at lunch club. Over 125 people are involved.
- ***A Parenting Brown-Bag Group*** that meets bi-weekly.
- ***Development of a plan and identification of resources to create a Lactation Room*** for new mothers

- **Days of Caring.** A cross-agency, group-based annual community service project. Nearly 200 people participated in 2008.
- **InsideSAMHSA newsletters.** By employees, for employees.
- **Journey to Fitness Team.** A SAMHSA team of employees that trains together and completes the Marine Corps Marathon each year. More than 20 employees participate each year.
- An **employee musical** incorporated into SAMHSA's award winning "Recovery Month Campaign."
- 20+ other PeopleFirst organizational improvement projects.

In addition to PeopleFirst, SAMHSA has a long-standing **Health and Wellbeing Program** whose mission is to empower individuals to protect and improve their health by developing a lifestyle that supports physical, mental and emotional fitness, and promotes a higher energy level in a positive workplace atmosphere.

The underlying goal of the Committee is to serve as a catalyst to encourage all employees to take action to improve their own health. In reference to women's health, this Committee has provided resources which are designed to do three things:

- Motivate women toward healthier lifestyles
- Educate women to take greater responsibility and a more active role in their health, i.e., annual mammograms, fitness tips, and seminars on women's health issues
- Empower women to make better-informed healthcare decisions

In addition, the Committee has offered specific health screening services for women, i.e., mammograms, high cholesterol, high blood pressure, osteoporosis, HIV and provided information and resources to address substance abuse to include alcohol use and prescription drugs, obesity, proper nutrition, cervical cancer, colorectal cancer, depression, anxiety and other health related concerns.

SAMHSA has five Subcommittees under the Health and Wellness Committee:

1. **The Fitness Subcommittee** supports the SAMHSA Prevention and Wellness Center. It offers a variety of wellness programs to benefit the body and mind. This Committee promotes opportunities for SAMHSA's workforce to engage in regular fitness or increase current fitness level. Women and all staff are encouraged to increase their level of fitness in some measurable way for:
 - Improved cardio respiratory health
 - Reduced body fat
 - Increased muscular endurance and strength
 - Reduced blood pressure
 - Increased flexibility
 - Reduced stress
 - Improved self-esteem
2. **The Nutrition Subcommittee** provides opportunities for women and all employees to interact onsite with reputable resources regarding healthy diet and nutrition.
3. **The Wellbeing Subcommittee** provides opportunities for women and all SAMHSA's employees to participate in general contemporary well-being activities that promote positive problem solving and life management strategies.

4. **Health Literacy Subcommittee** provides for women and all of SAMHSA's employees to have opportunities to increase their knowledge about health issues, particularly those illnesses that can be prevented or mitigated.
5. **Safety Subcommittee** assures the safety and health of SAMHSA's workers by setting and enforcing standards; providing training, outreach, and education; and encouraging continual improvement in workplace safety and health.

Programs That Improve the Lives of Women and Girls

1. Program Description:

The Pregnant and Postpartum Women (PPW) Program

- In 2007, 7.7 Million women needed substance abuse treatment.
- An average of 5.2 percent of pregnant women, aged 15 to 44, reported using illicit drugs in the past month, compared to 9.7 percent of non-pregnant women in that same age group.
- However, among women aged 15 to 17, those who were pregnant had a higher rate of use (22.6 percent) than those who were not pregnant (13.3 percent).

SAMHSA and its component Centers serve health professionals and the public by disseminating scientifically sound, clinically relevant information on best practices in the treatment of addictive disorders, and working to enhance public acceptance of that treatment. CSAT provides staff and leadership for the PPW Program.

The focus of the PPW Program is to:

- Expand availability of sustainable, comprehensive, quality residential treatment, recovery support, and family services for pregnant and postpartum women and their minor children impacted by perinatal and environmental effects of substance abuse.
- Preserve and support the family unit by including fathers of the children, partners of the women, and other extended family members in the treatment program.

