

## **Report to Congress**

### **HHS Activities to Improve Women's Health As Required by the Affordable Care Act**



**2017**

U.S. Department of Health and Human Services  
Office of the Secretary  
Office of the Assistant Secretary for Health  
Office on Women's Health

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## **I. EXECUTIVE SUMMARY**

The Patient Protection and Affordable Care Act of 2010 (P.L. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (P.L. 111-152), which are collectively known as the Affordable Care Act, included numerous provisions related to the health of women. Specifically, section 3509, entitled “Improving Women’s Health,” details requirements related to women’s health for various U.S. Department of Health and Human Services (HHS) agencies and offices. The Secretary of HHS, through the HHS Office on Women’s Health (OWH), is required to issue a report to Congress not later than one year after the date of enactment of this section and every second year thereafter, describing the activities carried out under section 229 of the Public Health Service Act (as amended). This report is the fourth that HHS has provided to Congress under this provision, and it fulfills the requirement for 2017.

The Affordable Care Act codifies the establishment of an Office on Women’s Health within the Office of the Secretary of HHS. The following HHS offices and officials also focus on women’s health:

- “Office of Women’s Health and Gender-Based Research” at the Agency for Healthcare Research and Quality (AHRQ);
- “Office of Women’s Health” at the Centers for Disease Control and Prevention (CDC);
- “Office of Women’s Health” at the Food and Drug Administration (FDA);
- “Office of Women’s Health” at the Health Resources and Services Administration (HRSA);
- “Office of Research on Women’s Health” at the National Institutes of Health (NIH); and
- Associate Administrator for Women’s Services at the Substance Abuse and Mental Health Services Administration (SAMHSA)

While all of these offices were already in existence prior to the Affordable Care Act, in some instances, the legislation gives them new authority and protection from termination or reorganization without the direct approval of Congress.

The HHS offices and officials that focus on women’s health report to the authorities described below:

- The HHS Office on Women’s Health is led by a Deputy Assistant Secretary for Women’s Health who may report to the HHS Secretary.
- The AHRQ Office of Women’s Health and Gender-Based Research is led by a director who is appointed by the Director of AHRQ.
- The CDC Office of Women’s Health is headed by a director who is appointed by the Director of the CDC.
- The FDA Office of Women’s Health reports to the Commissioner, Food and Drug Administration.

- The HRSA Office of Women's Health is headed by a director appointed by the HRSA Administrator.
- The NIH Office of Research on Women's Health reports directly to the NIH Director.
- The Associate Administrator for Women's Services at SAMHSA reports directly to the SAMHSA Administrator.

There is also an HHS Coordinating Committee on Women's Health (CCWH), which is chaired by the Deputy Assistant Secretary for Women's Health and composed of senior level representatives from each of the agencies and offices of the Department of Health and Human Services. The Directors of the AHRQ Office of Women's Health and Gender-Based Research, CDC Office of Women's Health, FDA Office of Women's Health, and HRSA Office of Women's Health will serve as members of the HHS Coordinating Committee on Women's Health.

The Affordable Care Act charges the OWH Office on Women's Health, the AHRQ Office of Women's Health and Gender-Based Research, the CDC Office of Women's Health, the FDA Office of Women's Health, and the HRSA Office of Women's Health with specific functions and tasks related to women's health. Specifically, the HHS Office on Women's Health, as well as the Directors of the Offices of Women's Health at the CDC, AHRQ, HRSA, and FDA shall establish women's health-related goals and objectives. The Directors of the Offices of Women's Health at the CDC, AHRQ, HRSA, and FDA must also report on the current level of their agency's activities related to women's health. The directors of those offices at the CDC, AHRQ, and HRSA also shall identify women's health projects that should be conducted or supported by the agency and consult with health professionals and other groups on policies.

The Affordable Care Act does not provide deadlines to complete these requirements. As detailed in previous reports, HHS has undertaken a number of activities and initiatives to meet the requirements of section 3509 since 2010. This report provides a summary of activities carried out by HHS agencies and offices from March 23, 2015, to March 23, 2017. Since the last report in 2015, HHS has expanded on efforts previously reported and begun new initiatives to address the requirements of section 3509.

## II. INTRODUCTION

HHS is the U.S. government's principal agency for protecting the health of all Americans and providing essential human services. HHS improves women's health through programs that cover a spectrum of activities that impact health, public health, and human services' outcomes throughout the lifespan as well as through research, direct clinical service delivery, and policy development. Improving the health of women has been one of HHS's strategic priorities for more than 30 years.

The Affordable Care Act contains provisions designed to address women's health through improvements in health systems, policies, and programs. Section 3509 of the Act, "Improving Women's Health," directs HHS to take various steps to make women's health a priority. Specifically, section 3509 calls for the following:

- establishing goals and objectives for issues of particular concern to women;
- monitoring HHS activities related to Women's health and "coordination of activities"; and
- facilitating access to women's health information through the National Women's Health Information Center."

The status of women's health across communities, states, regions, and the nation is one of disparity and inequality. Women, particularly those in minority populations, face additional social and economic barriers affecting their health and well-being.<sup>1</sup> Women are more likely to be covered as dependents, which puts them at a greater risk to lose health insurance coverage, if spouses lose their job or if women become widowed or divorced.<sup>2</sup> Women are more likely than men to live in poverty, are less likely to be employed, and on average are more likely to earn less than men.<sup>3</sup>

HHS has taken numerous steps to address these concerns and disparities. For example, the increased participation of women in clinical trials research is one critical way to address gaps in knowledge about women's health. This report, required under section 3509 of the Affordable Care Act, details recent HHS activities focused on improving women's health.

OWH and the OWH-led HHS Coordinating Committee on Women's Health (CCWH) are the focal points for activities across HHS to safeguard and improve the health of all women. OWH provides national leadership and coordination to improve the health of women and girls through policy, education, and model programs in support of its vision that all women and girls have the opportunity to achieve the best possible

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<sup>1</sup> Kaiser Family Foundation. *PUTTING WOMEN'S HEALTH CARE DISPARITIES ON THE MAP: Examining Racial and Ethnic Disparities at the State Level*. June 2009.

(<https://kaiserfamilyfoundation.files.wordpress.com/2013/01/7886.pdf>).

<sup>2</sup> Kaiser Family Foundation. *Women's Health Insurance Coverage*. October 2016. (<http://kff.org/womens-health-policy/fact-sheet/womens-health-insurance-coverage-fact-sheet/>). Accessed 11/13/16.

<sup>3</sup> National Women's Law Center. *Insecure & Unequal: Poverty and Income Among Women and Families 2000-2013*. September 2014. ([http://www.nwlc.org/sites/default/files/pdfs/final\\_2014\\_nwlc\\_poverty\\_report.pdf](http://www.nwlc.org/sites/default/files/pdfs/final_2014_nwlc_poverty_report.pdf)).

health. CCWH works strategically to provide guidance on women’s health policy, programming, and evaluation efforts; increase collaboration with federal and non-federal partners; advance evidence-based programs and policies; support sex- and gender-specific initiatives; and address gaps and disparities in women’s health. Along with partners across HHS, OWH and CCWH are working every day to improve the health of all women and girls. This report provides a snapshot of these activities from March 23, 2015, to March 23, 2017.

### **III. AGENCY/OFFICE-SPECIFIC REQUIREMENTS**

Section 3509 of the Affordable Care Act, entitled “Improving Women’s Health,” specifically addresses the following HHS components: OWH, AHRQ, CDC, FDA, HRSA, NIH, and SAMHSA.

The activities described below reflect the progress of each agency and office in improving women’s health in the reporting period (March 23, 2015–March 23, 2017).

## **HHS Office on Women's Health (OWH)**

OWH was established in 1991 in the Office of the Assistant Secretary for Health (OASH), within the Office of the HHS Secretary. The mission of OWH is to provide national leadership and coordination to improve the health of women and girls through policy, education, and innovative programs. OWH informs and influences policies, educates the public and professionals, and develops and expands innovative approaches to preventing disease and promoting health and healthy behaviors. (See **Table 1.**)

OWH is the main point of contact for other federal agencies and non-federal partners on issues related to women's health. It is committed to improving the health of women across the lifespan, with special attention to eliminating disparities in health status.

In addition to the national staff located in Washington, D.C., OWH works with Regional Women's Health Coordinators (RWHCs) who are located in the 10 HHS Regional Offices. The RWHCs cover the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, and the U.S. Pacific Island Jurisdictions.

The RWHCs coordinate and implement public health initiatives that promote a greater focus on women's health issues at the regional, state, and local levels. They advance the mission of OWH and represent the Deputy Assistant Secretary for Health-Women's Health (DASH-WH) by administering programs that improve the health of women in communities across the country. Through the RWHCs, OWH's work is sensitive to the local, state, and regional needs in women's health. They identify high-priority health conditions in their geographic areas, establish networking relationships, and implement initiatives addressing regional women's health concerns.

RWHCs work closely with state and territorial women's health offices or their designated women's health coordinators. By providing technical assistance and sharing resources with these non-federal women's health leaders, the RWHCs have built a nationwide network of connections. Thus, OWH has a ready infrastructure for rapidly disseminating health information and implementing HHS programs that benefit women and girls.

Region I\* – Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont

Region II – New Jersey, New York, Commonwealth of Puerto Rico, and U.S. Virgin Islands (St. Thomas, St. Croix, and St. John)

Region III – Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, and West Virginia

Region IV – Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee

Region V – Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin

Region VI – Arkansas, Louisiana, New Mexico, Oklahoma, and Texas

Region VII – Iowa, Kansas, Missouri, and Nebraska

Region VIII – Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming

Region IX – Arizona, California, Hawaii, Nevada, and the U.S. Pacific Island Jurisdictions (American Samoa, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Guam, Republic of the Marshall Islands, and Republic of Palau)

Region X – Alaska, Idaho, Oregon, and Washington

\* For the names and contact information for the RWHCs in each of the 10 regions, go to <https://www.womenshealth.gov/about-us/work-us/your-community>.

The following sections describe the specific requirements in section 3509 of the Affordable Care Act (amending Part A of Title II of the Public Health Service Act [42 U.S.C. 202 et seq.]) related to OWH. Each section describes progress on or completion of each requirement and, when appropriate, current activities and next steps.

### ***Establishment of an Office***

The requirements of section 229(a) of the Public Health Service Act (PHSA), [amending 42 U.S.C. 237a] have been fulfilled. OWH, in the OASH, within the Office of the Secretary, was established in 1991.

### ***Women's Health-Related Goals and Objectives***

OWH fulfilled the requirements of section 229(b)(1) of the Public Health Service Act, as amended by section 3509 of the Affordable Care Act, to “establish short-range and long-range goals and objectives within the Department Of Health and Human Services and, as relevant and appropriate, coordinate with other appropriate offices on activities within the Department that relate to disease prevention, health promotion, service delivery, research, and public and health care professional education, for issues of particular concern to women throughout their lifespan.”



OWH's first five-year strategic plan, implemented in fiscal year 2009, was a model for other offices within OASH. In 2016, OWH updated its strategic plan and refined its vision, mission, and goals. (See **Table 1.**)

<b>Table 1. HHS Office on Women's Health Vision, Mission, and Goals</b>	
<b><i>Vision</i></b>	All women and girls achieve the best possible health.
<b><i>Mission</i></b>	The Office on Women's Health provides national leadership and coordination to improve the health of women and girls through policy, education, and model programs.
<b><i>Goals</i></b>	<p>The Office on Women's Health provides national leadership to</p> <p>Goal 1. Inform and influence policies.            Goal 2. Educate the public.            Goal 3. Educate professionals.            Goal 4. Develop and expand innovative approaches.</p>

OWH's current strategic plan aligns its goals on issues of particular concern to women and girls as well as on the means to address them through policy, programs, communication, collaboration, and performance measurement. A new Performance Management System (PMS) developed by OWH creates a streamlined electronic data entry and analysis system that captures performance reporting requirements. Streamlining this process enables OWH to better track, and therefore, improve its overall performance, among other benefits.

OWH has routinely exceeded several of its targets. For example, one of OWH's overarching goals is to shape policy at the local, state, national, and international levels. OWH exceeded the goal for this measure by reaching 137 communities, state and local agencies, federal entities, and non-governmental or international organizations through its grants and community-based programs and initiatives. These entities have adopted or incorporated programs, policies, or recommendations generated or promoted by OASH.

The FY 2016 target for the number of promising practices identified by research, demonstrations, evaluation, or other studies to help prevent disease and improve the health of individuals and communities was 20. OWH exceeded that target, having had 37 promising practices identified.

In addition, the FY 2016 target for the number of *unique* public health contributions made by OWH to communities, governmental agencies, non-governmental and

international organizations was 25. It was measured by non-duplicative programs, reports, services, and events derived from the guidance and direction of OASH leadership and coordination. OWH exceeded that target because the office made 76 unique health contributions, which showed that more of OWH's disease prevention and health promotion efforts were integrated into communities and organizations.

This measure considers the number of initiatives/entities to which OWH provided leadership as well as those contributions made to committees, workgroups, advisory councils, etc. Examples of these types of initiatives include the Federal Women's Health Web Council, the Coordinating Committee on Women's Health (CCWH), and Chronic Fatigue Syndrome Advisory Committee (CFSAC).

Evaluation for OWH initiatives is ongoing and varies from program to program. The PMS's reporting function provides a more streamlined process for the continual assessments of the impact, outcomes, and utility of OWH's efforts to promote women's health. Follow-up analyses can be performed to show the cost effectiveness, program outcomes, and policy impacts of OWH's efforts. The measures for data analysis, outcome, and impact are determined during the funding announcement phase and are monitored throughout the project.

The following sections describe in greater detail OWH's progress on its goals.

### ***Expert Advice and Consultation***

OWH fulfilled the requirements of section 229(b)(2) to "provide expert advice and consultation to the Secretary concerning scientific, legal, ethical, and policy issues relating to women's health." OWH also advises the ASH on issues related to the advancement of women's health. OWH coordinates women's health initiatives and programs for the entire Department. Thus, OWH is uniquely positioned to look at all these activities across HHS, encompassing research, regulation, quality improvements, health services, and prevention programs.

These activities are consistent with, and reflect OWH's commitment to, providing national leadership to inform and influence policies on women's and girls' health. (See **Table 1**, OWH Goal 1.) Examples of these efforts follow.

- During the time period covered by this report, OWH was an HHS representative to the *White House Council on Women and Girls*. OWH collaborated with other federal partners in proposing actions that affect the lives of women and girls, especially related to their health and well-being.
- OWH participated in the development of the National HIV/AIDS Federal Action Plan as established by the White House's release of "National HIV/AIDS Strategy for the United States: Updated to 2020 (NHAS)" and the Executive Order "Implementing

the National HIV/AIDS Strategy for the U.S. for 2015–2020.” OWH’s participation resulted in gender-specific statements in the documents. The four goals of NHAS are reducing new HIV infections, increasing access to care and improving health outcomes for people living with HIV, reducing HIV-related disparities and health inequities, and achieving a more coordinated national response to the HIV epidemic. OWH’s RWHCs work closely with partners at the regional level to increase awareness of the NHAS.

- During the time period covered by this report, OWH was an HHS representative to the *Office of the Vice President’s Working Group on Violence Against Women*. The Working Group brought high-level attention to this issue and the profound consequences for those who experience family and intimate partner violence (IPV). The Working Group also focused on strengthening policies and making programmatic changes.

- OWH has a representative on the Opioids and Controlled Substances Subcommittee of the HHS Behavioral Health Coordinating Council (BHCC). The BHCC was established in 2010 to share information and identify and facilitate collaborative, action-oriented approaches to address the HHS behavioral health agenda without duplication of effort across the Department.

- OWH is examining the prevention, treatment, and recovery issues for women who misuse, have use disorders, and/or overdose on opioids. This effort builds on the *HHS Secretary’s Opioid Initiative* aimed at reducing prescription opioid and heroin-related overdose, death, and dependence. As a first step in this process, on September 29–30, 2016, OWH convened the *OWH National Meeting on Opioid Use, Abuse, and Overdose in Women*. More than 100 experts and stakeholders examined issues associated with the opioid crisis through the lens of women’s health. This meeting provided an opportunity to foster a national conversation about best practices in opioid use disorder prevention and treatment for women. It also supported a vigorous collaboration among researchers, public health practitioners, clinicians, policy makers, women with lived experience, and others. In July 2017, OWH released a white paper on the impact of opioids on women and a report of the September 2016 meeting’s proceedings.

- OWH sponsored an initiative called the *National Worksite Breastfeeding Support for Employers of Overtime Eligible (Hourly) Employees: Innovative Strategies for Success*. In it, OWH focused on worksites in non-office settings that were particularly challenging both to the employers of hourly workers and to those mothers who sought to express milk for their child. In doing so, OWH developed a searchable online resource that provides solutions to help employers in 22 industry sectors address time and space challenges in non-office, non-traditional settings. This resource also has 28 videos highlighting employer solutions from various industry groups, including manufacturing, retail, agriculture, education, health care, and information technology. The resource can be found here: [www.womenshealth.gov/breastfeeding/employer-solutions](http://www.womenshealth.gov/breastfeeding/employer-solutions)

In 2015–2107, OWH is conducting formative research to explore how to strengthen and enhance this online resource. Research will also explore how to advance dissemination to extend its reach and increase its utility. Evaluation efforts include the collection of metrics and continuing to engage and leverage partnerships. The results will be crucial to ensuring appropriate worksite support for nursing moms.

- OWH has representatives on the *Women and Trauma Federal Partners' Committee*. This Committee coordinates and promotes the development of policies and services among federal agencies that effectively support women and girls who have been affected by exposure to trauma. Other participating federal departments and agencies include the Departments of Labor (DOL), Justice (DOJ), Defense (DoD), State, Education (DOE), Agriculture (USDA), Veterans Affairs (VA), and Housing and Urban Development (HUD). As a result of their involvement with this Committee, the RWHCs in Regions II and V conducted trainings on the impact of trauma on women and girls and the principles of trauma-informed care for a diverse group of federal stakeholders.
- OWH has an ex-officios representative on the Breast and Cervical Cancer Early Detection and Control Advisory Committee. CDC's national Breast and Cervical Cancer Early Detection Program (BCCEDP) provides low-income, uninsured, and underserved women access to timely breast and cervical cancer screening and diagnostic services. The committee makes recommendations regarding BCCEDP's goals and objectives; implementation strategies; and program priorities, including surveillance, epidemiologic investigations, education and training, information dissemination, professional interactions and collaborations and policy.
- OWH manages the *Chronic Fatigue Syndrome Advisory Committee* (CFSAC). The purpose of the CFSAC is to provide advice and recommendations to the Secretary of HHS, through the ASH, on issues related to myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS). Research has shown that ME/CFS is three to four times more common in women than in men, a rate similar to that of autoimmune conditions such as multiple sclerosis and lupus. CFSAC focuses on policy, research, education, and access to care for those with this condition. The advisory committee includes ex-officio representatives from CDC, FDA, HRSA, NIH, AHRQ, and the Social Security Administration (SSA). In September 2016, the committee's charter was approved for two more years, and in the same process it was revised to include ex-officios from the VA and DoD. These two government agencies provide services to patients with ME/CFS and conduct research on illnesses with similar symptoms to ME/CFS such as Gulf War Syndrome. In addition, the number of members in the committee was increased from 11 to 13, so patients and caregivers would have a greater voice.

At the May 2016 meeting, two working groups reported and provided recommendations to the HHS Secretary. The first set of recommendations focused on the creation of Centers of Excellence working on ME/CFS and the second set on recommendations to the Institute of Medicine/NIH *Pathway to Prevention Reports*.

Both sets of recommendations were sent to the HHS Secretary for review and consideration. At the CFSAC meeting held in January 2017, the committee reviewed recommendations on educating pediatric healthcare providers to increase awareness of their role in assisting pediatric ME/CFS patients and their families in acquiring appropriate special services through schools. Meeting participants explored commonalities between ME/CFS stakeholders and HHS agencies around research goals.

### ***Monitoring HHS Activities***

OWH fulfilled the requirements of PHSA section 229(b)(3) to “monitor the Department of Health and Human Services’ offices, agencies, and regional activities regarding women’s health and identify needs regarding the coordination of activities, including intramural and extramural multidisciplinary activities.”

The DASH-WH, who also serves as the Director of OWH, chairs the HHS Coordinating Committee on Women’s Health (CCWH). OWH identifies ways to coordinate and expand the Committee’s efforts throughout the Department, thus maximizing HHS resources and outcomes for women and girls.

- OWH co-leads the *HHS Steering Committee on Violence Against Women (VAW)* with the Administration for Children and Families (ACF). Its mission is to lead HHS in developing a blueprint for a world free from violence against women and girls, integrating the work of each agency into its implementation. This Committee is composed of experts on VAW from agencies and offices within HHS that meet bimonthly to collaborate on VAW issues, identify gaps in program initiatives, and propose strategies and solutions to address these gaps.
- OWH is an active HHS partner in the U.S. Department of Transportation’s *Coordinating Council on Access and Mobility (CCAM)*. CCAM was established in 2004 and later codified as the Human Service Transportation Coordination in the Fixing America’s Surface Transportation (FAST) Act of 2015. CCAM goals include promoting interagency cooperation and minimizing duplication and overlap of federal programs and services, so transportation-disadvantaged persons have access to more transportation services and to the most appropriate, cost-effective ones. The council has been tasked with developing a strategic plan to strengthen interagency collaboration, address outstanding recommendations, and eliminate burdensome regulatory barriers. Members include the Secretaries of Health and Human Services, Education, Labor, Veterans Affairs, Agriculture, Housing and Urban Development, and the Interior as well as the U.S. Attorney General and the Commissioner of Social Security.
- The Region IX RWHC serves as the OWH representative on the *HHS Workgroup on Asian, Native Hawaiian, and Pacific Islanders Issues (WANHPII)*. The workgroup was established in 1997 to improve communication, coordination, agency policies,

programs, and evaluations that impact the health, health care, human services, and well-being of Asian American, Native Hawaiian, and Pacific Islander communities.

As a result of participating in WANHPH, the Region IX Offices on Women's Health, Minority Health, and Pacific Health partnered to compile a *Catalogue of Promising Practices which Address Non-Communicable Diseases in the U.S.-Affiliated Pacific Islands*. It highlights 308 culturally competent programs and initiatives focused on mitigating the epidemic of unhealthy eating, sedentary lifestyles, tobacco use, and binge drinking in women and their families in the Outer Pacific. In 2015–2016, more than 500 copies of the catalogue were shared at the White House Summit on Asians and Pacific Islanders, the CDC Chronic Disease Committee, the Cancer Council of the Pacific conference, the Pacific Island Health Officers Association meeting, and the Pacific Health Solutions through Research and Pacific conference in New Zealand.

- OWH has participated as a federal partner in NIH's National Institute for Diabetes and Diseases of the Kidneys (NIDDK) *Healthy Bladder Initiative* since its inception and has facilitated the collaboration of other HHS offices. NIH has undertaken a new research effort to prevent lower urinary tract symptoms/conditions in women. This effort addresses the bladder functioning as an important contributing factor to many chronic medical conditions but recognizes it is rarely discussed, thus negating cost-effective, self-management strategies that can lead to greater patient health outcomes and quality of life. In addition, OWH is an active member in NIDDK's *Urinary Incontinence Coordinating Council*.
- OWH was a representative to the *HHS LGBT Issues Coordinating Committee* until January 2017. The committee coordinated LGBT (lesbian, gay, bisexual, and transgender)-related policies across the Department and recommended future actions that HHS can take to improve the health and well-being of LGBT individuals.
- OWH co-leads the Policy Operating Group (POG) of the *HHS Task Force to Prevent and End Human Trafficking*. The Task Force is led by the Acting Assistant Secretary for ACF and the Acting Assistant Secretary for Health. The Task Force meets twice yearly and the POG meets bimonthly. The three subcommittees within the POG are Victim Services, Public Awareness and Prevention, and Research and Policy.
- OWH is an active member of the *HHS Reentry and Criminal Justice Working Group*. It shares information about efforts across the Department to support individuals involved in the criminal justice system—from arrest to incarceration (or other forms of justice system supervision)—to return to the community. Its work advances HHS's priorities in public health.
- The Region X RWHC co-chairs the *Regional Human Trafficking Workgroup* with ACF. The group is composed of regional staff from OASH, the Office of the Assistant Secretary for Planning and Evaluation (ASPE), HRSA, ACF, and the Office

of Refugee Resettlement (ORR). An Anti-Human Trafficking Awareness event was coordinated and held in January 2016 for HHS employees in Region X. The King County Prosecutor’s Office in Washington State and the chairperson of the Commercial Sexual Exploitation of Children group shared their efforts to stop human trafficking in King County.

- OWH leads the *Federal Women’s Health Web Council*, which was established in 2011. Its members represent agencies and offices across the federal government that create and maintain digital women’s health information. OWH’s leadership of the Council provides opportunities for improving the quality and accessibility of women’s digital health information across federal sources.

### ***Coordinating Committee on Women’s Health***

As noted, OWH has fulfilled the requirements of section 229(b)(4) to “establish a Department of Health and Human Services Coordinating Committee on Women’s Health, which shall be chaired by the Deputy Assistant Secretary for Women’s Health and composed of senior level representatives from each of the agencies and offices of the Department of Health and Human Services.”

In 1983, almost eight years before OWH was established, the ASH appointed the first-ever *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.” This Task Force was the precursor to the CCWH.

After much study, the Public Health Service Task Force issued Volume I of *Women’s Health: Report of the Public Health Service Task Force on Women’s Health Issues*. It included the Task Force’s findings and a series of recommendations for addressing women’s health. In response to those recommendations, the Department created the HHS CCWH to facilitate intradepartmental communication. (See **Table 2.**)

<b>Table 2. HHS Coordinating Committee on Women’s Health (CCWH): Vision, Mission, and Objectives</b>	
<b><i>Vision</i></b>	All women and girls lead safe and healthy lives.
<b><i>Mission</i></b>	Provide Department-wide leadership to address the health, safety, and quality of life of women and girls.
<b><i>Objectives</i></b>	<ul style="list-style-type: none"> <li>• Recommend and provide guidance on women’s health policy, programming, and evaluation efforts</li> <li>• Collaborate and coordinate initiatives with federal and non-federal partners</li> </ul>

	<ul style="list-style-type: none"> <li>• Deliver science-based and culturally competent health information and resources</li> <li>• Identify and develop a coordinated response to emerging issues that affect women’s and girls’ health and well-being</li> </ul>
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Since the establishment of the predecessor to CCWH in 1984, significant advances have been made that improve the physical and mental health of women in the United States. Along with the U.S. Congress, the White House, and millions of women, health care providers, and researchers, the HHS agencies and offices represented on the Committee have played a key role in these achievements. By working together, among other achievements, the CCWH has seen access to health care improved, new programs implemented, new treatments and screening techniques developed or funded, key policy changes executed, lifesaving vaccines approved, and landmark reports issued.

### ***National Women’s Health Information Center***

OWH fulfilled the requirements of PHSA section 229(b)(5) to establish a National Women’s Health Information Center (NWHIC) to “facilitate the exchange of information regarding matters relating to health information, health promotion, preventive health services, research advances, and education in the appropriate use of health care.”

OWH began planning for NWHIC in 1994 when the Internet was still new to people’s homes, and it launched the *womenshealth.gov* website in 1998. Today OWH offers a comprehensive suite of communication tools under its *Digital Strategy* to ensure that women and girls have the health information they need on the platforms they are most likely to use.

OWH’s health content is evidence-based, comprehensive, and in plain language, primarily written at the 6<sup>th</sup>- to 8<sup>th</sup>-grade reading level. OWH offers this health content through

- two mobile-friendly flagship websites: *www.womenshealth.gov* and *www.girlshealth.gov*;
- social media channels on Twitter, Facebook, Pinterest, and YouTube, with over 1.5 million followers combined;
- a women’s health information and referral helpline (1-800-994-9662) in English and Spanish;
- the only on-demand national breastfeeding telephone helpline (1-800-994-9662); and
- consumer health publications in PDF and other print-friendly formats.



The *womenshealth.gov* website is the foundation that anchors OWH's digital communication efforts. The website provides in-depth, plain-language consumer health information on more than 100 women's health topics in a mobile-friendly and 508-compliant format. In calendar year 2015, there were more than 19 million visitors to *womenshealth.gov*, and the most popular topics were yeast infections, polycystic ovary syndrome (PCOS), and the menstrual cycle.

Through the *girlshealth.gov* website, OWH addresses the health information needs of girls. Information on the website helps motivate girls ages 10–16 to choose healthy behaviors by providing them with information on fitness, nutrition, drugs, stress management, relationships, self-esteem, self-harm, peer pressure, and bullying. The website consistently focuses on reaching out to parents, guardians, or other trusted adults to get more information and assistance with sensitive issues such as sexual health, bullying, and building healthy relationships. The website uses an interactive, mobile- and user-friendly format to keep girls engaged and interested in learning more about their health. *Girlshealth.gov* is the number one Google return when searching for "girls' health," and during calendar year 2017, there were more than 2.2 million user sessions.

OWH constantly monitors the performance of *womenshealth.gov* through a combination of evaluation tools, including universal analytics through Google Analytics and the Foresee American Customer Satisfaction Index (ACSI) survey. The average user satisfaction for the ACSI survey score in 2015 for *womenshealth.gov* was 83 (on a scale of 1–100), higher than the all-government website average of 75. In 2015, the Foresee ACSI survey also showed that 86 percent of *womenshealth.gov* users were likely to recommend the site to another person.

OWH also uses universal analytics *within* Google Analytics, which means that metrics for the flagship websites are publicly available through the <https://analytics.usa.gov/> website. Finally, OWH uses the data from Google Analytics, the Foresee ACSI survey, user feedback received through the *Contact Us* portion of the website, and federal partners to create a feedback loop for continual improvement and refinement for OWH's websites and digital media.

The next primary component of NWHIC is OWH's social media channels. OWH was an HHS pioneer in using social media and specifically twitter in 2007 and 2008 to communicate important health messages to women. As a result, OWH enjoys a following on Twitter today. At the end of October 2016, OWH had more than 974,000 followers of the @womenshealth Twitter channel and more than 586,000 followers of the @girlshealth Twitter channel. They are the second and third most popular Twitter channels, respectively, among all HHS Twitter channels, behind the @CDCemergency channel. OWH is also building an audience on Twitter of Spanish-speakers and bilingual people who are interested in women's health information. OWH's @SaludDLaMujer Twitter channel, launched in September 2010, has 3,446 followers. The number of followers on all OWH social media channels continues to increase, indicating that the content continues to be useful.

In addition to these Twitter channels, OWH has a presence on Facebook with 32,680 “likes” on the women’s health Facebook page. Facebook allows for engagement and discussion with the American public, increasing OWH’s ability to positively affect women’s and girls’ health.

In 2014 OWH also launched a new channel on the social network Pinterest. The large majority of Pinterest users are women (85 percent), and Pinterest allows OWH to share visual and graphic-based content that promotes healthy living for women and girls. At present, OWH has 1,442 followers on Pinterest, and OWH shares the visual materials created for both Twitter and Facebook on Pinterest. The government’s *Digital Strategy* discussed the need to meet people wherever they are online, which OWH does by actively participating in these popular social media platforms.

The other major component of NWHIC is the *Information and Referral Helpline* and the *National Breastfeeding Helpline*. The *Information and Referral Helpline* offers a toll-free telephone number for callers at 1-800-994-9662, Monday through Friday, 9 a.m. to 6 p.m., Eastern Standard Time. Trained information and referral specialists answer questions on women’s and girls’ health in English or Spanish. Assistance includes person-to-person responses and referrals to other information or helpful resources.

OWH provides the American public with the only national breastfeeding helpline as part of the *Information and Referral Helpline*. All information and referral specialists are also trained breastfeeding peer counselors who provide information, support, and answers to basic breastfeeding questions in English or Spanish. On average, roughly one-quarter of the telephone calls to the *Information and Referral Helpline* are about breastfeeding.

OWH meets the requirements of PHSA section 229(b)(5)(D) on NWHIC to “provide technical assistance with respect to the exchange of information (including facilitating the development of materials for such technical assistance).”

### ***Private-Sector Efforts***

OWH has fulfilled the requirements set forth in section 229(b)(6) to “coordinate efforts to promote women’s health programs and policies with the private sector.” As noted above, many of OWH’s efforts include significant collaborations with the public and private sectors to improve the reach, sustainability, and effectiveness of OWH’s efforts, consistent with OWH’s strategic plan. These initiatives highlight OWH’s central convening function between public and private entities. This section describes some of OWH’s outreach to, and partnerships with, the private sector.

- OWH participates in the *Women’s Preventive Services Initiative Steering Committee*, a five-year project tasked with providing recommendations and policy guidance for insurance coverage for the provision of selected services for women without cost-sharing

under the Affordable Care Act. The committee is led by the American College of Obstetricians and Gynecologists (ACOG) and includes an independent committee of stakeholders, including representatives from public health, legal and clinical professional organizations, and patient advocates.

- In July 2016, OWH awarded nine cooperative agreements totaling approximately \$2 million per year to organizations that support colleges and universities in their efforts to prevent sexual assault on their campuses. The *College Sexual Assault Policy and Prevention Initiative* provides three years of funding to increase awareness of sexual assault on college campuses and implement successful prevention policies. The initiative also supports the implementation and evaluation of the recommendations from the White House Task Force on Campus Sexual Assault – the *Not Alone* and *It's On Us* campaigns. Those awarded will collaborate with and provide technical assistance to organizations in positions to influence policy at post-secondary schools (colleges, universities, technical schools, community colleges, and trade schools).
- OWH developed “*It's Only Natural, Mother's Love, Mother's Milk,*” a national campaign developed to address disparities in breastfeeding, specifically, low rates for African American mothers. According to CDC data from its National Immunization Survey (data analyzed 2011–2015), breastfeeding initiation rates are significantly lower in black infants (by at least 15 percentage points) than in white infants. This disparity is especially significant in the South<sup>4</sup>.

OWH is encouraging the campaign's promotion through its partners, including federal and non-federal organizations such as the U.S. Breastfeeding Committee and Early Head Start. In Year Two (2015–2016), OWH conducted evaluation research and pilot testing of the campaign to assess its overall relevance, applicability, pertinence, and effectiveness of community implementation strategies. The evaluation effort assessed the effectiveness of campaign messages and materials in increasing breastfeeding rates and addressing disparities within the target states. Results from the evaluation effort indicated that mothers valued the messages from the campaign and that *It's Only Natural* played an important role in “normalizing” breastfeeding and combating much of the stigma associated with breastfeeding in African American communities.

- OWH's Female Genital Cutting (FGC) Community-Centered Health Care and Prevention Projects are a three-year grant initiative providing \$6 million in funding to eight organizations across 13 sites. The grant initiative has two primary goals: 1) to address the gaps or problems in FGC-related health care services for women living in the

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<sup>4</sup>[https://www.cdc.gov/breastfeeding/data/nis\\_data/analysis.html](https://www.cdc.gov/breastfeeding/data/nis_data/analysis.html)

U.S. who have experienced FGC; and 2) to address the prevention of FGC among girls living in the U.S. who are at risk of having the procedure conducted at home or abroad<sup>5</sup>.

- OWH developed ACE and Healthy Weight: An Intervention Design Project in 2015. A strong link exists between Adverse Childhood Experiences (ACEs) and obesity in adulthood, and survivors of complex trauma are disproportionately female. This project sought to determine the key characteristics of trauma-informed interventions that would effectively address complex weight issues in obese women who have experienced ACEs. The interventions included de-stigmatization, relaxation or meditation, anger management, family support, wellness programs, and structured exercise programs. An Expert Panel advised incorporating a focus on diet, physical activity, and behavioral changes, with a strong focus on trauma.

- OWH funded a landmark two-year study entitled *Healthy Weight in Lesbian and Bisexual (HWLB) Women: Striving for a Healthy Community*, which ended in the summer of 2016. Several recent studies have shown that lesbian and bisexual women have a higher prevalence of obesity compared with heterosexual women. To address this disparity, OWH awarded grants to five research organizations who partnered with LGBT (lesbian, gay, bisexual, and transgender) community organizations in 10 cities to deliver tailored and evidence-based interventions to improve the participants' overall health. At the conclusion of the project, 95 percent of participants achieving at least one of nine health promotion objectives.

On July 7, 2016, OWH released the results in a series of eight articles that were published in a supplement for the journal *Women's Health Issues*. The findings received widespread national media coverage, resulting in more than 50 articles and TV news programs across the country. The HWLB initiative highlights the importance of community engagement in conducting successful, culturally sensitive research.

- In 2015 and 2016, the Region VII RWHC collaborated with HIV/AIDS Resource Network Program, Lincoln University, and other community partners such as Missouri Department of Health and Senior Services, Kansas City Care Clinic, and Columbia Health Department to host HIV/AIDS events. The goal of these activities was to increase awareness of HIV and decrease high-risk behaviors among the college students. Free HIV testing was provided to the students.

### ***Exchange of Information***

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<sup>5</sup> Goldberg, H., Stupp, P., Okoroh, Ekwutosi, Besera, G., Goodman, D., Isabella, D. (2016) Female Genital Mutilation/Cutting in the United States: Updated Estimates of Women and Girls at Risk, 2012. *Public Health Reports*. 131, 1-8.

As previously noted, OWH fulfilled the requirements of section 229(b)(7) “through publications and any other means appropriate, provide for the exchange of information between the Office and recipients of grants, contracts, and agreements...and between the Office and health professionals and the general public.” This exchange of information supports OWH’s goals two and three.