The Pregnant and Postpartum Women (PPW) Program has proven successful in helping to reach those in need of substance abuse services by:

- Providing comprehensive services to women during pregnancy significantly improving the lives of women, children, and their families.
- In 1992, in accordance with section 508 of the Public Health Service Act, SAMHSA developed a gender and culturally specific residential treatment program for pregnant and postpartum women.

a) Relevant Statistics:

- To date, 2,309 women have been served nationally by PPW grantees.

- 13.9 percent of women served reported using methamphetamine.
- To date, between in-take and 6-month follow-up, females reporting:
 - No substance use – increased 111 percent
 - No arrests – increased 10.7 percent
 - Being employed – increased 139.5 percent
 - Being socially connected – increased 6.8 percent
 - Being housed – increased 5.9 percent

2. Future Programs

a) *Target Population(s):*

- PPW Programs should use the Recovery-Oriented Systems of Care Approach (ROSC) to achieve sustainability and communicate their effectiveness at the local level.
- The benefits of ROSC for PPW programs include:
 - An approach that more effectively responds to individuals, families, and communities.
 - A framework for structuring policy development and Planning.
 - The opportunity to apply knowledge gained from recovery-oriented research to PPW programs.
 - The ROSC approach contributes to the effective application of the PPW program.
 - Recovery support services in conjunction with clinical treatment help to establish a more continuous treatment response.
 - The ROSC approach ultimately means that the program focuses on reducing the acute and severe relapses that substance abusing clients often experience.

b) *Benchmarks:*

- Reaching those in need of services.
- Providing adequate resources.
- Developing culturally-appropriate, evidence-based interventions.
- Building and sustaining a qualified workforce.
- Integrating substance use disorder services into the public health paradigm.

c) *Other:*

- In FY 2008, SAMHSA awarded 16 grants, totaling \$7.6 million, and continued funding for 8 existing grants at \$3.4 million.
- In FY 2009, CSAT expects to fund 10-11 new PPW Grants, totaling approximately \$4.9 million.

- The 2010 President's Budget request includes \$16 million for Pregnant & Postpartum Women programs and activities -- level with the 2009 Omnibus.
- In the future, CSAT plans to identify and document unique needs of three specific populations served by the PPW program:
 - young PPW women (ages 18-24);
 - older minor children;
 - fathers of the children; and
 - increase technical assistance in areas of trauma, sustainability, designing and implementing services and interventions for children, 17 and under.

Program Description 2:

Fetal Alcohol Spectrum Disorders (FASD) Prevention and Diagnosis and Intervention Initiatives

- SAMHSA's Center for Substance Abuse Prevention (CSAP) spearheaded the FASD initiatives which are intended to prevent FASD or to diagnose and provide interventions to those with an FASD.
 - SAMHSA's 15 FASD prevention initiatives are integrating evidence-based interventions within local and State Women, Infants, and Children (WIC); Healthy Start; and substance abuse treatment programs.
 - The evidence-based interventions include alcohol screening and brief intervention, Project CHOICES, and the Parent-Child Assistance Program. The goal of these initiatives is to eliminate alcohol consumption by pregnant women.
 - The eight FASD diagnosis and intervention initiatives are integrating FASD screening, diagnosis, and interventions within local and State child mental health and developmental disabilities programs, and local juvenile justice and child welfare programs.
 - These initiatives are to improve the functioning and quality of life of children and youth with an FASD and their families.
 - These initiatives started February 1, 2008.

Fetal Alcohol Spectrum Disorders (FASD) Center for Excellence

- SAMHSA created the FASD Center for Excellence in 2001.
- The FASD Center for Excellence is funded through a contract (\$9.8 million) and has a five-part strategy of products and services:
 - Training and technical assistance: build capacity among individuals, programs, agencies, States, and systems.
 - Information dissemination: call center, print and multimedia products, Web site (www.fasdcenter.samhsa.gov), and an ongoing survey of the literature to identify gaps and trends in the field.
 - Capacity building: subcontracts with programs and agencies across the nation who are formalizing and implementing promising interventions and treatment practices.