- OWH provided funds to the Administration on Community Living (ACL) on an initiative for older adults and caregivers that supported the development and promotion of select educational materials on how to seek oral health care from safety net providers. This cross-federal initiative involved ACL, HRSA, the National Institute of Dental and Craniofacial Research (NIDCR), and OWH. The initiative began to widely promote and disseminate the educational materials to senior centers, Area Aging and Disability Resource Centers, congregate meal sites, ombudsman programs, National Family Caregiver Support Programs, and long-term care facilities in 2017.
- The Region IX RWHC partners with the San Francisco Healthy Mothers Workplace Coalition, which consists of private-sector employers, non-profit organizations, city and federal government agencies, commissions, and academia. Its goal is to promote health and equity for working mothers and their infants by honoring businesses that adopt mother-friendly workplace policies. As a result of the partnership, OWH’s educational materials, campaigns, and initiatives on breastfeeding and employer options for lactation accommodation have been incorporated into the coalition’s toolkit and resource guides. Another local county coalition is also using OWH’s information in their outreach efforts, thus further expanding the utility of OWH’s educational efforts.
- The Region VI RWHC planned and coordinated four regional training events to 1) increase awareness of human trafficking; 2) provide education and training to the general public and healthcare professionals; 3) organize regional approaches to human trafficking; and 4) create federal and inter-state workgroups to address human trafficking.
- OWH and the Office on HIV/AIDS and Infectious Disease Policy (OHAIDP) created a memorandum of agreement (MOU) to increase awareness of the impact of HIV/AIDS on women and girls. This MOU focused on 1) assessing and reviewing content relative to girls and women on the *AIDS.gov* website; and 2) addressing new opportunities to raise awareness of Hepatitis B and C among women and healthcare providers.
- In collaboration with OHAIDP, OWH co-chaired the first Cis and Transwomen Track for the *2016 U.S. Conference on AIDS*. This partnership led to the development of two conference sessions entitled *PrEP for Women by Women: A Gateway to Healthcare* and *Improving the Coordination of Services for Young Women Living with HIV/AIDS*.
- The Region IX RWHC and the Region IX Office on Minority Health partnered with Ventanillas de Salud to promote a Region IX *Latina Heart Health Month Campaign* in 2015. *Ventanillas de Salud* is a free service offered at the Mexican consulates that focuses on preventing disease, promoting healthy habits, and making referrals to health services. The goal of the campaign was to provide each of the region’s consulates with

OWH's heart health information in English and Spanish. Almost 2,000 educational materials were disseminated to 18 consulates.

- In 2015, the Region X Minority Health and Women's Health teams helped coordinate *Improving the Health and Well-being of Latinas: Tools and Resources for Public Health and Social Service Providers* events held in Western and Eastern Washington State. In 2016, the events were expanded to include Idaho. Tools and information were provided to participants for their use when working with Hispanic/Latina women on health issues. These events reached approximately 410 public health and social service providers, including community health workers, lay health workers, case managers, and community health educators.
- The Region X RWHC held a webinar series with non-governmental partners in observance of National Women's Health Week in May 2016. The first webinar was on ending gender-based violence on campus. It included partners from the University of Washington, Lifewire, and the Operation for Prostitution Survivors (OPS). The second webinar, The Importance of Managing High Blood Pressure and Ways to Do So, included the Hope Heart Institute as a partner. For the third webinar, the Region X RWHC partnered with the Centers for Medicare and Medicaid (CMS) to provide information on women's health preventive services and Coverage to Care. An estimated 100 persons attended all three webinars.
- The Region III RWHC convened a two-day workshop for HHS-funded training and technical assistance centers (TTACs) throughout the region: Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, and West Virginia. The workshop was entitled the *Affordable Care Act Outreach and Enrollment: Training of Trainers*. It provided participants with the skills necessary to develop their own training tools and resources, which they would then use to train their own constituents. Participants included community health centers, health departments, hospitals, and community-based organizations. The workshop was facilitated by Enroll America and co-hosted by the Region III RWHC and HRSA Region III.
- The Region IX's *RHA News* is sent to over 300 health professionals and members of the public on a monthly basis. It regularly includes women's health information such as HHS news, funding opportunity announcements, training opportunities, and educational events.
- The Region IX RWHC partners annually with the Communications Workers of America (CWA) Local 9000 to educate their members about women's health campaigns and initiatives during Women's History Month in March. This local union chapter campaigned successfully to include the OWH website in their CWA brochure, which they distribute to all new members.

- The Region X RWHC, in partnership with CMS Region X, collaborated with AARP, the Heart Health Institute, and the Washington Dental Service Foundation to host a tele-town hall event on older women's health during the 2015 National Women's Health Week. The tele-town hall reached 12,000 older women in Washington State and addressed topics such as the Affordable Care Act, heart disease in women, and oral health.

### ***Translating Research and Best Practices***

Programs developed by OWH translate research and best practices into usable actions that improve the health of women and girls. This information is obtained through standard robust methodologies and reaches the general public, academicians, health professionals, state and local agencies, and others through various avenues. Examples of current projects that support this objective follow.

- OWH's *Coalition for a Healthier Community (CHC)* supported the implementation of a national gender-based wellness program to enable communities to support evidence-based or evidence-informed prevention interventions that address gender constraints affecting women's and girls' health in their specific communities. Grantees worked to improve patient-provider communication as well as individuals' and communities' knowledge and understanding of health information. The initiative will assist in identifying major gender-based health issues affecting women and girls in their local communities.

In 2015, OWH's CHC initiative was featured in a special issue of the international journal *Evaluation and Program Planning*. It focused on the role that gender-based approaches in public health policies play in addressing barriers to women's health in the U.S. Using the CHC initiative as a basis for analysis, the publication addressed how community health policies can be improved by implementing gender-based health care programs. Articles in the special issue presented findings on coalition forming, gender-based analyses, health outcomes, and program development and implementation.<sup>6</sup>

- OWH completed Phase 2 of *Project Connect: A Coordinated Public Health Initiative to Prevent Domestic and Sexual Violence* in August 2015. Project Connect was a national initiative that focused on training health care providers working in adolescent health, reproductive health, and other public health settings, so they can better respond to sexual and intimate partner violence. OWH identified and partnered with statewide and tribal teams to identify, respond to, and prevent these types of violence against women and children. OWH collaborated with ACF and Futures Without Violence, the national technical assistance provider. The project expanded into six new states and five new health sites operated by and serving Native Americans/Alaskan Natives and Asian Pacific Islanders. Both phases of Project Connect trained more than 7,000 health care providers to assess for, and respond to, sexual and intimate partner violence in more than 80 clinical

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<sup>6</sup> Walker, E. M. and Alexander, S. (2015). Gender-based health interventions in the United States: Issues in evaluation and program planning. *Evaluation and Program Planning*. Vol. 51, 1–88.

settings serving more than 400,000 patients. Project Connect funding stemmed from health provisions in the Violence Against Women Reauthorization Act of 2005. Data collection was finalized and the final evaluation report for the project was completed in March 2016.

- OWH awarded cooperative agreements for the *IPV Provider Network: Engaging the Health Care Provider Response to Interpersonal Violence (IPV) Against Women*, totaling more than \$3.7 million, to five sites in August 2015. This three-year initiative focuses on testing and evaluating interventions that will integrate IPV assessment and intervention into basic care as well as encouraging collaborations between healthcare providers (including public health programs), and IPV service programs in the community. Outcomes from the initiative include integration of the Affordable Care Act's IPV screening and counseling benefit into routine clinical practice, utilizing continuous quality measurement and process improvement techniques, and identifying evidence-based IPV interventions that are culturally and legally appropriate.
- OWH, in partnership with the HHS IDEA Lab, has contracted with SemanticBits, Inc., to upgrade its existing online data query system, Quick Health Data Online, and provide it with current and more complex online functionality. The updated data query system, now named the *Health Information Gateway*, will provide evidence to better inform research, policy, and programs by providing counts and rates for health measures, risk factors, and major diseases from national and state-level data by sex, race/ethnicity, age, and other sociodemographic variables.
- The *Women's Health Leadership Institute (WHLI)* is an OWH leadership training program for experienced community health workers (CHWs)/promotores de salud. It teaches them how to use a public health systems approach to reduce health disparities and chronic diseases in their communities. WHLI graduates have engaged in such community change activities as improving local parks, establishing smoke-free zones, removing abandoned cars, establishing community gardens, etc.

In 2015, the University of Arizona, Mel and Enid Zuckerman College of Public Health conducted a national survey of CHWs. It measured, among other things, the extent to which WHLI and non-WHLI trained CHWs used their leadership skills to effect concrete change that benefited community members. The survey asked if the respondent was a graduate of the WHLI. A sufficient number of WHLI graduates were included in the survey to justify comparing their survey responses with CHWs who had not received training in leadership competencies. Participants reported statistically significant pre/post improvements in all the competencies. Interviewees credited WHLI with increasing their capacity to listen to others, create partnerships, and initiate efforts to address community needs. Compared to a national CHW sample, WHLI participants were more likely to engage community members in attending public meetings and organizing events. These activities led to community members taking action on an issue and a concrete policy change. These results were described in a peer-reviewed article published in the *Health Promotion Practice Journal* in May 2016.



- The Region V RWHC leads the *Trauma-Informed Medicine e-Cases (TIme)*, a multiyear initiative now in its third year. The contractor MedU created online interactive case-based learning modules for physicians, advanced practice nurses, and physician assistants to teach them about the principles and practices necessary to provide trauma-informed care. The first two years of cases are complete, and the learning modules will begin pilot testing in early 2018. At present, the e-Cases have not been accredited for CME/CE.
- OWH provided funds to ACL in 2013 for a three-year project entitled *Creating the Foundation for National Replication of Community-Based Oral Health Programs for Older Adults*. Nearly one-third of older adults have untreated tooth decay and many have severe gum disease. Severe gum disease is associated with chronic and serious health conditions, including diabetes, heart disease, stroke, and respiratory disease. The purpose of the initiative is to identify and promote vetted, low-cost, community-based oral health services for older adults. OWH and ACL assessed the existing fragmentation across federal programs, which results in a lack of oral health prevention and treatment services for older adults. In addition, a “how-to” *Community Guide to Adult Dental Program Implementation* for communities interested in starting an oral health program for older adults is now available on the oral health website: <https://oralhealth.acl.gov/>.
- OWH is collaborating with HRSA on a caregiver training project for healthcare providers in HRSA’s *Unified Curriculum on Alzheimer’s and Related Dementias for Primary Care Providers*. Family caregivers provide care for nearly 80 percent of people with chronic physical and cognitive health care issues, which equates to an estimated 1.3 billion hours of unpaid assistance to older adults with chronic disabilities each year. Caregivers are more likely to be female (62 percent) and middle-aged (50 percent are between 45 and 64 years of age). To address this critical health issue, OWH provided funding to HRSA to add caregiver-themed modules to their curriculum. This curriculum targets health care professionals to improve health care delivery and emphasize the importance of family caregivers as part of the healthcare team. Five modules were targeted to family caregivers themselves, underscoring the importance of maintaining their own health while being caregivers. The modules were disseminated in 2017.
- In 2016, OWH collaborated with the Federal Transportation Agency (FTA) to review and award over \$7 million in community-grants for its *Rides2Wellness* program. Its goal is to reduce transportation barriers that negatively impact individuals’ ability to access health care services. In 2017, OWH again participated with the FTA in the conceptualization and review of a modified *Rides2Wellness* grant program.
- The *Labor of Love: Innovations in Breastfeeding Research and Practice Conference* was sponsored by the Indiana State Department of Health’s Office of Women’s Health in collaboration with the Region V RWHC. The conference was designed for breastfeeding advocates and health professionals who were aware of the significant health impacts that breastfeeding has on both mothers and babies. It highlighted cutting-edge research and techniques to improve the participants’ practices in support of breastfeeding mothers.

Topics included postpartum mental health, trauma-informed services, community engagement, technology use in lactation practice, and engaging clinicians.

- The *Oral Health for Older Adults: Community Services Project Development Guide* is an OWH collaboration and three-year interagency agreement with ACL. The team conducted an environmental scan of existing community-based oral health programs for older adults nationwide. More than 200 programs were vetted on nine evaluation points, and models were identified that represented “promising practices” for replication in new communities. A searchable electronic database was designed, and a “how-to” guide will disseminate this array of models. The launch was in fall 2016. A dissemination strategy was implemented in FY 2017.
- OWH, in partnership with the ACF Office on Trafficking in Persons (OTIP), developed the *SOAR (Stop. Observe. Ask and Respond) Human Trafficking Training for Health Care and Social Service Providers*. The training educates health care providers, social workers, behavioral health professionals, and public health professionals about the ways to recognize and respond to human trafficking victims. Trainings were conducted during both in-person and virtual sessions through late September 2016, and attendees were eligible to receive continuing education credits for their participation in the training. A total of 1,253 individuals registered for the SOAR training sessions, and 774 received the training across the 17 sessions. Of those individuals trained, 28 percent were social workers, 25 percent were public health professionals, 18 percent were health care providers, and 13 percent were behavioral health professionals.
- The *Healthier Pregnancy Initiative* addresses successful practices in implementing the U.S. Preventive Services Task Force (USPSTF) screening and referral recommendations around obesity, alcohol, depression, intimate partner violence, tobacco, and breastfeeding in prenatal and perinatal care settings. Its goal is to catalyze change among health care providers and organizations, so they operationalize these Affordable Care Act preventive services. The Region V RWHC partnered with AHRQ to host the initiative’s website, which includes an archived webcast, topic-specific interview presentations, a presentation on trauma-informed care, fact sheets for providers on the six preventive services addressed, and other tools and resources for providers and clinics.
- OWH and ACF OTIP collaborated to establish the *Human Trafficking Data Collection Project*, which will coordinate human trafficking-related research, data, and evaluation to support evidence-based practices in victim services and improve baseline knowledge. Data fields will collect information on the demographics of victims, the services provided to them, and the costs of those services. A pilot data collection process began in the fall of 2016 and was completed in the fall of 2017. Data analysis and a quality review will follow.
- *Helping Women Reenter: A Guide for Those Helping Women Transition after Incarceration* is the result of a multiyear initiative led by the Region V RWHC. Three demonstration sites across the country were tasked with enhancing health services for women through trauma-informed, gender-responsive approaches to providing reentry

services. This guide will be disseminated to assist decision makers in prisons and jails, other service providers, and policy makers better understand this vulnerable and at-risk population of women. A future goal is to translate the content into e-learning modules that can form the basis of an implementation initiative.

### ***Public Awareness Activities***

OWH works closely with other offices and agencies to highlight the needs of specific populations through public awareness activities that focus on designated days or weeks in the year.

- *National Women's Health Week* (NWHW) is an annual health observance held every May and led by OWH. The goal is to empower women to make their health a priority. NWHW emphasizes five prevention steps to improve women's physical and mental health.

1. Visit a health care professional to receive regular checkups and preventive screenings.
2. Get active.
3. Eat healthy.
4. Pay attention to mental health, including getting enough sleep and managing stress.
5. Avoid unhealthy behaviors such as smoking, texting while driving, and not wearing a seatbelt or bicycle helmet.

In honor of the 2016 *National Women's Health Week*:

- The President issued the seventh Presidential Proclamation for NWHW.
- About 49,000 visits to the website were made by approximately 37,500 unique visitors.
- 28 national organizations helped support and promote NWHW.
- 23 ambassadors—celebrities, athletes, and entrepreneurs who are champions for women's health issues—helped promote NWHW and its messages to a wide range of fans.
- 466 people and organizations supported OWH's Thunderclap, which reached nearly 7.9 million people through social media. (*Thunderclap* is a web-based platform that sends synchronized social media posts on Facebook, Twitter, and Tumblr.)
- From April 7–May 31, 4,714 women pledged to be a well woman, which is a commitment to being as healthy as they can and taking steps to improve their physical and mental health.
- Newspapers, magazines, television and radio stations, websites, blogs, and wire services across the country ran stories, generating a total of 903,267,677 media impressions.

- From April 12–May 31, 2016, a total of 23,940 tweets about NWHW were sent from 12,960 users, reaching 40,398,994 people for a total of 433,011,109 impressions.
- *National Women’s and Girls’ HIV/AIDS Awareness Day* (NWGHAAD) is observed across the country every March 10. This event raises awareness of the disease's impact on women and girls, shares facts about HIV/AIDS and prevention, and asks participants to take action in various ways, including getting tested and providing services to those living with the disease. OWH coordinates NWGHAAD, and its partners promote the observance in communities across the nation. The RWHCs promote NWGHAAD at the regional and state level by coordinating events with community- and faith-based organizations, thus increasing awareness of the disease among high-risk populations. In 2016, OWH partnered with the District of Columbia’s Department of Health and local schools for an awareness walk and rally to celebrate NWGHAAD.

### ***Reporting***

OWH has fulfilled the requirements set forth in PHSA section 229(d) that “the Secretary shall prepare and submit to the appropriate committees of Congress a report describing the activities carried out under this section during the period for which the report is being prepared.” OWH has assisted the Secretary in preparing and submitting this report to the appropriate committees of Congress not later than three years after the date of enactment of the Affordable Care Act.

### ***Transfer of Functions***

OWH has fulfilled the requirements set forth in PHSA section 229(e)(2): “There are transferred to the Office on Women’s Health (established under section 229 of the Public Health Service Act, as added by this section), all functions exercised by the Office on Women’s Health of the Public Health Service prior to the date of enactment of this section.”

## **Agency for Healthcare Research and Quality (AHRQ)**

### **Office of Women's Health and Gender Research**

The following sections describe the specific requirements in section 3509 of the Affordable Care Act related to the Agency for Healthcare Research and Quality (AHRQ) (amending Title IX of the Public Health Service Act [42 U.S.C.299 et seq.]).

#### ***Establishment of an Office (Sec. 925(a))***

AHRQ continues to fulfill the requirements set forth in section 925(a) of the Public Health Service Act, which mandates the establishment of an Office of Women's Health and Gender-Based Research, headed by a Director who is appointed by the Director of AHRQ. AHRQ's Office of Women's Health and Gender Research is housed in the Division of Priority Populations Research, which was originally established through the agency's authorizing legislation in 1999. The Division of Priority Populations Research is responsible for maintaining the Agency's focus on the health care of all priority populations, including women and minorities; inner-city, rural and frontier areas; low-income groups; children; the elderly; and individuals with special health care needs, including those with disabilities and in need of chronic or end-of-life health care.

#### ***Report on Current Level of Activities***

In fulfillment of the requirements of section 925(b)(1), publications during the reporting period have included the annual *National Healthcare Quality and Disparities Reports (QDR)*, the *Chartbook on Women's Health Care* based on the 2014 *QDR Report*, and an annual budgeting report, all of which contained information specific to women's health.

In addition, AHRQ supports a broad portfolio of investigator-initiated research grants that aim to improve the quality and affordability of health care for all Americans. This portfolio includes a number of research projects focused specifically on improving health care for women and girls. From promoting appropriate use of mammograms among safety net providers to studying the cost and quality of maternity care, AHRQ's research strives to improve the quality of care for women and girls in every health care setting. Many investigator initiated research grants were awarded by AHRQ during the reporting period, including

- 1) "Evidence-based Dissemination for Mammography Adherence in Safety Net Communities," an R18 funding mechanism;
- 2) "Impact of No Cost Contraception on Utilization and Direct Medical Expenditures," an R01 funding mechanism;
- 3) "Improving PreHospital Emergency Maternal and Child Care: A Modern Approach to EMS," an R18 funding mechanism;
- 4) "Hospital Variation in Costs and Outcomes of Care for Childbirth," an R01 funding mechanism; and

- 5) “Variation in Provider Breast Cancer Surveillance Strategies Following Initial Treatment: Contribution of Patient and Provider Factors, Association with Outcomes, and Stakeholder Insights,” an R01 funding mechanism.

Furthermore, in September 2014, Patient-Centered Outcomes Research Institute (PCORI) and AHRQ collaborated to award a multi-institutional, five-year, \$20-million project to evaluate the effectiveness of different treatment strategies for women with uterine fibroids, titled COMPARE-UF (Comparing Options for Management: Patient-Centered Results for Uterine Fibroids). COMPARE-UF is a clinical registry that aims to collect prospective data to understand which fibroid treatment options are most effective and what factors influence treatment outcomes. The information learned from this registry will help women with uterine fibroids make informed decisions about their treatment options. As of October 2016, COMPARE-UF had established a governance structure, policies, and procedures for collaborative research involving patients, clinicians, methodologists, researchers, and stakeholders. Additionally, over 500 patients have been recruited and 100 of these patients have contributed baseline samples of anti-mullerian hormone (AMH), which is a marker of potential fertility. Detailed information about this registry can be accessed through the COMPARE-UF website at <http://compare-uf.org/>.

### ***Women’s Health-Related Goals and Objectives***

AHRQ continues to fulfill the requirements of section 925(b)(2) to establish short-range and long-range goals and objectives within the Agency and to coordinate with other appropriate agencies and offices on activities of particular concern to women. The Priority Populations Division staff has established networks within the agency in order to more frequently communicate across the Agency’s offices and centers regarding activities related to women’s health.

AHRQ has fulfilled the requirements of section 925(b)(3). The Office of Women’s Health and Gender Research regularly networks and collaborates with agency research portfolios to maximize women’s health and gender research perspectives. Examples follow.

### ***Women’s Health Projects***

- The Medical Expenditure Panel Survey (MEPS) is a nationally representative survey managed by AHRQ that provides annual national estimates of the health care use, medical expenditures, sources of payment, and insurance coverage for the U.S. civilian noninstitutionalized population. In addition to collecting data to support annual estimates for a variety of measures related to health care use and expenditures, the MEPS provides estimates of measures related to health status, demographic characteristics, employment, and access to health care.

All of the standard MEPS tables and nearly all of the empirical analyses conducted using the data use sex as a primary control variable. Thus, most MEPS-based analyses are

related at least to some extent to women's health issues. Direct examples include a 2016 MEPS statistical brief, entitled "The Uninsured in America: Estimates of the Percentage of Non-Elderly Adults Uninsured throughout Each Calendar Year, by Selected Population Subgroups and State Medicaid Expansion Status: 2013 and 2014," and a 2015 brief entitled "Veterans' Usual Source of Care, 2009-2012: Estimates for the U.S. Civilian Noninstitutionalized Population." Other examples of MEPS statistical briefs, datasets, summary data tables, and research papers, along with more detailed information about the survey, can be accessed through the MEPS website at [www.meps.ahrq.gov](http://www.meps.ahrq.gov).

- The Healthcare Cost and Utilization Project (HCUP) is a family of health care databases created by AHRQ in partnership with 47 state data organizations. It is designed to provide annual local, state, and national estimates of the health care use, cost, and quality across all payers, including the uninsured. In addition to collecting data to support annual estimates for a variety of measures related to health care use and cost, the HCUP provides estimates of healthcare quality and safety measures, demographic characteristics, market and hospital characteristics, and variations in provision of health care.

All of the standard HCUP products and nearly all of the empirical analyses conducted using the data use sex as a primary control variable. Thus, most HCUP-based analyses are related at least to some extent to women's health issues. Several direct examples include the HCUP statistical briefs: "Variation in the Rate of Caesarean Section Across U.S. Hospitals, 2013," "Teen Hospital Stays for Childbirth, 2004-2013," "Trends in Bilateral and Unilateral Mastectomies in Hospital Inpatient and Ambulatory Settings, 2005-2013," and "Procedures to Treat Benign Uterine Fibroids in Hospital Inpatient and Hospital-Based Ambulatory Surgery Settings, 2013." Other examples of HCUP statistical briefs, datasets, summary data tables, and research papers, along with more detailed information about the data and tools, can be accessed through the HCUP website at <http://www.hcup-us.ahrq.gov/>

- AHRQ's Evidence-based Practice Center (EPC) Program funds researchers, research centers, and academic organizations to work together with AHRQ to produce effectiveness and comparative effectiveness research for clinicians, consumers, and policymakers. The EPC program reviews and synthesizes published and unpublished scientific evidence, and compiles research findings that are synthesized and/or generated and translates them into useful formats for various audiences. Many EPC products are related to women's health issues. One example is a technical brief entitled, "Strategies for Improving the Lives of Women Aged 40 and Above Living with HIV/AIDS." It provides an evidence map and highlights the paucity of stratified analyses addressing this population of interest and calls for prioritization of research needs. Other examples of EPC products, including comparative effectiveness reviews, technical briefs, and research summaries, can be accessed through the EPC website at <https://effectivehealthcare.ahrq.gov/index.cfm>.

AHRQ's Division of Priority Populations is co-leading a multiyear, \$3-million project with the Center for Quality Improvement and Patient Safety that is focused on perinatal

safety. The goal of the *Safety Program for Perinatal Care* (SPPC) is to decrease maternal and neonatal adverse events and improve patient safety, team communication, and quality of care within labor and delivery (L&D) units. The program ended in 2016 and AHRQ plans a second phase of work in 2017–2018. A Summary Report of the program is available at <https://www.ahrq.gov/professionals/quality-patient-safety/hais/tools/perinatal-care/about.html#background>.

The program is based on three pillars: teamwork and communication skills, selected perinatal safety strategies, and *in situ* simulation training. A toolkit based on these three pillars was developed to support program implementation by individual L&D units. The program builds on AHRQ’s CUSP Framework. CUSP is designed to improve the foundation of how physicians, nurses, and other clinical team members at the unit level work together by building capacity to address safety issues and combining clinical best practices and the science of safety. A Federal Partner Workgroup on Maternal Health has been established with AHRQ, CDC, NICHD, HRSA’s MCHB, CMS, and others to coordinate cross-agency activities on perinatal safety and maternal health initiatives.

### ***Consultation with Women’s Health Professionals***

- In 2016, the Office for Women’s Health and Gender Research consulted with workgroups that support the *National Healthcare Quality and Disparities Reports*, the USPSTF, and the AcademyHealth Gender and Health Special Interest Group.
- The office is serving as an expert on HRSA’s *Alliance for Innovation on Maternal Health: Improving Maternal Health and Safety*. The office is collaborating with the National Council on Patient Safety in Women’s Health Care to coordinate and enhance initiatives to improve perinatal safety.
- AHRQ has also provided technical consultation to ACOG, the American Association of Birth Centers, the Society of Maternal Fetal Medicine, HRSA’s Collaborative Improvement & Innovation Network (CoIIN) to Reduce Infant Mortality, the Office of Communications, and individual contractors and grantees. Collectively, these collaborations allow for targeted dissemination and outreach efforts to key stakeholders.

### ***CCWH Membership***

AHRQ’s Office of Women’s Health and Gender Research has fulfilled the requirements set forth in section 925(b)(5) by serving as an active and responsive representative on CCWH.



## **Centers for Disease Control and Prevention (CDC)**

### **Office of Women's Health**

The following sections describe the specific requirements in section 3509 of the Affordable Care Act related to the Centers for Disease Control and Prevention (amending Part A of Title III of the Public Health Service Act [42 U.S.C. §241 et seq.]).

#### ***Establishment of an Office (Sec. 925(a))***

CDC's Office of Women's Health was established in 1994 within the Office of the Director as a free-standing office. CDC thereby already had fulfilled the requirement in section 310A(a) under section 3509 [amending 42 U.S.C. §242(s)] by having an existing Office on Women's Health. CDC relocated the Office of Women's Health within the Office of the Associate Director for Programs in the Office of the Director. In 2013, CDC relocated the Office of Women's Health within the Office of Minority Health and Health Equity within the Office of the Director.

#### ***Report on Current Level of Activities***

CDC Office of Women's Health (OWH) continues to monitor the agency's activities that focus on the health and safety of women and girls at every stage of life. Updates are disseminated to internal and to external audiences through meetings, reports/materials, and online.

#### ***Women's Health-Related Goals and Objectives***

The CDC OWH goal is to support and protect the health and safety of women and girls by addressing health issues and identifying solutions. To accomplish this goal the OWH objectives include reporting on multivariate analyses of risk factors and other conditions that effects women's health; exploring women's health related quality of life (physical, mental, social and emotional functioning) disparities and outcomes; and collaborating with CDC and external organizations/agencies leadership to determine shared priorities that will improve the well-being of women and girls. Additionally, CDC OWH will continue to provide exemplary assistance and service in support of CDC's mission.

## ***ADOLESCENT HEALTH***

### ***Girls' Health***

A cadre of initiatives, including *Community Transformation Grants*, *Racial and Ethnic Approaches to Community Health*, and *Partnerships to Improve Community Health*, are implementing community-level strategies to improve women's and girls' health.

## ***Teen Pregnancy***

CDC works with communities, states, and national organizations to identify underserved populations at risk for teen pregnancy, to identify teen pregnancy risk factors, and to advance strategies based on applied research to reduce teen pregnancy. As part of the *Teen Pregnancy Prevention Initiative*, and in collaboration with other HHS operating divisions, CDC provides scientific and programmatic assistance to nine state- and community-based organizations to evaluate the impact of a multicomponent, community-level effort to reduce teen birth rates in 10 targeted communities.

- **Youth Risk Behavior Surveillance System**

The Youth Risk Behavior Surveillance System (YRBSS) collects and analyzes data of six types of health-risk behaviors among youth in order to assist states/territories/tribes and the nation monitor their prevalence as well as the effect of public health and health care interventions. The risk behaviors contribute to the leading causes of death and disability among youth and adults, including those that contribute to unintentional injuries and violence; unintended pregnancy and sexually transmitted diseases (including HIV); alcohol, tobacco, and other drug use; unhealthy dietary behaviors; and inadequate physical activity. YRBS is conducted biennially and includes representative samples of students by sex in grades 9–12.

- **Promoting Adolescent Health Through School-Based HIV/STD Prevention**

Girls and women are at disproportionate risk for nearly all sexually related diseases as well as the negative consequences of having children before physical and cognitive maturity. Through a five-year cooperative agreement under funding announcement PS13-1308, CDC supports the education agencies of 18 states and 17 districts (including Washington, D.C.) to prevent sexually transmitted diseases (STDs) and teen pregnancy by improving their sexual health education programs and increasing access to sexual health services recommended by the USPSTF.

## ***Birth Defects and Disabilities***

- **National Birth Defects Prevention Study: Identifying Modifiable Risk Factors for Adverse Reproductive Outcomes**

The National Birth Defects Prevention Study (NBDPS) examines potential risk factors for adverse reproductive outcomes. Interviewing began on October 1, 1997, and was completed for births through 2011. Researchers continue to analyze this rich source of information on birth defects. Understanding the risks and causes of birth defects can help prevent them. This study provides important clues to help ensure that every child is born in the best possible health.

- **Birth Defects Study to Evaluate Pregnancy Exposures**

The Birth Defects Study to Evaluate Pregnancy Exposures (BD-STEPS) builds upon the foundation of birth defects research from the NBDPS. This new study examines findings from the NBDPS and follows up on leads to understand more about what causes birth defects and how to prevent them. BD-STEPS began collecting data on children born on or after January 1, 2014. Results from BD-STEPS will provide women and their health care providers with information on risk factors that a woman may be able to change and on the impact of prevention efforts.

- **Women with Disabilities and Breast Cancer Screening Right to Know Campaign**

CDC supports 18 state-based disability and health programs to promote equity in health, prevent chronic disease, and increase the quality of life for people with disabilities. A large focus of these efforts with state partners includes working to improve mammography use among women with disabilities. Health promotion campaigns and messages about breast cancer screening that are specifically designed to include women with disabilities are intended to reduce disparities in mammography use.

CDC's Disability and Health Branch conducted a study to explore the barriers to breast cancer screening for women who have physical disabilities. We discovered that the barriers include:

- Thinking, “It won’t happen to me”
- Focusing on other health issues
- Difficulty with positioning while getting a mammogram
- Not knowing where to go for accessible screening
- Inaccessible facilities and equipment
- Healthcare provider’s knowledge and attitudes

Women with disabilities also identified the lack of health promotion messages and materials that reflect their unique needs as a problem and requested that CDC address this issue. As a result of this study, a family of health promotion materials (e.g., posters, MP3 files, low-tech fliers, print advertisements, and tip sheets) has been designed to increase awareness of breast cancer among women with physical disabilities and encourage these women to get screened. Materials share the tagline “Breast Cancer Screening. The Right To Know,” and feature four women with physical disabilities who have survived breast cancer.

- **State Disability and Health Programs**

CDC's Disability and Health Branch funds 19 State Disability and Health programs that work to improve the health and quality of life among men and women with mobility limitations and/or intellectual disabilities within their communities using

evidence-based strategies. Each program addresses disparities that are specific to the population with disabilities in that state, some emphasizing mammography use in breast cancer screening for women with disabilities.

## ***Blood Disorders***

### ***Evaluation of Health Promotion and Prevention Programs for Blood Disorders***

Activities under this cooperative agreement promote the health, wellness, and the adoption of healthy behaviors aimed at reducing or preventing complications of blood disorders, including excessive menstrual bleeding in women. One of the activities is "Better You Know," a public health education campaign to increase awareness about the signs, symptoms, and diagnosis of bleeding disorders among women. The campaign targets providers and women experiencing heavy menstrual bleeding who may be at risk for having a bleeding disorder.

### ***Community Counts Bleeding Disorders Surveillance Project***

The purpose of this project is to gather and share information about common health issues, medical complications, and causes of death that affect people with bleeding disorders cared for in the U.S. Hemophilia Treatment Centers (HTCs). Women with bleeding disorders is a sub-group of this population and information about bleeding complications during menses, pregnancy and childbirth are collected.

## ***Breastfeeding***

- ***CDC Breastfeeding Report Card***

The CDC *Breastfeeding Report Card* provides national- and state-level data to help public health practitioners, health professionals, community members, childcare providers, and family members work together to protect, promote, and support breastfeeding. The *Report Card* indicators measure types of support in key community settings as well as the most current data on the breastfeeding goals outlined in Healthy People 2020. Mothers who receive quality maternity care that includes support for breastfeeding are more likely to initiate breastfeeding, to exclusively breastfeed, and to breastfeed for a longer duration.

Mothers who receive quality maternity care that includes support for breastfeeding are more likely to initiate breastfeeding, to exclusively breastfeed, and to breastfeed for a longer duration. The 2016 CDC Breastfeeding Report Card provides a compilation of data on breastfeeding practices and support for use by states to target efforts and monitor progress. The Report Card shows that 51.8 percent of U.S. infants born in 2013 are breastfed at six months, compared to 46.6 percent in 2009. Increases in breastfeeding

duration at six months, though modest, are moving towards the Healthy People 2020 objective of 60.6 percent.

- **Best Fed Beginnings**

To further support efforts to increase breastfeeding initiation, exclusivity, and duration, CDC funded a cooperative agreement with the National Initiative for Children's Healthcare Quality (NICHQ) to lead the Best Fed Beginnings (BFB) project. During 2014, NICHQ continued its work with 89 hospitals nationwide to use quality improvement methods to improve maternity care practices to fully support breastfeeding. To date, 76 of the 89 Best Fed Beginnings Hospitals achieved Baby-Friendly designation and the other 13 reached the final phase of designation. As a result of this project, over 226,000 more newborns are receiving optimal care every year. In addition, CDC funded the EMPower Breastfeeding Initiative that is assisting an additional 93 hospitals from 24 states to implement the Ten Steps to Successful Breastfeeding and become Baby-Friendly. As of July 2017, 11 EMPower hospitals have achieved Baby-Friendly designation and 66 hospitals have entered the final phase of the designation pathway, indicating they are implementing the Ten Steps. These 11 hospitals included hospitals in Arkansas and West Virginia, meaning that all 50 states and Washington, D.C. now have at least one Baby-Friendly facility, and nationally approximately 21% of all births are in Baby-Friendly facilities.

- **State and Local Public Health Funding and Support for Breastfeeding**

In 2013, CDC initiated a 5-year program, the "State Public Health Actions to Prevent and Control Diabetes, Heart Disease, Obesity and Associated Risk Factors and Promote School Health." It funds 32 states to support breastfeeding activities to improve maternity care practices, worksite support, and peer and professional support for breastfeeding. CDC also launched funding through the Association of State and Territorial Health Officials (ASTHO) to support these activities in the remaining 18 states and the District of Columbia. In 2014, CDC launched new funding aimed at increasing breastfeeding duration through community-based peer and professional support. Funds were awarded to the National Association of County and City Health Officials (NACCHO) to work with 63 local health departments (LHD) and community based organizations (CBO) to establish peer and professional breastfeeding support and provide lactation training for healthcare professionals. In 2016, NACCHO funded an additional 7 LHDs in communities surrounding EMPower hospitals to promote greater collaboration, continuity of care and develop post discharge referral systems.

- **Resources and Guidance to Improve Breastfeeding**

CDC works to improve breastfeeding-related practices in maternity care centers and workplaces to support mothers who are or who intend to breastfeed. CDC provides support and assistance to states, communities, hospital learning collaboratives, and community-based organizations to provide resources to breastfeeding mothers. CDC monitors breastfeeding rates and practices and develops and disseminates evidence-based practice guidance for improving breastfeeding initiation and duration. These resources include the *Surgeon General's Call to Action to Support Breastfeeding*, *CDC Guide to*

*Breastfeeding Interventions, Maternity Practices in Infant Nutrition and Care (mPINC)* customized benchmark reports to nearly 2,700 U.S. maternity care facilities and state reports to all states, and the *CDC Breastfeeding Report Card*.

## **Cancer**

- ***Inside Knowledge: Get the Facts About Gynecologic Cancer***

In FY 2015, CDC continued to support a communications campaign *Inside Knowledge: Get the Facts About Gynecologic Cancer* to raise awareness of the five main types of gynecologic cancer: cervical, ovarian, uterine, vaginal, and vulvar. It encourages women to pay attention to their bodies and know what is normal for them, so they can recognize the warning signs of gynecologic cancers and seek medical care. Per Senate Report language in FY 2016 and FY 2017, CDC is taking steps to integrate components of the *Inside Knowledge* campaign and *Know: BRCA* to the extent possible, to ensure coordination of public health messages related to ovarian cancer, leveraging of resources, and maximizing economies of scale. <http://www.cdc.gov/cancer/knowledge/index.htm>

- **Breast Cancer in Young Women**

CDC continues to work with public, non-profit, and private partners to address breast cancer in women under the age of 40 and those at higher risk for developing the disease by conducting research, convening the Advisory Committee on Breast Cancer in Young Women, funding education and survivorship programs, and educating young women and medical providers about breast cancer and breast health as authorized by the Education and Awareness Requires Learning Young (EARLY) Act, section 10413 of the Affordable Care Act.

The Bring Your Brave (BYB) ([www.cdc.gov/bringyourbrave](http://www.cdc.gov/bringyourbrave)) public education campaign was launched in May 2015. The campaign utilizes personal stories to educate young women, including those at high risk for having early breast cancer, about breast health and risk factors for breast cancer. This includes helping women understand their family history, including whether they may be at higher risk for hereditary breast and ovarian cancer. To date, BYB has generated more than 100 million impressions on Twitter, Facebook, Pinterest and YouTube; almost 1.5 million video views; more than 265,000 visits to the website; more than 1 million engagements on social media through retweets, shares and conversations.