- Partnerships: national, state, and local levels to provide support for program development and capacity building.
- Building infrastructure and collaboration: convene national meetings and summits on FASD.

a) *Relevant Statistics:*

- FAS alone cost the United States more than \$4 billion in 1998.
- The average lifetime cost for each child with FAS is \$2 million.
- \$1.6 million for medical care services
- \$0.4 million for loss of productivity

One prevented case of FAS saves:

- \$130,000 in the first 5 years
- \$360,000 in 10 years
- \$587,000 in 15 years
- More than \$1 million in 30 years

Lupton, Burd, and Harwood (2004)

Program Description 3:

In Focus: Violence and Trauma and Trauma Informed Care Program for Women and Girls

The Trauma Informed Care program is designed to help States and communities become “trauma-informed” to offer effective aid to trauma survivors within the contexts in which they live and work.

Impacts of Violence and Trauma

- In the early 1990s CMHS began to listen, document, and to develop a way to respond to the voices, pleas, and experiences of a rising tide of women and girls receiving services in the public mental health system who spoke movingly of the pain and disability created by their personal histories of violence and trauma experienced as a result of physical and/or sexual abuse– frequently beginning in childhood.
- Initially, attention focused on the pervasiveness of physical and sexual violence and its aftermath of trauma (up to 90-100 percent of women and girls in the mental health system have suffered these experiences), trauma’s major and enduring physical health consequences, the precipitous spiritual questioning trauma engendered, the multiple and health debilitating self soothing addictive habits undertaken, and the inter-relationship of acute trauma symptoms with commonly labeled psychiatric and substance use disorders.
- It is important to stress that the range of the impacts of trauma are not limited to mental health and substance abuse disorders, but do typically involve chronic related health problems, need for appropriate supported housing, counseling and support for issues and barriers faced in seeking and achieving educational and employment opportunities, extended support in addressing consequent family welfare issues, and possible contact with rape and domestic violence programs, victim assistance programs, and even criminal justice sanctions and incarceration.

- For women consumers, interventions to address trauma’s impacts often require involvement of the full spectrum of public health services in ongoing trauma resolution and recovery efforts. Trauma, it is now believed, is a “public health crisis”.
- It is also a health care reform crisis. Women’s unresolved trauma legacies have an acute impact on overall health care issues.
- Issues requiring particular attention are the multiplicity of women’s health problems (many of which are driven by histories of violence and abuse), high health care needs but low use due to access and cost issues, and the “gender gap” in female insurability.

Relevant data

- Women’s high rates of experiences of violence and trauma and numerous unmet health care needs are connected in direct and indirect ways (for example, it is legal in 9 states and the District of Columbia, for insurers to deny applicants who are survivors of domestic violence). In addition, many women experience more than one type of violence and abuse, whose impacts can act together as a common etiology underlying many different health conditions.
- Therefore, an untreated history of violence and abuse in women is a strong predictor of higher health care use (when accessible) and higher costs (not even including the costs to the workplace as mentioned above).
- These conditions continue to prevail even in the face of evidence that effective trauma interventions reduce overall health care use and cost.
- In seeking this behavioral health and trauma care, women find that most health care provider organizations and workplace employers have been slow to address violence and abuse as health issues, and thus women and girls seldom receive targeted treatment. Not surprisingly, none of these entities are advocates for behavioral health services for trauma recovery.

2. Future Program Needs/Barriers and other concerns

- Within this context, it has become strikingly clear that the majority of existing providers lack the capacity to effectively assist women with histories of abuse and trauma.
- This fact alone has stimulated a burgeoning revolution in mental health and human services organization and delivery.
- A number of troubling service delivery breakdowns have contributed to the momentum of this revolution, including: lack of appropriate women-centered means of screening /assessment for trauma; lack of provider training in clinical and community-based trauma treatment approaches; and persistent and inappropriate provider misdiagnosis, under-diagnosis, or failure to diagnose trauma.

- Compounding problems further, providers typically offer only the standard regimen of services-as-usual for these women, often leading to a revolving door of treatment and discharge followed by return for more of the same.
- Even when correctly diagnosed, trauma is still typically viewed as a one episode event in the lives of these women, rather than an ongoing series of violent and abusive events woven throughout the life cycle.
- Little or no attention is paid to the inter-generational cycle of trauma that keeps recurring in each new generation of children within trauma-impacted families, nor to the generation to generation impacts of “historical trauma” suffered by groups such as African-Americans, American Indians, Hispanics, Asians, and others. Thus, a new services philosophy and set of values and practices has evolved into a management framework and set of operating principles directed at reframing the current “top down” provider systems into “partnerships for recovery” between women and girls and their coaches or mentors in the practice of trauma informed care.

Program Description 4:

After the Crisis: Retraumatization from Disasters Technical Assistance Initiative (SAMHSA/CMHS/National Center for Trauma Improved Care (NCTIC/GAINS) 2004 until 2013)

- Considerable work has been done over the past 30 years concerning the role of mental health systems in disaster response. State and Federal governments, and national disaster response organizations have provided leadership in addressing mental health needs in both disaster preparedness and response. Some attention has been paid to the needs of people diagnosed with mental illnesses, who may be at higher risk for distress following disasters, and whose stress symptoms may manifest in ways that mimic exacerbation of psychiatric illness.
- A growing body of evidence suggests that increased vulnerability probably reflects the high rates of previous forms of trauma, especially childhood physical and sexual abuse, which can range up to 90 percent or more among this population. Higher rates of post-disaster distress among people with psychiatric diagnoses may also be related to the increased risk of victimization (particularly interpersonal violence) following a disaster.
- In addition, disasters pose unique problems for people with mental health problems and abuse histories residing in psychiatric facilities and in correctional settings, and those who experience violent crimes in the aftermath of a disaster.

Relevant Data and other information:

- Despite this evidence of increased vulnerability, people with mental health problems and abuse histories often rise above the immediate distress of a disaster to provide leadership and support to others.
- In the past few years, some of the most exciting and innovative approaches to mental health disaster response have been peer-run and peer-delivered services.

- Peer-run programs are inherently consistent with established principles of disaster response, since they emphasize outreach, occur in natural community settings, emphasize people's strengths, avoid mental health labels, and are likely to be culturally sensitive because they are delivered by people who are themselves community members.
- However, information about peer-run programs is not widely available and is only beginning to be integrated into mainstream disaster response.
- The significant retraumatizing impact of terrorism and natural disasters has recently come to public attention.
- Since trauma has a cumulative and repeating impact across the lifespan, it can be anticipated that people with prior trauma histories will be especially vulnerable to the impact of a disaster and that they will be more likely than others to be revictimized in the aftermath.
- It can also be anticipated that responding to people with prior trauma histories may pose special difficulties.

Program Description 5:

Integrating Services for Female Victims of Crime: Bringing Together Mental Health, Criminal Justice, and Victims Services CMHS/Council of State Governments/Office of Violence against Women, Department of Justice through 2010

- SAMHSA's CMHS is successfully collaborating with the Council of State Governments (CSG) /Office of Violence against Women (OVW), and the Department of Justice (DOJ) to address women diagnosed with mental illness and victims of crime.
- In order to improve the response to women diagnosed with mental illness who have been victims of crime, CMHS and CSG are coordinating a multi-year project focused on this population of women.
- CSG developed an Issue Brief that summarizes the latest research regarding this issue, identifies some programs and resources that serve women with mental illness who are recent victims of crime, and recommends an action agenda for the Federal Government.
- Based on the issue brief and input from mental health and victim services experts, CSG has drafted policy and practice recommendations to serve this population of crime victims, and recently coordinated a meeting of key leaders in the fields of mental health and victim services to respond to these recommendations. These recommendations will serve as a foundation from which mental health and victim service providers can build new, collaborative responses to women with mental illness who have been victims of crime.