- **National Breast and Cervical Cancer Early Detection Program**

Through the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), CDC provides low-income, uninsured, and underserved women access to timely breast and cervical cancer screening and diagnostic services. NBCCEDP funds all 50 states, the District of Columbia, 5 U.S. territories, and 11 American Indian/Alaska Native tribes or tribal organizations to provide screening services for breast and cervical cancer. In program year 2015, the NBCCEDP screened 219,819 women for breast cancer with mammography and diagnosed 3,870 breast cancers. Additionally, 144,039 women were screened for cervical cancer with the Pap test. 171 cervical cancers were diagnosed, as

were 5,766 premalignant lesions, of which 40 percent were high grade.

<http://www.cdc.gov/cancer/nbccedp/index.htm>

- ***KNOW:BRCA Initiative***

The *Know:BRCA* education initiative aims to build awareness about how BRCA gene mutations affect risk for breast and ovarian cancer. It was authorized by the Education and Awareness Requires Learning Young (EARLY) Act, section 10413 of the Affordable Care Act. The EARLY Act authorizes CDC to develop initiatives to increase knowledge of breast health and breast cancer among women, particularly among those under age 40 and those at higher risk for developing the disease. Since the launch of *Know:BRCA* in June 2014 through summer of 2016, 2720 women have completed the *Know:BRCA* assessment and learned their risk for a BRCA gene mutation. On average more than 100 assessments are completed each month. Components of the *Know:BRCA* initiative are undergoing a formal evaluation as of fall 2016. Findings are anticipated in fall 2017.

Note: Per Senate Report language in FY 2016 and FY 2017, CDC is taking steps to integrate components of the *Inside Knowledge* campaign and *Know:BRCA* to the extent possible, to ensure coordination of public health messages related to ovarian cancer, leveraging of resources, and maximizing economies of scale. [www.knowbrca.org](http://www.knowbrca.org)

## ***Community Health***

- ***Community-Based Initiatives***

Through a cadre of past and current community health initiatives, communities across America have been able to implement population-level strategies that have led to improvements for women's and girls' health. Several projects specific to women work to increase the use of quality clinical preventive services for breast cancer and cervical cancer screenings; increase access to tobacco-use cessation services for women, pregnant women, and young mothers; increase use of quality clinical preventive services for women with gestational diabetes or with a risk or history of gestational diabetes, or for overweight pregnant women; increase access to medical services for pregnant or postpartum and parenting women experiencing depression, substance abuse, and domestic violence; improve practices to support breastfeeding and/or increase access to baby-friendly hospitals; and enhance usability of WIC food vouchers or Supplemental Nutrition Assistance Program (SNAP) benefits at healthier food retailers.

## ***Diabetes***

### ***States and Gestational Diabetes Mellitus (GDM)***

CDC provided over \$940,000 to the National Association of Chronic Disease Directors through a five-year cooperative agreement (2010 – 2015). The project's nine collaborative states (Arkansas, Florida, Idaho, Missouri, North Carolina, Ohio, Oklahoma, Utah, and West Virginia) and four tribes (Choctaw, Chickasaw, and Navajo

Nations, and Alaskan Natives) developed strategies to improve GDM surveillance and improve prenatal care and postpartum follow-up. Outcomes from state projects demonstrate the impact that public health collaborations can have on surveillance and quality of care for women with GDM, and prevention of type 2 diabetes.

### ***Global Health***

CDC supports multiple global efforts to improve women's and girls' health, including early childhood and maternal nutrition, maternal and perinatal mortality and morbidity surveillance, prevention of birth defects through food fortification with folic acid, congenital syphilis elimination, promotion of cookstoves, and prevention of violence and unintentional injuries and violence. Most countries with a CDC office work on the elimination of mother-to-child-transmission of HIV; prevention of malaria during pregnancy; and programs related to vaccine-preventable diseases, which are conducted through partnerships with the World Health Organization's (WHO) regional and country office.

#### ***Prevention of Mother-to-Child Transmission of HIV***

As a key partner in the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), CDC works with Ministries of Health and other partners to develop and rapidly scale up services to prevent HIV-related morbidity and mortality among HIV-infected pregnant and breastfeeding women and their exposed infants, children and adolescents living with HIV. Our programs work closely with national stakeholders in 24 countries to expand access to quality HIV clinical services for HIV-infected pregnant and breastfeeding women, promote testing for early infant HIV diagnosis, and improve coverage of care and treatment for HIV-infected children and adolescents. In FY 2016, CDC-funded programs helped to provide ARVs for more than 95 percent of pregnant women identified as HIV-positive at CDC-supported PMTCT facilities, delivering treatment for more than 415,000 HIV-positive pregnant women during pregnancy and childbirth to reduce the risk of mother-to-child transmission (n=416,041). CDC contributed over half (55%) of all ARVs/ART provided by PEPFAR programs. In FY17, CDC-funded \$82.3 million for PMTCT programming to 126 grantees in 24 countries.

#### ***Prevention of Malaria during Pregnancy***

CDC conducts surveillance, monitoring and evaluation, and research to optimize the effectiveness of malaria interventions, including those to address malaria in pregnancy. For example, CDC in collaboration with the Kenya Medical Research Institute (KEMRI) and with funding from the Bill and Melinda Gates Foundation, led a large, randomized controlled trial to assess a new drug, dihydroartemisinin-piperaquine (DP), as a possibility to replace the current standard, sulfadoxine-pyrimethamine (SP), for the prevention of malaria in pregnancy, the results of which have recently been published in the Lancet, a weekly general medical journal.



CDC, KEMRI and Liverpool School of Tropical Medicine, with funding from the President's Malaria Initiative (PMI), also conducted an evaluation of the feasibility of replacing the current SP regimen with DP. In addition, CDC worked with KEMRI on studies assessing provider knowledge of and adherence to guidelines for the management of malaria in pregnancy as well as the safety of antimalarial treatments in early pregnancy. As an active member of the Roll Back Malaria/Malaria in Pregnancy Working Group, CDC contributes to global policy guidance. CDC also co-implements with USAID the President's Malaria Initiative to scale up effective interventions—long-lasting insecticide-treated nets (ITNs), rapid tests to diagnose malaria and artemisinin-based combination therapies to treat malaria patients, intermittent preventive treatment for pregnant women (IPTp), and indoor residual house spraying (IRS)—to 19 African countries and 6 countries in the Greater Mekong Subregion.

### ***Roll Back Malaria/Malaria in Pregnancy Working Group***

As an active member of the Roll Back Malaria/Malaria in Pregnancy Working Group, CDC contributes to global policy guidance. CDC also co-implements with USAID the President's Malaria Initiative to scale up effective interventions—long-lasting insecticide-treated nets (ITNs), rapid tests to diagnose malaria and artemisinin-based combination therapies to treat malaria patients, intermittent preventive treatment for Pregnant females (IPTp), and indoor residual house spraying (IRS)—to 19 African countries and 6 countries in the Greater Mekong Subregion.

### ***DREAMS***

DREAMS was announced on World AIDS Day 2014 and is a \$385 million partnership with PEPFAR, Bill & Melinda Gates Foundation, Girl Effect (NIKE), Johnson & Johnson, ViiV Healthcare and Gilead Sciences. DREAMS is implemented in 10 African countries: Kenya, Lesotho, Malawi (USAID only), Mozambique, South Africa, Swaziland, Tanzania, Uganda, Zambia, and Zimbabwe. These countries account for nearly half of all the new HIV infections that occurred among adolescent girls and young women globally in 2014. CDC supports over \$73.5 million in DREAMS programming and funds 34 implementing partners. CDC-supported DREAMS programs include but are not limited to the following activities: Empower adolescent girls and young women through condom promotion and distribution, community-based HTC, post violence care, PrEP, social asset building, safe spaces, and expanded and improved contraceptive mix

- Reduce risk in sex partners of adolescent girls and young women through condom promotion and distribution, community-based HTC for male partners, and increased access to VMMC and ART through improved linkages
- Mobilize communities for change through community mobilization and norms change programs such as SASA! and Stepping Stones
- Strengthen families through combination socioeconomic approaches and parenting and caregiver programs such as Families Matter!

### ***Early Childhood and Maternal Nutrition***

CDC annually monitors vitamin and mineral intake nationally. CDC also works with global partners such as UNICEF and the Food Fortification Initiative to help developing countries implement mass food fortification and supplementation programs to eliminate vitamin and mineral deficiencies in iron, vitamin A, iodine, folate, and zinc among vulnerable populations, especially pregnant women, infants, and children.

### ***Congenital Syphilis Elimination***

This effort focuses on the burden of disease and progress made since CDC launched the initiative in 2007. Congenital syphilis elimination is included in the *WHO Global Health Sector Strategic Plan for Sexually Transmitted Infections (STIs), 2016-2021*, and the *WHO Global Health Sector Strategic Plan for HIV, 2016-2020*.

### ***Heart Disease and Stroke Prevention***

#### **WISEWOMAN**

WISEWOMAN provides screening for heart disease and stroke risk factors for low-income, uninsured, or under-insured women aged 40–64 years who are enrolled in the NBCCEDP. The initiative improves the management and control of hypertension by integrating innovative health system-based approaches, partnering with pharmacists, and working with community-based organizations. WISEWOMAN currently funds 19 states and 2 tribal organizations and launched a new program design. In addition to providing cardiovascular screening to eligible women, it emphasizes evidence-based lifestyle programs provided by community organizations such as the YMCA, Weight Watchers, and organizations that provide Diabetes Primary Prevention programs. From July 2008 to June 2016, the WISEWOMAN program provided 268,673 cardiovascular screenings to 192,391 low-income women. Additionally, since the program added a new behavioral focus, program participants received 81,653 evidence-based healthy behavior support services between July 2013 and June 2016.

### ***HIV/AIDS / STIs***

#### ***HIV Testing for Pregnant Women***

CDC and the Research Triangle Institute are developing a new cost-effectiveness analysis of repeat HIV testing of women during pregnancy. This project will use the methods developed by Sansom, SL et al.<sup>7</sup> This model compared the outcomes of universal, voluntary repeat testing during the third trimester with those associated with no retesting in the third trimester. The original study found that a second HIV test during pregnancy could be an important tool for preventing perinatal transmission in high-risk populations of women and might be a cost-effective intervention nationwide. Data inputs used to

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<sup>7</sup> Sansom SL et al. Human Immunodeficiency Virus Retesting During Pregnancy: Costs and Effectiveness in Prevention Perinatal Transmission. *Obstetrics & Gynecology*. 2003; 102: 782-790.

estimate HIV incidence and other key assumptions in the original study have changed since that time. Thus, an analysis using more recent data should generate a new threshold for recommending jurisdiction-wide repeat screening and enable jurisdictions to revise policies and procedures on repeat HIV testing.

### ***Female Sex Worker Systematic Review***

CDC conducted a systematic review of published literature of female sex workers (FSW) in the U.S. Fourteen publications met the review criteria. A manuscript of the meta-analysis was published in 2015. Study findings suggest that current HIV/ STI prevention efforts in the U.S. do not adequately address the needs of FSW. Interventions are needed to address issues facing FSW in order to reduce HIV/STI transmission in this high-risk group.

### ***Real AIDS Prevention Project (RAPP)***

This community-level intervention engaged low-income women who lived in high HIV-prevalence neighborhoods and housing projects and supported their community-level efforts to prevent HIV. Strategies include using peer advocates to distribute stories showed women at risk for HIV moving through the stages of change to adopt HIV protective behaviors. The materials have been updated to include high-impact prevention activities to support condom use, knowing one's HIV status, linkages to medical care, and medication adherence for HIV-positive women.

The Sister to Sister was a gender-specific, one-on-one, skills-based, safer sex intervention for sexually active heterosexual women who were 18–45 years old. It was an effective, brief, 20-to 30-minute intervention that nurses and other professional clinic staff can easily integrate into their standard clinical practice in primary health care settings. It was designed to provide women with the knowledge, motivation, confidence and skills necessary to decrease their risk for STDs, especially HIV.

### ***Systematic Review of Behavioral STI Intervention for Female Sex Workers***

The lives of female sex workers (FSW) in the US are typically marked by substance abuse, violence, trauma, and poverty. These factors place FSW at risk for acquiring and transmitting HIV and other sexually transmitted infections (STIs), specifically HIV and sexually transmitted diseases (STD). The purpose of this systematic review is to examine STI interventions conducted in the US that aim to reduce sexual-or drug-related risk behavior among FSW. Eighteen studies describing 19 unique interventions met our selection criteria: five exclusively targeted FSW, two reported stratified data for FSW, and 12 included at least 50 percent FSW. Results indicate that 15 interventions provided STI information, 13 provided substance abuse prevention information, and few included content tailored to specific needs of FSW. Findings suggest that current STI prevention efforts in the US do not adequately address the needs of FSW. Interventions are needed to address issues facing FSW in order to reduce HIV/STI transmission in this high-risk group. Data were published in 2015.

### ***Recent Temporal Trends and Their Role in STI Transmissions in the U.S.***

Data from the National Survey of Family Growth was used to examine the demographic characteristics of FSW and their male clients, the recent sexual behaviors of the two groups, and receipt of STI services and self-reported gonorrhea by the two groups. Recent temporal trends in reported sale and purchase of sexual services in the U.S. general population were also examined.

### ***Get Yourself Tested Campaign for High Schools***

The Get Yourself Tested (GYT) for High Schools project aims to adapt a national-level sexual health campaign to inform young people about STIs, encourage and normalize testing for STDs, and connect young people to testing centers. Launched in 2009, the “GYT: Get Yourself Tested” campaign was initially developed to broadly address STI awareness and testing among young people in general, aged 15–25 years. National level evaluation data show that GYT campaign awareness is associated with increased STD testing (usually for chlamydial infection), and healthy communication with partners, friends, and health care providers.

The GYT campaign has been customized and adapted by college campuses and local and state health departments. CDC’s Division of Adolescent and School Health (DASH) proposed adapting this social marketing campaign for high school settings that may have special restrictions or unique circumstances that the current GYT campaign does not address and developing tools and resources for schools and districts to localize and implement their own GYT campaign in high schools.

This project consists of two phases and is currently in the middle of phase 2. Phase 1 consisted of a pilot test of adapting a GYT social marketing campaign for a high school in Chicago Public School system. Increases in HIV and STD testing at the referral clinic and knowledge of where to get tested and intent to be testing in the future were found. Phase 2 is an extension of Chicago pilot test of a GYT campaign in high schools. This work consists of developing a toolkit for school districts and community clinics or health departments to use to develop and implement their own GYT campaigns. As of today, toolkit materials have been developed and feedback from the field will be obtained in the coming months to improve current CDC tools.

### ***Assessing the Clinically Preventable Burden And Cost-Effectiveness of Chlamydia and Gonorrhea Screening Compared to Other Clinical Preventive Services***

Previous work by the National Commission on Prevention Priorities (NCP) has examined the impact and cost-effectiveness of US Preventive Services Task Force (USPSTF) and ACIP-recommended preventive services.<sup>8</sup> This work is being updated to reflect changes in USPSTF and ACIP recommendations since the last report. An analysis of chlamydia and gonorrhea screening in sexually-active young women shows that screening delivers health benefits for < \$35,000/QALY gained. This analysis was presented at the 2016 STD Prevention Conference and will be a part of the broader project, which is ongoing.

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<sup>8</sup> See Maciosek MV, et al. Am J Prev Med 2006; 31(1):52-61).

### ***Evaluation of initiatives to increase chlamydia screening in sexually-active young women***

Annual chlamydia screening of sexually-active young women is recommended by CDC and the USPSTF, but screening rates are relatively low. This project will evaluate several health department interventions (e.g., public health detailing and quality improvement initiatives) to improve chlamydia screening. Projects will evaluate the outcomes and costs associated with the interventions. Awardees include STD programs in Pennsylvania, Baltimore, California, and New York State.

### ***Tubal Factor Infertility (TFI) Case Control Study***

This study compared women with and without TFI to explore risk factors, specifically chlamydia seropositivity. Publication: Population-attributable fraction of tubal factor infertility associated with chlamydia.<sup>9</sup>

### ***Minority AIDS Research Initiative (MARI)***

The fourth round of MARI, which will conclude 4/31/2020, funds 8 junior investigators with projects covering important HIV prevention topics; 2 of 8 include adolescent and adult females. 1) Dr. Yzette Lanier will enroll adolescent and young adult females and males as part of a study that focuses on heterosexual youth couples and their HIV prevention methods; 2) Dr. Oni Blackstock will enroll adult women who are at risk of acquiring HIV in a study that assesses interest and uptake of Pre-Exposure Prophylaxis (PrEP). Both of these studies will take place in the Bronx, NY.

### ***National Programs to Improve the Health and Educational Outcomes of Young People***

Funds from this program will be used to support Sexual Health Including HIV, other STD, and Teen Pregnancy Prevention (SH); increase Capacity of Education and Health Agencies; increase Capacity of Juvenile Justice and Correctional Centers, Alternative Schools, and Shelters for Homeless and Runaway Youth; increase Capacity of Schools and Community-based Organizations to Reach LGBT Youth; and to establish or maintain an HIV Materials Review Panel that will review all written materials, audiovisual materials, pictorials, questionnaires, surveillance instruments, proposed group educational sessions, educational curricula and like materials, including website materials.

### ***Using Qualitative Inquiry Methods to Understand Issues in HIV Prevention, Care, and Treatment in the United States (iQual Project)***

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<sup>9</sup> See Gorwitz RJ, et al. Am J Obstet Gynecol. 2017 Sep;217(3):336.e1-336.e16. doi: 10.1016/j.ajog.2017.05.026. Epub 2017 May 19

In FY 2014, CDC funded a task to conduct qualitative interviews with 40 transgender women (20 HIV positive, 20 HIV negative) about their HIV prevention, care, and treatment seeking experiences. Participants referred medical providers who were also interviewed about providing HIV prevention and care for transgender patients. Interviews were conducted in Atlanta, Washington D.C., and Philadelphia.

***Development and evaluation of a web-based intervention tool for use with persons living with HIV attending routine HIV primary care visits (Positive Health Check)***

In 2015, CDC funded Positive Health Check, a CDC-developed brief, interactive video-based online intervention for people living with HIV (PLWH) attending HIV primary care clinic visits to support retention in HIV medical care, antiretroviral therapy (ART) initiation, sexual risk reduction, adherence to ART, and (briefly) injection drug use (IDU) risk reduction and pregnancy planning. The RCT will be implemented in HIV primary care clinics to all eligible PLWH.

**Secretary's Minority AIDS Initiative Funding for Care and Prevention in the United States (CAPUS) Demonstration Project**

The purpose of this project was to fund health department grantees to implement demonstration projects to reduce HIV-related morbidity, mortality, and related health disparities among racial and ethnic minorities in the United States.