Relevant Statistics/Data

- Women with mental illness are over 40 percent more likely to be victims of violent crime than other women.

- Mental health service providers, victim advocates, and other policymakers and practitioners generally know little about women with mental illness who have experienced violence.
- Furthermore, State and local government officials and advocates have few, if any, resources available to them—resources that can be tapped to help protect, inform, serve, and treat this population and minimize the likelihood that they are victimized again.

Future Programs:

SAMHSA’S CMHS developed a new initiative entitled “*Cross-Generational Trauma-Informed Peer Leadership/Mentoring.*” CMHS is collaborating with NCTIC on this initiative. This program is designed to continue through 2013.

- This initiative develops sustained leadership for trauma-informed systems change and collaboration among older and younger women to address issues of trauma and women, and to enhance strategic planning for the prevention of violence and abuse and the promotion of mental health and wellness.
- The objectives address the particular concerns of women, especially young women and transition-aged youth, as related to trauma’s impact on their spiritual, social, mental, and physical wellness.
- This initiative represents a mentoring model that allows for partnering of older and younger women to provide for leadership development and transition planning.
- Goals are to create empowerment strategies for consumers/survivors in integrating their perspectives within TIC systems/organizational changes activities; to provide a forum for professionals and peers to share dynamically in leadership activities and mentoring relationships; and to promote concepts of healing and recovery for women.
- To accomplish the above, the establishment of a Women’s Leadership Sub-Council under NCTIC will be implemented which will provide recommendations specific to engaging youth and young women in trauma-informed systems change and develop a framework for a guide to developing a national leadership institute.

Program Description 6:

Federal Partners Subcommittee on Women and Trauma

- Under the on-going Federal Partnership on Mental Health Transformation sponsored through the SAMHSA /CMHS, a new Committee has recently been formed to focus on Women and Trauma.
- Co-Chaired by CMHS and the Department of Labor, the Committee currently has representation from 23 agencies, including the Departments of Justice, Defense, and Housing and Urban Development, and sub-agencies, such as the Centers for Disease Control and Prevention, the Office on Disability Employment Policy, and the Administration for Children and Families.

- The Committee has identified as its primary goal, to build awareness and stimulate action regarding women and trauma issues within the health and human services, justice, education, and workforce policy systems to coordinate and advance all appropriate Federal agencies' services and supports for women and trauma issues.
- Core strategies for achieving this goal are in development, and include the following:
 - To promote prevention of trauma related issues using models of early intervention to augment positive outcomes for women's health, wellness and healthy communities.
 - Build awareness regarding women and trauma issues within the health and workforce policy systems.
 - Identify ways of impacting current workforce training agenda to train current providers.
 - Develop outline for national public health strategy to promote awareness of "at risk" trauma indicators and linkages to responsive trauma health services.
- In developing the Committee Action Plan, members acknowledge the tremendous cost that unrecognized and unaddressed trauma has on women, their families, their work, and their communities. The Committee acknowledges that trauma is a public health concern that ripples across and impacts every facet of life for women and those around them. As such, the Subcommittee sees its work as inextricably linked to health care reform, as well as to the psychological, social, educational, and physical empowerment of women and girls.

Other SAMHSA programs Targeting Women and Girls

SAPT Block Grant: Prevention Set-Aside and SPF-SIG

- The SAPT Block Grant is based on a congressionally-mandated formula that is administered by two of SAMHSA's three Centers (i.e., CSAP and CSAT) with 20 percent of the total funding designated for substance abuse prevention.
- The Strategic Prevention Framework implements a five-step process to promote protective factors, reduce risk-taking behaviors, build assets and resilience, and prevent problem behaviors across the lifespan.
- Listed are two examples from states whose sub-recipients' programs are targeted toward women:

Kentucky

KIDS NOW Plus is a program of the Department of Mental Health and Substance Abuse, and it is designed to work with pregnant women who need help abstaining from alcohol, tobacco, and other drug use. The program's components include screening pregnant women for substance abuse, prevention services, and case management to help women gain access to resources.