***Comprehensive High-Impact HIV Prevention Projects for Community-Based Organizations***

Community-based organizations are uniquely positioned to complement and extend the reach of HIV prevention efforts implemented by state and local health departments and education agencies to support the optimization of services across public, private, and other community-based organizations to achieve objectives of increased identification of HIV infection, referral for Pre-exposure prophylaxis (PrEP) and non-occupational post-exposure prophylaxis (nPEP) services, earlier entry to HIV care, and increased consistency of care. The High-Impact HIV Prevention Program model for HIV-positive and high-risk HIV-negative persons will consist of the following required program components: (1) establishing formalized collaborations; (2) program promotion, outreach, and recruitment; (3) targeted HIV testing; (4) HIV prevention for HIV-positive persons; (5) HIV prevention for high risk HIV-negative persons; (6) condom distribution; and (7) HIV and organizational planning. Because there is not one singular approach that will work effectively to address the overarching goals of the project, applicants should evaluate approaches that include the required components and those additional components that will, when combined, have the greatest public health impact. These combined activities should also have the greatest potential to address the social and structural determinants of health that are known to create the most significant barriers to

testing, linkage to, retention in, and re-engagement with care and prevention and essential support services in the organization's jurisdiction. This framework acknowledges that prevention and care/treatment synergistically contribute to reducing HIV-related morbidity, mortality, and related health disparities among racial and ethnic minorities in the United States, the Commonwealth of Puerto Rico, and the U.S. Virgin Islands. This program will support the national implementation of high-impact HIV prevention programs by community-based organizations under two core funding categories described below.

### ***Formative Research and Evaluation***

Currently, there are eleven existing Act Against AIDS (AAA) campaigns and partnership initiatives that have either launched or are currently in the planning phases. The three existing consumer campaigns are "Start Talking. Stop HIV" (STSH), "Let's Stop HIV Together" (LSHT), and "Doing It". The three existing provider campaigns are "Prevention Is Care" (PIC), "HIV Screening. Standard Care." (HSSC), and "One Test. Two Lives" (OTTL). Additionally, one HIV care campaign has been developed with outreach to both consumers and providers – "HIV Treatment Works" (HTW). The two partnership initiatives that promote community engagement, awareness, and mobilization – "Partnering and Communicating Together to Act Against AIDS" (PACT) and "Business Responds to AIDS" (BRTA). In FY2016, the three existing consumer HIV testing campaigns – "Testing Makes Us Stronger" (TMUS), "Take Charge. Take the Test" (TCTT), and "Reasons" – ramped down and were replaced by a new general HIV testing campaign, "Doing It". In addition, "One Conversation at a Time", the HIV communication campaign designed for Hispanics/Latinos became inactive in September 2016. In FY 2017, two new provider initiatives to address Pre-Exposure Prophylaxis (PrEP) and the needs for transgender women across the HIV continuum will launch. Process evaluation for all AAA campaigns and initiatives will be conducted. This will consist of monthly media monitoring that allows the examination of the online environment, including blogs, Twitter, Google News, and websites, to determine how AAA and its specific campaigns and initiatives are being discussed and the nature of dialogue about HIV among the various campaign audiences. Outcome evaluation will also be design/implemented for select campaigns that demonstrate sufficient exposure to the targeted campaign audiences.

### ***Act Against AIDS: Doing It National HIV Testing Campaign***

This testing campaign aims to increase awareness, reduce the stigma often associated with HIV/AIDS, and influence social norms concerning the idea of testing by emphasizing that HIV testing is a normal part of life—everyone is Doing It.

### ***Implementing a National Framework to Eliminate Mother-to-Child HIV Transmission (EMCT) in the United States***

Implementing a National Framework to Eliminate Mother-to-Child HIV Transmission (EMCT) in the United States. The purpose is to update and support the implement the EMCT Framework by funding an EMCT Stakeholders group to update CDC’s EMCT Framework, develop strategies for jurisdictions to describe progress in elimination of perinatal HIV infection and to develop educational and best-practice sharing networks.

### ***Accelerating the Prevention and Control of HIV, Viral Hepatitis, STDs and TB in the U.S.-Affiliated Pacific Islands***

PS13-1301/PS18-1801 are two concurrent a five-year cooperative agreements (2013-2022). The purpose of PS13-1301 and PS18-1801 are to support the NCHHSTP Program Collaboration and Service Integration (PCSI) initiative in the US-Affiliated Pacific Islands. PCSI promotes improved integrated HIV, VH, STD, and TB prevention and treatment services at the client level, through enhanced collaboration at the jurisdiction and organizational program levels. There are four program strategies: (1) Program Collaboration and Service Integration (PCSI), (2) Surveillance, Data Management, and Reporting, (3) Health Systems Strengthening, and (4) Disease-Specific Prevention and Care.

### ***Immunizations***

#### ***Improve testing and treatment of Hepatitis B infected women (New and Ongoing)***

Through a 3-year Perinatal Hepatitis B Prevention Program, Auxiliary Prevention Projects, CDC-RFA-PS16-1602, CDC supports improving the identification of Hepatitis B-infected pregnant women for Perinatal Hepatitis B Prevention Program case management and prophylaxis of their infants, and the collection of demographic and clinical data, including data on maternal antiviral therapy, for ascertainment of factors associated with perinatal Hepatitis B transmission and vaccine response. The goals of this project will benefit the mother and her infant.

In addition, in coordination with the Advisory Committee on Immunization Practices (ACIP), updated CDC ACIP Hepatitis B vaccine recommendations are being developed. These recommendations are proposed to include testing HBsAg-positive pregnant women for HBV DNA to guide the use of maternal antiviral therapy (in accordance with American Association



for the Study of Liver Diseases guidelines). In October 2016, the Advisory Committee on Immunization Practices (ACIP) approved new hepatitis B vaccination recommendations for both adults and children. The CDC has approved the recommendations for adults 19 years and older and children and adolescents which were published in Morbidity and Mortality Weekly Reports (MMWR) earlier in 2017.

### ***Improve identification of Hepatitis C virus (HCV) infection women (new)***

Analytic work to support the development of recommendations and policies to: 1) prevent transmission of HCV to women of childbearing age and therefore transmission of HCV to infants during future pregnancies; and 2) to identify HCV infected pregnant women to provide treatment and cure to prevent transmission to infants is ongoing within DVH using large datasets including vital statistics data (birth certificates) and commercial laboratory data.

### ***Increasing Human Papillomavirus (HPV) Vaccination Coverage among Adolescents***

Using 2013 and 2014 Prevention and Public Health Funds, respectively, CDC awarded \$17.4 million to 22 immunization program awardees to increase HPV vaccination coverage among adolescents. During the 15-month project period, awardees are conducting activities in five project areas including: developing a joint initiative with immunization stakeholders; implementing a comprehensive communication campaign targeted to the public; implementing Immunization Information System (IIS)-based reminder/recall; using assessment and feedback to evaluate and improve immunization providers' performance; and implementing strategies to improve immunization providers' adherence to current Advisory Committee on Immunization Practices (ACIP) recommendations for HPV vaccination of adolescents.

### ***Analyses of the impact and cost-effectiveness of human papillomavirus (HPV) vaccine on U.S. women***

Several modeling studies have been conducted to assess the impact and cost-effectiveness of varying HPV vaccination scenarios on women's health. A study of the cost-effectiveness of 9-valent HPV vaccine when administered to women previously vaccinated with 4-valent HPV vaccine cost approximately \$100,000-\$200,000 per quality-adjusted life year (QALY) gained under varying assumptions.<sup>10</sup> Nonavalent HPV vaccine was cost-saving or cost < \$10,000/QALY gained for both sexes when compared to quadrivalent HPV vaccine as an alternative.<sup>11</sup> Modeling studies suggest that HPV vaccination will not reduce racial and ethnic disparities in cancer burden, although the burden is expected to decrease for all races and ethnic groups with vaccination.<sup>12</sup> Finally, a 2-dose schedule for the nonavalent HPV vaccine is likely to be cost-effective than the

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<sup>10</sup> Chesson HW, et al. *J Infect Dis* 2016; 11(1):1694-1700.

<sup>11</sup> Chesson HW, et al. *Hum Vaccin Immunother* 2016; 12(6):1363-1372.

<sup>12</sup> Burger EA, et al. *Cancer* 2016; 122(13):2057-2066.

3-dose schedule.<sup>13</sup> These studies have concluded and have been presented to the Advisory Committee on Immunization Practices (ACIP).

### ***Identification of Pregnant Women with Hepatitis B Infection through Laboratory–Health Department Collaboration***

An estimated 25,000 infants each year are at risk for perinatal transmission of Hepatitis B virus (HBV) infection, the most important cause of chronic HBV infection, with 25 percent risk of premature death from liver failure or liver cancer. Most perinatal and infant HBV infections are preventable when prophylaxis starts at birth. CDC collaborated with the four largest U.S. commercial laboratories, health departments, and professional societies and organizations. By 2014, all four laboratories had implemented the reporting of positive HBV tests with improved identification of tests from pregnant women to state and local health departments. CDC plans to evaluate the effectiveness of these new lab reporting mechanisms on the identification of pregnant HBsAg-positive women by PHBPPs in 2015. Additional activities include developing a CDC/ACOG prenatal test guide for physicians to increase uptake of these designated prenatal HBsAg tests and to recruit hospitals and smaller laboratories to develop similar methods to report pregnancy status. CDC has identified action steps for other laboratories to implement these methods, and an effort is underway to expand this reporting and engage all laboratories providing HBsAg testing services in this public health initiative.

### ***Internet Panel Survey of Pregnant Women***

The Internet Panel Survey of pregnant women has been conducted since the 2010-11 influenza season. The objective is to provide rapid estimates of national influenza vaccination coverage, estimates of receipt of tetanus, diphtheria and acellular pertussis vaccine (Tdap), and information on knowledge, attitudes, and beliefs related to vaccination among pregnant women. For each influenza season, an early-season survey (conducted in November) and late season survey (conducted in April) are conducted. <http://www.cdc.gov/flu/fluview/pregnant-women-nov2015.htm>

### ***Vaccination Coverage Questions in the National Health Interview Survey (NHIS)***

Starting with the 2012 NHIS, new questions were added regarding pregnancy status and timing of receiving influenza vaccination to better determine whether a woman was pregnant during the influenza vaccination period and received influenza vaccine as recommended. Link: [http://www.cdc.gov/flu/fluview/pregnant-coverage\\_1516estimates.htm](http://www.cdc.gov/flu/fluview/pregnant-coverage_1516estimates.htm)

### ***Tdap Vaccine during Pregnancy***

Every year since 2010 between 10,000 and 50,000 cases of pertussis have been reported in the U.S., with cases reported in every state. In recent years, up to 1,450 infants have been hospitalized due to pertussis and about 10 to 20 have died each year. Since January 2013, the tetanus, diphtheria and acellular pertussis (whooping cough) vaccine (Tdap) has been recommended for pregnant women during each pregnancy to protect infants until

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<sup>13</sup> Laprise JF, et al. *J Infect Dis* 2016; 214(5):685-688.

they are old enough to receive pertussis vaccines. Recent data from CDC's Vaccine Safety Datalink and a CDC internet survey suggest that only 10 to 15 percent of pregnant women receive Tdap. In 2014, CDC conducted research with obstetric providers and pregnant women on barriers and motivators to administering and receiving Tdap. This research will inform campaigns to promote Tdap during pregnancy. Additional formative research with obstetric providers and pregnant women is planned for 2016–2017 to better understand knowledge, attitudes, and practices regarding the broader platform of maternal immunization.

### ***Preteen/Adolescent Vaccine Communication Campaign***

Communication activities to raise clinician awareness and knowledge of the new two-dose HPV vaccination schedule began in late October 2016: A web portal for partner organizations and public health programs engaged in activities to improve HPV vaccination and decrease HPV infection, cancer, and disease; A 2017 digital and print media campaign targeting clinicians who are not routinely recommending HPV vaccine for their patients ages 11 and 12 years; A 2017 back-to-school digital media *HPV Vaccine is Cancer Prevention* campaign for parents of 11-12 year olds to increase the number of preteens completing the HPV vaccination series prior to their 13<sup>th</sup> birthday; A pilot study and communications intervention with clinicians in health systems to improve HPV vaccination rates in accordance with HEDIS measures.

Link: [www.cdc.gov/vaccines/teens](http://www.cdc.gov/vaccines/teens)

Link: [www.cdc.gov/hpv](http://www.cdc.gov/hpv)

### ***Influenza Vaccine Protecting Expecting Mothers and Their Newborns***

CDC recommends that health care providers encourage pregnant women to get an annual flu vaccine, especially during an H1N1 predominant season, as was seen during 2013-2014 and 2015-2016. During the 2013-2014 influenza season, CDC reported the overall coverage of rate of vaccination for pregnant women was 52.2 percent, in the 2014-2015 seasons it was 50.3 percent, and in the 2015-2016 it was 49.9 percent.

Link: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6436a2.htm>

Link: [http://www.cdc.gov/flu/fluview/pregnant-coverage\\_1516estimates.htm](http://www.cdc.gov/flu/fluview/pregnant-coverage_1516estimates.htm)

### ***Increasing Adult Immunization Rates through Healthcare Provider Partnerships with Obstetrician-Gynecologists***

The American Congress of Obstetricians and Gynecologists (ACOG) will implement strategies on a clinical practice level and on a national level. On a clinical practice level, ACOG will work with 20 ob-gyn practices in Massachusetts and LA County, California. ACOG will assist practices to improve their immunization rates and office practice techniques by identifying interventions that will improve workflow and overall immunization rates. ACOG will provide targeted resources, training and coaching to the practices, along with incentives for accomplishing project milestones. ACOG will sponsor a Learning Lab and other exchange opportunities for the participating practices to share successes, challenges, and ideas with each other and with ACOG. ACOG will also facilitate linkages between the ob-gyn pilot practices and with public health

departments and pharmacies. Public health departments will provide critical support by providing technical assistance with state immunization information systems as well provider and patient educational resources and programs. On the national level, ACOG will disseminate tools and resources for achieving immunization “best practices” to all of its 35,000 practicing ob-gyn members, and will enhance its popular website, [ImmunizationforWomen.org](http://ImmunizationforWomen.org)

### ***Monitoring Health Through Surveillance***

#### ***National Assisted Reproductive Technology (ART) Surveillance System (NASS).***

Under Congressional mandate, CDC collects data from U.S. based clinics that use Assisted Reproductive Technology (ART) to assist couples in achieving pregnancy, and calculates standardized success rates for each fertility clinic. CDC publishes annual reports describing national, state-specific, and clinic-specific data on perinatal outcomes of ART. For each U.S. state and territory, data are provided on embryo transfer practices, and contribution of ART to all infants born in the state, multiple deliveries, as well as low birthweight and prematurity. ART surveillance data are used to address a number of public health issues, including disparities in access to fertility treatments and adverse perinatal outcomes of these treatments. Related analyses such as the prevalence of severe maternal morbidity among ART births have been explored. The analyses of ART surveillance data have contributed to significant improvements in ART practices and outcomes in the U.S. Link: <http://www.cdc.gov/art/nass/index.html>

#### ***Abortion Surveillance System***

CDC has conducted abortion surveillance since 1969 to document the number and characteristics of women obtaining legal induced abortions in the United States. The most recent abortion surveillance report, which was published in 2015, shows that the total number and ratio of reported abortions decreased 4 percent and the abortion rate decreased 5 percent in 2012 compared with 2011.<sup>14</sup> Because unintended pregnancy is the major contributor to abortion, CDC’s abortion surveillance reports can help program planners and policy makers identify groups of women at greatest risk for unintended pregnancy and help guide and evaluate prevention efforts. Link: <http://www.cdc.gov/mmwr/preview/mmwrhtml/ss6208a1.htm?s>

#### ***Pregnancy Risk Assessment Monitoring System***

CDC supports the Pregnancy Risk Assessment Monitoring System (PRAMS), a survey of new mothers that asks a range of questions to understand maternal and infant health. Topics include attitudes about the pregnancy, prenatal care, alcohol and tobacco use, sleep position, infant’s early development, health care, and health insurance coverage. PRAMS data are used by researchers to investigate emerging issues in the field of

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<sup>14</sup> Centers for Disease Control and Prevention. Abortion Surveillance – United States, 2012. *MMWR* 2015;64 (No. SS-10:1-40.).

reproductive health and by state and local governments to plan and review programs and policies aimed at reducing health problems among mothers and babies. PRAMS provides data not available from other sources about pregnancy and the first few months after birth and allows comparisons among participating states because the same data collection methods are used in all participating states. Forty-seven states, New York City, Washington, D.C., Puerto Rico, and the Great Plain Tribal Chairmen's Health Board participate in the system, which covers approximately 83 percent of all live births in the United States. Link: <http://www.cdc.gov/PRAMS/index.htm>

### ***Pregnancy Mortality Surveillance System***

Since 1986, CDC's Pregnancy Mortality Surveillance System (PMSS) is ongoing and uses data from 52 U.S. reporting areas (50 states, New York City, and Washington, D.C.) to identify and describe rates and causes of pregnancy-related death. Extending maternal health surveillance to include the identification and review of severe pregnancy complications and the factors that are associated with them has the potential to improve maternal health and health care by providing information to influence the delivery of health services and health policy. CDC has published a manual describing strategies for conducting pregnancy-related or maternal mortality surveillance in the U.S. available for use by state or local health departments. Link: <http://www.cdc.gov/reproductivehealth/MaternalInfantHealth/PMSS.html>

### ***Sudden Unexpected Infant Death Case Registry***

The Sudden Unexpected Infant Death (SUID) Case Registry, a state-based surveillance system in nine states, supplements current vital statistics-based surveillance methods, builds on existing child death review programs to conduct population-based surveillance of SUID at the state level, and identifies at-risk populations to target prevention activities. Grantees have improved data completeness, improved relationships with medical examiner/coroner and state vital statistics offices, established new local and state protocols and policies for infant death investigations, and implemented community-based infant death prevention recommendations, such as safe sleep messages. In FY2015, CDC awarded nine states funds to continue SUID Case Registry activities and awarded an additional three new states funds to begin SUID Case Registry activities. CDC also awarded one new state to begin Sudden Death in the Young (SDY) Case Registry activities, bringing the total to four states and two jurisdictions conducting SUID surveillance as a part of their SDY Case Registry activities. These grantees are funded through a joint collaboration between CDC and the National Institutes of Health. Sixteen states and two jurisdictions are now conducting population-based SUID surveillance. Link: <http://www.cdc.gov/sids/CaseRegistry.htm>

### ***National Health Interview Survey (NHIS)***

NHIS monitors the health of the U.S. population through the collection and analysis of data on a broad range of health topics. NHIS covers the civilian noninstitutionalized population of the United States with a sample of between 35,000 to 42,000 households per year. A major strength of this survey lies in the ability to analyze health measures by

many demographic and socioeconomic characteristics. Sex is one of the demographics that can be analyzed in the NHIS data and CDC does this in all general reports from this data source. The current NHIS sample design continues the oversampling of Black persons, Hispanic persons, and Asian persons. Furthermore, starting in 2011, the sample was expanded to allow for an increased number of states for which reliable estimates can be made. This annual survey obtains information, during in-person household interviews, on illnesses, injuries, activity limitation, chronic conditions, health insurance coverage, utilization of health care, and other health topics. NHIS data are used widely throughout HHS to monitor trends in illness and disability and to track progress toward achieving national health objectives. These data are also used by the public health research community for epidemiologic and policy analysis of such timely issues as characterizing those with various health problems, determining barriers to accessing and using appropriate health care, and evaluating federal health programs.

### ***National Health and Nutrition Examination Survey (NHANES)***

NHANES is a nationally representative health examination survey that combines an in-home interview and a standardized physical examination at a mobile examination center (MEC). Approximately 5,000 persons per year are sampled to be included in this annual survey. Information obtained from this survey can be analyzed and disseminated by sex and CDC does this in its reports. NHANES has collected data on chronic disease prevalence and conditions (including undiagnosed conditions) and risk factors such as obesity and smoking, serum cholesterol levels, hypertension, diet and nutritional status, immunization status, infectious disease prevalence, health insurance, and measures of environmental exposures. Findings from this survey are used to determine the prevalence of major diseases and risk factors for diseases. Information is also used to assess nutritional status and its association with health promotion and disease prevention.

### ***National Survey of Family Growth (NSFG)***

NSFG provides national data on factors affecting birth and pregnancy rates, adoption, and maternal and infant health. This annual survey includes approximately 5,000 men and women 15–44 years of age in the household population of the United States each year. Information obtained from this survey should be analyzed separately by sex due to the way the sample is designed and the interview is created, which CDC does in its reports. Data elements include sexual activity, marriage, divorce and remarriage, unmarried cohabitation, forced sexual intercourse, contraception and sterilization, infertility, breastfeeding, pregnancy loss, low birthweight, and use of medical care for family planning and infertility. The NSFG is used to study marriage, divorce, fertility, and family life, as well as reproductive, maternal and infant health topics.

### ***National Vital Statistics System (NVSS)***

NVSS collects and publishes official national statistics on births, deaths, and fetal deaths occurring in the United States. These data are provided through vital registration systems, which are maintained and operated by the individual states and territories where the original certificates are filed. Fetal deaths are classified and tabulated separately from other deaths. There are five vital statistics files—Birth, Mortality, Multiple Cause-of-

Death, Linked Birth/Infant Death, and Compressed Mortality. The birth data are a fundamental source of demographic, geographic, and medical and health information on all births occurring in the United States. The mortality data are a fundamental source of demographic, geographic, and cause-of-death information. Multiple cause-of-death data reflect all medical information reported on death certificates and complement traditional underlying cause-of-death data. Multiple-cause data give information on diseases that are a factor in death, whether or not they are the underlying cause of death; on associations among diseases; and on injuries leading to death. National linked files of live births and infant deaths are used for research on infant mortality. The compressed mortality file is a county-level national mortality and population database. NVSS collects and presents U.S. resident data for the aggregate of 50 states, New York City, and DC, as well as for each individual state and DC. Mortality data can be analyzed and disseminated by sex and CDC does this in its reports.

### ***National Ambulatory Medical Care Survey (NAMCS)***

NAMCS is a national survey designed to provide information about the provision and use of medical care services in office-based physician practices in the United States. The target universe of NAMCS physicians comprises those classified as providing direct patient care in office-based practices, including additional clinicians in community health centers. Data are collected from medical records for approximately 30,500 to 130,000 visits per year on type of providers seen; reason for visit; diagnoses; drugs ordered, provided, or continued; and selected procedures and tests ordered or performed during the visit. Patient data include age, sex, race, and expected source of payment. Data are also collected on selected characteristics of physician practices. The survey provides statistics on the demographic characteristics of patients and services provided, including information on diagnostic procedures, patient management, and planned future treatment. Information obtained from this survey can be analyzed and disseminated by patient sex and CDC does this in its reports.

### ***National Hospital Ambulatory Medical Care Survey (NHAMCS)***

NHAMCS collects data on the utilization and provision of medical care services provided in hospital emergency and outpatient departments. The survey selects a representative sample of 100,000 patient visits per year to emergency departments and outpatient departments of non-federal, short-stay, or general hospitals. Telephone contacts are excluded. Data are collected from medical records on types of providers seen; reason for visit; diagnoses; drugs ordered, provided, or continued; and selected procedures and tests performed during the visit. Information obtained from this survey can be analyzed and disseminated by patient sex and CDC does this in our reports.

### ***National Hospital Care Survey (NHCS)***

One of CDC's newest surveys, the NHCS will collect data to produce national estimates on characteristics of hospital care, inpatient care, and care delivered in emergency departments, and out-patient departments. NHCS has integrated data collected from the National Hospital Discharge Survey (NHDS) and the National Hospital Ambulatory Medical Care Survey. A new sample of hospitals is being recruited for this survey.

Hospitals are providing data on all inpatients from their administrative claims database or electronic health record. Data on hospital characteristics is also being collected. CDC will allow for linkages to the National Death Index as well as CMS data. Patient demographic information collected will include patient sex and CDC will disseminate results by sex in the general reports from this survey, once data are ready for analysis. The first NHCS national estimates will be for the 2018 data collection, which are expected in late 2019, at the earliest.

### ***The Behavioral Risk Factor Surveillance System (BRFSS)***

The Behavioral Risk Factor Surveillance System (BRFSS) is the nation's premier system of telephone surveys that collect state data about health risk behaviors, chronic health conditions, and use of preventive services among US residents. For more than 30 years, CDC, all 50 states, DC, and participating US territories have used the BRFSS to collect uniform, state-specific information about a wide range of behaviors that affect the health of US adults. BRFSS completes more than 400,000 interviews each year, making it the largest continuously conducted health survey system in the world. State data related to women's health include mammograms and Pap tests.

### ***State and Local Area Integrated Telephone Survey***

The State and Local Area Integrated Telephone Survey (SLAITS) collects important health care data at State and local levels. This data collection mechanism was developed by CDC. It supplements current national data collection strategies by providing in-depth State and local area data to meet various program and policy needs in an ever-changing health care system. Much data exists at national and regional levels but are not available at State and local levels. National data are useful for establishing public health priorities for the country; however, much demographic and geographic diversity exists throughout the Nation. SLAITS provides a mechanism to collect data quickly on a broad range of topics at the national, State, and local levels. A partial list of examples of research areas include health insurance coverage, access to care, perceived health status, utilization of services, and measurement of child well-being. Information obtained from this survey can be analyzed and disseminated by sex and CDC does this in our reports.

### ***New Vaccine Surveillance Network***

Pilot the acquisition of maternal vaccination for hospitalized infants aged <6 months and explore methods to estimate vaccine effectiveness of maternal vaccination to prevent influenza associated hospitalization in infants.

### ***Reproductive Health***

#### ***Group B Strep Prevention during Pregnancy***

Group B Streptococcus disease (GBS, group B strep) remains the leading cause of early-onset neonatal sepsis in the U.S. To prevent and improve maternal and neonatal management for GBS at the point-of-care, in September 2013 CDC developed a free



smartphone application, Prevent Group B Strep for obstetric and neonatal providers. It currently has 28,412 downloads.

### ***Maternal and Child Health Epidemiology Program***

Through the Maternal and Child Health Epidemiology Program (MCHEP), CDC, in collaboration with HRSA, assigns senior CDC MCH epidemiologists and fellows to public health agencies. In 2016, 14 senior MCH epidemiologist assignees and 6 fellows from the Council of State and Territorial Epidemiologists were working in 15 public health agencies or institutions. MCHEP supports diverse training opportunities in epidemiology, biostatistics, program evaluation, and scientific writing to improve the data and analytic skills of staff from state and local public health agencies through year-long training courses, professional continuing education, short courses, and professional conferences.

***Collaborative for Alcohol-free Pregnancy: Partnering for Practice Change*** CDC is working with national partners, medical societies, academic centers, and a variety of practitioners from six health disciplines (family medicine, medical assisting, nursing, obstetrics and gynecology, pediatrics, and social work) to prevent fetal alcohol spectrum disorders (FASDs) and risky drinking.

### ***Treating for Two: Safer Medication Use in Pregnancy***

To improve the health of women and babies, our Treating for Two: Safer Medication Use in Pregnancy Initiative is working to identify the safest treatment options for the management of common conditions before and during pregnancy. CDC recognizes that medication use in pregnancy is common and increasing and that many women need to take medications during pregnancy to treat serious conditions.

To follow new research and other relevant updates, please visit [www.cdc.gov/treatingfortwo](http://www.cdc.gov/treatingfortwo).

### ***Maternal Death Review Committees***

State and local Maternal Death Review Committees play an important role in identifying opportunities to prevent maternal mortality associated with pregnancy. However, a barrier for reviews has been the lack of a standardized data system to strengthen the uses of the review committee's data. Currently, about 28 states have or are forming a Maternal Mortality Review Committee, and 17 states are working with CDC to improve the data that is collected to make it more consistent across jurisdictions. In April 2016, CDC, the CDC Foundation, Merck for Mothers, and the Association of Maternal and Child Health Programs have partnered to develop and implement the Maternal Mortality Review Data System (MMRDS). Through this collaboration, CDC expects to produce a standard data-collection and analysis tool that will produce strong, accurate data on maternal deaths and foster collaboration, which can lead to effective interventions. The MMRDS will be a web-based resource portal that will help all states and jurisdictions to start or improving a maternal mortality review, and a national data report, expected in 2017, with information from all jurisdictions reporting data through MMRDS.

### ***Perinatal Quality Collaboratives (PQCs)***

CDC funds six state-based Perinatal Quality Collaboratives (PQCs), in New York, Ohio, California, Illinois, Massachusetts, and North Carolina for three years (FY2014 – FY2016) to improve the quality of perinatal care in their states, including efforts to reduce maternal morbidity and mortality, reduce scheduled births without a medical indication, improve breastfeeding rates, and reduce hospital-acquired neonatal infections and neonatal morbidity. PQCs are networks of perinatal care providers and public health professionals working to improve pregnancy outcomes for women and newborns by advancing evidence-based clinical practices and processes through continuous quality improvement. Because there are still some states without PQCs, as well as states with newly emerging collaboratives, these states may need more help getting started or furthering their efforts. Thus, CDC published *Developing and Sustaining Perinatal Quality Collaboratives: A Resource Guide for States* to support states in their efforts to improve maternal and child health through quality improvement collaboratives. In 2016, CDC launched a National Network of State PQCs to increase capacity in states to improve maternal and infant health by strengthening existing leadership; identify and disseminate best practices for establishing and sustaining PQCs; and identify and develop tools, training, and resources. Link: <http://www.cdc.gov/reproductivehealth/MaternalInfantHealth/PQC.htm>

### ***Assessment of Prenatal Syphilis Screening Laws***

This study will collect and code state laws regarding various syphilis testing requirements for pregnant women. These laws include both statutes and regulations from all 50 states and Washington, D.C. We will assess specific components of these laws, including what stages of pregnancy is testing required, whether all pregnant women must be tested or only those at high risk, and who has the duty to administer these tests.

### ***Medicaid Expansion among Women of Reproductive Age Project***

CDC funds Oregon State University for five years (FY2013 – FY2017) to study the use of medical services and health outcomes among low-income women of reproductive age (15-44 years) and their infants, before and after expansions in Medicaid eligibility due to the Affordable Care Act being implemented in Oregon. CDC and Oregon State University developed a comprehensive research agenda and are analyzing preliminary data. Preliminary analyses include examining the effects of Oregon's Coordinated Care Organizations (CCO's) on health care utilization and neonatal outcomes, and exploring the prevalence of Neonatal Abstinence Syndrome (NAS) and healthcare utilization among NAS infants. Findings have been shared with key Oregon state stakeholders, at health conferences, and peer-reviewed manuscripts are in development.

### ***National Public Health Action Plan for the Detection, Prevention and Management of Infertility***

CDC, in consultation with governmental and nongovernmental partners, developed the National Public Health Action Plan for the Detection, Prevention and Management of Infertility, in response to interest from Congress and stakeholders. Released in July 2014,

it highlights the need to better understand and address issues, at a population level, that contribute to and are caused by infertility in women and men and that may affect the health of the pregnancy. CDC's work has helped to address some of the actions proposed by this National Action Plan to help improve surveillance. Specifically, improvements have been made in the National Assisted Reproductive Technology Surveillance System, including expansion of variables pertaining to male infertility, and development of approaches for data linkages to allow estimation of ART effectiveness and safety at the patient level rather than only at the level of treatment cycle. Link: [http://www.cdc.gov/reproductivehealth/infertility/pdf/drh\\_nap\\_final\\_508.pdf](http://www.cdc.gov/reproductivehealth/infertility/pdf/drh_nap_final_508.pdf)

### ***U.S. Selected Practice Recommendations for Contraceptive Use, 2013***

The *U.S. Selected Practice Recommendations (SPR) for Contraceptive Use, 2013* (US SPR) provides guidance on how contraceptive methods can be used once they are deemed medically appropriate for an individual and on how to remove unnecessary barriers for patients in accessing and successfully using contraceptive methods. The US SPR includes recommendations on when women can start contraceptive methods, what exams and tests are needed before starting a method, what follow up is appropriate, and how to address side effects and other problems with contraceptive method use. It is updated regularly, most recently in 2016, as new evidence emerges and is a companion document to the U.S. Medical Eligibility Criteria (U.S. MEC) for Contraceptive Use. Link: <http://www.cdc.gov/reproductivehealth/contraception/usspr.htm>

### ***Tobacco Use Before, During, and After Pregnancy***

CDC released a new surveillance report in November 2013 entitled “Trends in smoking before, during, and after pregnancy—Pregnancy Risk Assessment Monitoring System, United States, 40 sites, 2000-2010” (MMWR Surveillance Summary 2013, Nov 8;62(6):1-19). Overall, small declines were observed in the prevalence of smoking during pregnancy from 2000-2010. However, high or increasing rates of smoking during pregnancy were observed among some states during the study period. Nearly 11 percent of women smoked during the last trimester of pregnancy. An estimated 220,000 infants were exposed to tobacco in utero based on data available for 27 PRAMS sites in 2010.

### ***Balance after Baby: Working to Decrease Gestational Diabetes Mellitus (GDM)***

Women diagnosed with GDM are at greater risk of developing Type 2 diabetes later in life compared to women who do not have GDM. To address this public health problem, CDC funded the development of a web-based intervention in 2009, Balance after Baby, tailored for postpartum women who had GDM in their last pregnancy. Results of the pilot showed that women randomized to the Balance After Baby intervention had more weight loss and improved glucose tolerance at one year postpartum compared with women in the control group. Therefore, the pilot has led to a larger two-year study with Spanish translation and mobile-phone compatibility, in two recruitments sites, to confirm feasibility, effectiveness, and accessibility. Funding for the larger study began in FY 2015.

Link:

<http://www.cdc.gov/reproductivehealth/MaternalInfantHealth/PregComplications.htm>

### ***Emergency Preparedness and Response (EPR) Activity***

CDC collaborated with external partners to develop preparedness tools for state and local public health use, including:

- “When There is an Emergency: Estimating the Number of Pregnant Women in a Geographical Area,” to guide users through the process of estimating the number of pregnant women in a United States jurisdiction at any given point in time, so as to inform local preparedness and response efforts.
- “Health Indicators for Disaster-Affected Pregnant Women, Postpartum Women and Infants: A Guide for Assessment and Surveillance of the Health of Disaster-Affected Pregnant and Postpartum Women and Infants,” in collaboration with 23 nationwide partners.
- Guidance for anthrax prophylaxis and treatment for pregnant and postpartum women, and authored a manuscript, “Workgroup on Anthrax in Pregnant and Postpartum Women. Special Considerations for Treatment of Anthrax in Pregnant and Postpartum Women.” [Emerging Infectious Diseases, (Internet), February 2014.]
- The Reproductive Health Assessment After Disaster Toolkit to assess post-disaster needs of women of reproductive age.

### ***Monitoring Severe Maternal Morbidity (SMM)***

Using data from the Nationwide Inpatient Sample (NIS), the largest all-payer hospital inpatient care database in the U.S., a series of analytical projects were performed to better identify and describe SMM. Analytic projects includes developing algorithms to identify severe maternal morbidity using administrative data, trends in severe maternal mortality, and racial ethnic disparities in maternal morbidity. These data are used to examine and monitor maternal morbidity at delivery or postpartum hospitalization. The review of SMM cases provides an opportunity to identify points of intervention for quality improvements in maternal care. Tracking SMM will help monitor the effectiveness of such interventions.

<http://www.cdc.gov/reproductivehealth/MaternalInfantHealth/SevereMaternalMorbidity.html>

### ***Increasing Access to Contraceptives Learning Community***

In 2014, CDC and the Association of State and Territorial Health Officials (ASTHO) worked with other partners to develop the Immediate Postpartum LARC Learning Community, which helps states reduce barriers to accessing immediate postpartum long-acting reversible contraception (LARC) by supporting peer-to-peer learning and technical assistance. This collaboration started in 6 states in 2014, and expanded to 13 states in 2015. In 2016, the Learning Community expanded to 27 states and one territory in 2016. The focus has expanded from immediate postpartum LARC to improving access to all

contraception, including LARC, for women of reproductive age. The Cohort 1 & 2 states identified six domains impacting policy implementation: provider training, pay streams (for billing and reimbursement), stocking and supply of devices, informed consent of patients, outreach to providers and consumers, stakeholder partnerships nationally and within the state, service location (urban and rural), and data and surveillance. Link: <http://www.cdc.gov/reproductivehealth/MCHepi/accomplishments.htm>

### ***U.S. Medical Eligibility Criteria for Contraceptive Use (U.S. MEC)***

The U.S. Medical Eligibility Criteria for Contraceptive Use, first issued in 2010, provide evidence-based guidance regarding the safety of contraceptive methods for women with select chronic conditions (e.g., diabetes and hypertension) or behaviors (e.g., smoking) who desire to avoid pregnancy or space their pregnancies. The latest version was released in 2016, and notable updates include the addition of recommendations for women with cystic fibrosis, women with multiple sclerosis, and women using certain psychotropic drugs or St. John's wort; revisions to the recommendations for emergency contraception, including the addition of ulipristal acetate; and revisions to the recommendations for postpartum women, women who are breastfeeding, and women with known dyslipidemias, migraine headaches, superficial venous disease, gestational trophoblastic disease, sexually transmitted diseases, human immunodeficiency virus, or who are using antiretroviral therapy.

Link: <http://www.cdc.gov/reproductivehealth/contraception/usmec.htm>

### ***CDC's 6/18 Initiative***

In 2015, CDC began work on the 6/18 Initiative, which identifies six common and costly health conditions and 18 proven specific interventions that form the starting point for discussion with purchasers, payers, and providers to improve health and control health costs. Unintended pregnancies (including teen pregnancies) are one of the six high-burden health conditions highlighted in the initiative, and the specific interventions include increasing access to the full range of contraceptive for women of childbearing age, reimbursing providers or provider systems for the full cost of FDA-approved contraception, including long-acting reversible contraceptives (LARC) or other contraceptive devices, in order to provide the full range of contraceptive methods.