North Carolina

For one of the SPF-SIG sites, the local needs assessment for Robeson County targeted Native American women. Currently, the grantee is in its implementation phase and is providing technical assistance to the community to identify the most appropriate strategy for this population.

HIV/AIDS

CSAP is administering several HIV/AIDS prevention targeting women of color.

- The Minority AIDS Initiative was created in 1999 when the Congressional Black Caucus initiated a partnership with the Department of Health and Human Services to significantly increase the national response to the HIV/AIDS epidemic in racial and ethnic minority communities.
- Women of color are particularly affected by HIV/AIDS. Black women accounted for two-thirds of new AIDS cases in 2007; Latinas represented 15 percent and white women, 17 percent.
- SAMHSA's Substance Abuse and HIV Prevention Discretionary Grant provides 5-year funding to community-based organizations and other non-profit entities to prevent substance abuse and new HIV transmission among minority women.
- SAMHSA's CSAP issued an RFA in FY 2008 that identified African American and Latino women as one of the six eligible subpopulations that applicants can apply for funds to provide gender-specific prevention services.
- CSAP's current MAI portfolio is comprised of 135 active grants, of which 10 percent target minority women for evidence-based services to prevent substance abuse and HIV.

Guidance to States: Treatment Standards for Women with Substance Use Disorders

- Under contract to SAMHSA, experts in the addiction treatment field and members of the National Association of State Alcohol and Drug Abuse Directors (NASADAD's) Women's Service Network published treatment standards with the objective of helping States to create or modify their own standards for the treatment of women with substance use disorders.
- The document is based on the experience and expertise of members of NASADAD's Women's Services Network, representing most State Alcohol and Drug Abuse Agencies.
- It addresses the delivery of a continuum of services (including clinical treatment, clinical support and community support services) to meet the unique needs and barriers to treatment for women with substance use disorders that often prevent women from succeeding in recovery.
- It also includes a description of each treatment element, recommendations for the key standards for each element and key considerations for special populations including pregnant women, women with children and women involved in the criminal justice system.

Behavioral Health Core Competencies for Working with Women and Girls

- This project will identify the competencies needed to implement gender-responsive behavioral health care services.
- The competencies development project is part of a larger Behavioral Health Workforce Initiative by SAMHSA.
- Competencies are a set of related knowledge, skills, and attitudes in a defined work setting that are necessary to perform successfully job duties and responsibilities.
- Competencies may also include other characteristics such as abilities, personal characteristics, values, and traits required for successful performance.
- This project will identify and describe core competencies for serving women; it will offer prevention and treatment agencies guidance to support the development of individual staff members capable of delivering effective services for women and girls.
- The competencies can be used in conjunction with emerging treatment standards and best practices for programs.

Overarching Recommendations

SAMHSA recommends that substance use and mental health are intrinsic components of an integrated approach to national health care. SAMHSA's recommendations include the following:

- Provide the necessary policy and service mechanisms that advance the mental health and the prevention and treatment of substance abuse for women and girls, their families and their communities. Their wellness is essential in reducing legal, social and other-related health care costs as envisioned in health care reform.
- Continue to promote the broad concepts of prevention and wellness – to include the prevention of addictions and mental illnesses -- through awareness, education, and environmental/behavioral change.
- Maintain the work of community mental health and substance abuse treatment providers who have special expertise in gender-appropriate care and are family-centered.
- Pursue data-based evaluation and accountability of public health programs that impact women and girls to identify service gaps, develop best practices, and support comparative effectiveness research.
- Continue efforts to develop operational standards for trauma-informed healthcare and core competencies of individuals who work with women and girls in the fields of substance use and mental health.
- Strengthen the evidence-base on gender-specific health services and programs for women of color in order to reduce health disparities, improve patient safety, and ensure quality care.

- Encourage collaboration across HHS and other Departments around the vital need to overcome stigma and eliminate barriers to treatment for mental and substance use disorders.