Link: <http://www.cdc.gov/sixteen/pregnancy/index.htm>

This CDC website provides an explanation on the evidence summary—  
<https://www.cdc.gov/sixteen/aboutsummaries/>

### ***Development of Contraceptive Use Performance Measures***

CDC has been working in collaboration with the Office of Population Affairs (OPA) to develop quality contraception measures to assess performance on increased use of effective contraception to reduce unintended pregnancy. These measures include: 1) use of most and moderately effective methods among all women at risk of unintended pregnancy; 2) use of most and moderately effective methods among postpartum women; and 3) use of LARC among all women and among postpartum women. In 2014–2015,

CDC's Division of Reproductive Health (DRH) provided feedback to OPA on preliminary measures, and The Centers for Medicaid/CHIP Services (CMCS) Maternal and Infant Health Initiative has awarded 14 states to collect and report data on these measures to assess performance on increased use of effective contraception to reduce unintended pregnancy.

### ***Levels of Care Assessment Tool (LOCATe)***

Risk-appropriate care is a strategy developed to improve health outcomes for pregnant women and infants. States may develop coordinated regional systems to help ensure that pregnant women and infants at high risk of complications receive care at a birth facility that is best prepared to meet their health needs. Definitions and monitoring of levels of care vary widely among states. To address this issue, CDC developed the CDC Levels of Care Assessment Tool (LOCATe). This web-based tool helps states and other jurisdictions create standardized assessments of levels of maternal and neonatal care. CDC LOCATe is based on the most recent guidelines and policy statements issued by the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, and the Society for Maternal-Fetal Medicine. As of 2017, a total of 12 states (California, Colorado, Georgia, Illinois, Michigan, Mississippi, New Mexico, North Carolina, Oklahoma, Tennessee, Utah, and Wyoming) and Puerto Rico are participating in CDC LOCATe. More information on LOCATe can be found here <https://www.cdc.gov/reproductivehealth/maternalinfanthealth/LOCATe.html>

### ***Working with Health Centers to Reduce Teen Pregnancy among Youth from Vulnerable Populations – Teens, Access, Quality (TAQ) Initiative***

CDC funds a five-year initiative (FY 2015-2020) to: 1) enhance publicly funded health centers' capacity to provide youth-friendly sexual and reproductive health services for youth from vulnerable populations, and 2) increase the number of youth from vulnerable populations accessing sexual and reproductive health services by (a) working with youth-serving systems to develop strategies to refer and link vulnerable youth to care and (b) increasing awareness of the health centers' services in the local community through communication efforts. Examples of vulnerable populations include youth who are out of school, living in foster care, homelessness, or with juvenile justice system... Funded sites encourage parent-teen communication in conjunction with state confidentiality and privacy laws.

Link: <http://www.cdc.gov/teenpregnancy/projects-initiatives/publicly-funded-health-centers.html>

### ***Mobile Phone Application for Advancing Teen Pregnancy Prevention***

A smartphone mobile application (app), referred to as Crush, was developed through a Phase I Small Business Innovation and Research (SBIR) contract. Crush was designed to disseminate medically accurate and comprehensive sexual and reproductive health information and tools targeting adolescent girls in the United States, with the aim of preventing teen pregnancy and promoting positive sexual and reproductive health behaviors. A Phase II SBIR contract is being used to further develop the Crush app and

to test the usability and efficacy of the app using an internet-based randomized controlled trial. The Crush trial will assess the efficacy of the app in affecting consistent contraceptive use and in linking youth to sexual and reproductive health services. The Crush trial will begin in November 2016; the target population is African American and Latino girls 15-17 years old. A waiver of parental consent was granted for this project consistent with federal regulations for research with adolescents. Public comments from a community based organization that works in these communities were received and taken into account during project development.

### ***Emergency Preparedness and Response: Online Training Course***

CDC developed a new online course for federal, state, and local public health and other health professionals. The course highlights preparedness and response resources and tools specific to the field of reproductive health in emergencies. Women of reproductive age (aged 15-44 years), including pregnant and postpartum women, may experience special risks and needs for public health and medical services when disasters and some infectious diseases strike. This course is designed to help address those needs, and includes practice exercises, describes challenges in surveillance of this population, and contains CDC resources about prophylaxis and treatment of pregnant and postpartum women for selected infectious diseases.

Link: <http://www.cdc.gov/reproductivehealth/emergency/training-course/index.html>

### ***Estimating the Prevalence of Female Genital Mutilation and Cutting (FGM/C) in the United States***

United States estimates indicate that as many as 513,000 women and girls may be at risk for female genital mutilation and cutting (FGM/C) in their lifetime. However, data is extremely limited. In collaboration with the HHS Office on Women's Health, CDC is developing a strategy and methodology for a potential study to better determine the prevalence of FGM/C in the United States. The intent of the study is to collect information directly from women of childbearing age about several aspects of FGM/C, including the likelihood that women and girls in the communities of interest have undergone the procedure and health care needs resulting from being subjected to FGM/C. CDC will start with a pilot study is planned for 2017-18, to be followed by a full study in several communities in various parts of the US. These efforts will provide critical data to inform any potential future plans or strategies.

### ***Rural Health***

#### ***Promoting HPV Vaccination Among Rural Appalachians***

Appalachian Kentucky has some of the nation's highest incidence rates of invasive cervical cancer (ICC). The human papillomavirus (HPV) is the major cause of ICC, and the HPV vaccine can prevent 70 percent of ICC. However, many women in this region are unaware of the benefits of immunization. From 2009-2014, CDC's Prevention Research Centers (PRC) Program funded researchers from the University of Kentucky Prevention Research Center (PRC) to lead efforts to understand and address cancer-related disparities in this underserved region. Researchers from the University of

Kentucky PRC developed and piloted a DVD entitled “1-2-3 Pap” that encourages rural Appalachian women to complete the HPV series, a primary strategy to prevent cervical cancer. Women who watched the DVD were more than twice as likely to complete the series as women who received standard care. The PRC worked with its partners to adapt this program, so it could be repeated in other underserved areas with high rates of cervical cancer. The program was eventually distributed throughout Kentucky, which led to requests for help from North Carolina and West Virginia to develop versions tailored to their states.

***Addressing the Seeds of HOPE (Health, Opportunities, Partnerships, Employment): Obesity Prevention and Economic Development Program Model for Women in Rural Eastern North Carolina***

Researchers are implementing and evaluating the dissemination of HOPE Works, a stress management, obesity prevention, and economic development program designed for women in rural eastern North Carolina (Sampson, Duplin, Robeson, and Lenoir counties). Seeds of HOPE addresses the need to reduce obesity and recognizes the context of economic and social factors that may affect weight control. An expanded model addresses health-related goals (healthy eating, physical activity, and weight management) as well as hope-related goals (such as education, job skills training, financial literacy, and business development). It’s emphasis on grassroots economic improvement responds to the community’s expressed need for economic stability as a basis for health.

***Tobacco***

***The Health Consequences of Smoking -Fifty Years of Progress: A Report of the Surgeon General***

Changes in patterns of smoking prevalence in women and the corresponding increases in smoking-related diseases and deaths in women were noted throughout the Surgeon General’s Report on Smoking and Health released in January of 2014, marking the 50th anniversary of the first report on the health consequences of smoking. The report provided updated or new data specific to women on smoking trends, chronic obstructive pulmonary disease, reproductive outcomes, and breast cancer.

***Tips from Former Smokers***

The impact of smoking on women and benefits of quitting is a major focus of the Tips from Former Smokers campaign. Since 2012, the Tips campaign has featured 19 women telling their stories about preterm birth, cancer, gum disease, asthma, and cardiovascular disease. Smoking remains the leading cause of preventable death and disease in the United States, killing more than 480,000 Americans each year. The Tips campaign, which profiles real people—not actors—who are living with serious long-term health effects from smoking and second-hand smoke exposure has continued through 2017. Since its launch, The Tips campaign has featured compelling stories of former smokers living with smoking-related diseases and disabilities and the toll that smoking-related illnesses have taken on them. Since its launch, CDC estimates that millions of Americans



have tried to quit smoking cigarettes because of the Tips® campaign and at least a half a million have quit for good.

## ***Violence***

### ***CDC Report on Intimate Partner and Sexual Violence in the U.S. Explores Victimization and Impact***

In September 2014, CDC released “Prevalence and Characteristics of Sexual Violence, Stalking, and Intimate Partner Violence Victimization - National Intimate Partner and Sexual Violence Survey, United States,” using 2011 data from the National Intimate Partner and Sexual Violence Survey (NISVS). NISVS provides data essential to informing intimate partner violence prevention efforts and providing services and resources to those victimized. These findings emphasize that sexual violence, stalking, and intimate partner violence are major public health problems in the U.S. On average, nearly 20 people per minute are victims of physical violence by an intimate partner, which equates to more than 10 million women and men. Nearly 2 million women are raped each year and more than 7 million women and men are victims of stalking each year.

### ***CDC Advances Research on Sexual Violence Prevention***

In 2016, the CDC released a report on the best available evidence on effective strategies for preventing sexual violence called STOP SV: A Technical Package to Prevent Sexual Violence. It includes strategies and approaches that are in keeping with CDC’s emphasis on primary prevention – stopping sexual violence before it starts – as well as those designed to reduce risk of victimization and to lessen the short- and long-term harms of sexual violence.

CDC continues to support research projects that rigorously evaluate the effectiveness of sexual violence prevention programs. Currently, CDC is funding 15 research projects in this area. This research will show effectiveness in reducing rates of sexual violence and increase options for prevention strategies grounded in practice.

## ***Women of Color***

### ***Increasing Breast and Cervical Cancer Screening Among Muslim Women***

#### **Utilizing Targeted Community Interventions to Increase Breast and Cervical Cancer Screening Among Muslim Women**

Mammography and Pap tests are underused by women who have no regular source of health care, women without health insurance, and women who immigrated to the United States. Some populations of Muslim women fall into these groups and some studies have indicated that Muslim women may have lower rates of breast and cervical cancer screening and higher rates of developing these cancers compared to the overall population. Currently, the largest concentration of Muslims in the United States resides in New York City (NYC) and the surrounding boroughs. In FY 2015, New York University (NYU) School of Medicine, a CDC

Prevention Research Center, was awarded to conduct research to reduce a gap in knowledge relative to Muslim women's healthcare and breast and cervical cancer screening among Muslim women. In response, NYU developed Muslim Americans Reaching for Health and Building Alliances (MARHABA). The aim of MARHABA study is 1.) to understand the barriers to and facilitators of breast and cervical cancer screening among Muslim women in NYC; and 2) inform the development and implementation of an intervention tailored towards increasing knowledge and adherence to breast and cervical cancer screening among this fast growing population. The study was guided by a Community Based Participatory Research (CBPR) framework. In CBPR studies, diverse stakeholders with various knowledge and expertise partner to understand community concerns and develop action-oriented solutions to address them. The project was led by NYU School of Medicine and a coalition consisting of representatives from several social service agencies, mosques, and leaders in the Muslim community to implement a culturally adapted lay health worker (LHW) intervention designed for Muslim women to increase breast and cervical cancer screening participation among Muslim women aged 40 and over in New York City. Data from key informant, one-on-one, and focus group interviews were used to report on barriers and facilitators to breast and cervical cancer screening for Muslim women in New York City.

For this study, a randomized control trial designed to increase receipt of breast and cervical cancer screening compare using LHW-led small media materials only to using LHW-led small media materials, as well as, patient navigation in getting women screened for breast and cervical cancer. All women will attend a one hour educational seminar on breast and cervical cancer screening and receive small media materials. One group will be asked to schedule a mammogram or pap test. The second group will receive up to five reminder calls for the women to schedule a screening appointment. Study results will be based on women reporting if they got a mammogram or Pap test, women's knowledge of breast and cervical cancer screening, and if women plan to get screened.

Although Muslim women may face unique barriers to screening, religion and social considerations can be leveraged to enhance the dissemination of educational materials to improve knowledge and facilitate cancer screening among Muslim women. The development of a large scale culturally and religiously tailored intervention and messaging concepts promoting breast and cervical cancer screening targeted for this disparate population is critical to reducing cancer disparities.

***An Assessment of the Determinants of HIV Risk Factors for African American & Hispanic Women at Risk for HIV Infection in the Southern U.S.***<sup>15</sup>

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<sup>15</sup> The citations for the completed project follows: McLellan-Lemal E, O'Daniels CM, Marks G, Villar-Loubet O, Doherty IA, Simpson C, Weiss S, Hanna B, Adimora, AA, White BL, Wheeling JT, Borkowf CB. (2012). Sexual Risk Behaviors among African-American and Hispanic Women in Five Counties in the Southeastern United States: 2008–2009. *Women's Health Issues*, 22(1), e9–e18. McLellan-Lemal E, Toledo L, O'Daniels C, Villar-Loubet O, Simpson C, Adimora AA, Marks G. (2013). "A man's gonna do what a man wants to do": African American and Hispanic women's perceptions about heterosexual relationships: a qualitative study. *BMC Women's Health* 2013, 13:27.

This project supports the CDC Health Protection goal: *Healthy People in Every Stage of Life*. Although this project can potentially impact people in all life stages, the focus of the project was on improving the health of adults. A cross-sectional, multi-site study of African American women from North Carolina and Alabama, and Hispanic women from Florida at risk for HIV infection seeks to identify and understand the behavioral, psychological, interpersonal, and socio-cultural factors associated with HIV infection in these populations.

### ***For Sisters Only (FSO) Expo Partnership***

CDC works alongside national and local partners such as V-103/WAOK, through events such as For Sisters Only to reach at-risk populations, including women, men, youth, men who have sex with men (MSM), and LGBT. This annual one-day marketing event attracts thousands of mostly African American families to Atlanta, GA. CDC's participation helps bring attention to HIV/AIDS in the African American community by exhibiting and disseminating HIV/AIDS education information, discussing prevention methods, facilitating testing with local partners, and establishing linkages to care and treatment.

### ***Healthy Relationships***

The Healthy Relationships Workshop is a skills-based, safer-sex intervention for African American men and women, 18–26 years of age. It is an effective, 4- to 8-hour intervention that historically black colleges and universities (HBCUs) can integrate into their freshmen orientation activities, as well as use for programming throughout the college experience. It was designed to provide college-aged African American men and women with skills to: engage in open conversations relating to healthy relationships; increase self-awareness of the risk of contracting a sexually transmitted infection; encourage the adoption of attitudes and behaviors that promote sexual health; and reinforce a sense of agency and self-efficacy regarding sexual interactions.

### ***Listeria in Queso Fresco-Learn the Facts; Lower the Risks Webinar***

A Listeria Educational Outreach Webinar was held in September 2014, which focused on increasing awareness about lowering the risk of Listeria infection among pregnant Latinas. They are 24 times more likely than non-Latinas to contract it, due to the cultural practice of eating queso fresco. Complications can occur during pregnancy, including miscarriage, stillbirth, premature labor, and illness and death in infants. The webinar previewed new educational materials on Listeria that were written in both Spanish and English, including a fotonovela in Spanish and English. As a follow-up to the webinar, the CDC listeriosis website was updated with educational materials after the webinar. This is an ongoing activity.

The website now has resources for pregnant women in English and Spanish, including the referenced fotonovela.

Link: <https://www.cdc.gov/listeria/risk-groups/pregnant-women.html>

Link: <https://www.cdc.gov/spanish/listeria/education.html>

### ***Zika in Pregnancy Activities***

An increase in the number of infants with microcephaly in Brazil was noted in September 2015, following identification of local mosquito-borne Zika Virus (ZIKV) transmission. On January 22, 2016, CDC activated its Emergency Operations Center, and escalated activation to Level 1 on February 8, 2016. Since then, a causal link between Zika infection during pregnancy and microcephaly and other serious brain anomalies (congenital Zika infection) has been established (Rasmussen et al., 2016). As of October 2016, 59 countries and territories worldwide, including 49 countries and territories in the Americas, are reporting active Zika Virus transmission. The CDC response to the Zika outbreak has focused on promoting healthy pregnancies and preventing Zika infection in women who are pregnant and those who want to become pregnant.

The activities described below fall into three areas of public health response: Surveillance, Research and Program Development, and Dissemination of Prevention Programs and Messages.

## **1. SURVEILLANCE**

### ***U.S. Zika Pregnancy and Infant Registry (USZPIR)***

In collaboration with state, tribal, territorial, and local health departments, the Centers for Disease Control and Prevention (CDC) established the USZPIR as an enhanced surveillance system to monitor pregnancy and fetal/infant outcomes among pregnant women and fetuses/infants with laboratory evidence of possible Zika virus (ZIKV) infection. The USZPIR includes data on pregnant women and their infants and will include information up through the child's 2<sup>nd</sup> or 3<sup>rd</sup> birthday, depending on the jurisdiction. USZPIR includes data from all U.S. states, the District of Columbia (D.C.) and all territories.\* Summary data are reported monthly on the CDC website. Data from the USZPIR have informed clinical guidance and enhanced understanding of the full range of health problems associated with ZIKV and other factors that might affect the risk for birth defects. A list of clinical guidance documents and other publications based on USZPIR data is provided at the end of this document.

\*Note: U.S. Zika Pregnancy and Infant Registry includes the U.S. Zika Pregnancy Registry and the Puerto Rico Zika Active Pregnancy Surveillance System.

### ***Population-Based Zika Birth Defects Surveillance***

Because not all pregnancies with Zika virus infection will be identified given lack of testing or the possibility of testing outside the appropriate time, CDC supported jurisdictions to establish or enhance existing population-based birth defects surveillance systems to monitor all infants and fetuses with birth defects potentially related to ZIKV, regardless of the availability of Zika testing data. Leveraging existing birth defects surveillance systems allowed for comprehensive monitoring of the prevalence of birth

defects potentially related to maternal Zika virus infection during the early time period of the Zika virus outbreak in U.S. states and territories.

### ***Proyecto Vigilancia de Embarazadas con Zika (VEZ)***

CDC and Colombia's national public health institute and Ministry of Health are collaborating to enhance surveillance of pregnant women with Zika virus disease and their infants to learn more about the virus and its effects during pregnancy. Proyecto VEZ enrolled over 1,200 pregnant women with symptomatic Zika virus disease with and without laboratory evidence of Zika virus infection and collected information from their medical records throughout pregnancy, collected samples from mothers and infants at delivery, and is following the infants for up to two years after birth. Objectives of this project include evaluating the relationship between Zika virus infection during pregnancy and a range of adverse pregnancy, birth, and infant outcomes, describing the range of adverse fetal and infant outcomes associated with congenital Zika virus infection and estimating the risk of each adverse outcome by trimester of maternal Zika virus infection.

### ***Zika Supplement for Current Pregnancy Risk Assessment Monitoring System (PRAMS)***

The Puerto Rico Department of Health (PRDH), in collaboration with CDC, collected data using a methodology adapted from the Pregnancy Risk Assessment Monitoring System (PRAMS) (4) to obtain island-wide and regionally representative information regarding experiences related to prevention and detection of Zika virus infection during pregnancy among women who had a live birth from August 28, 2016 to December 3, 2016. Thirty-six hospitals in Puerto Rico reporting  $\geq 100$  births in 2015 (representing  $>98\%$  of live births) were eligible, and all agreed to participate. More information on this project can be found here: <https://www.cdc.gov/mmwr/volumes/66/wr/mm6622a2.htm>

## **2. RESEARCH AND PROGRAM DEVELOPMENT**

### ***Contraceptive Assessment in Puerto Rico during Zika (CAPRZ)***

CDC collaborated with the Puerto Rico Department of Health's Behavioral Risk Factor Surveillance unit to implement a population-based cell phone survey among women of reproductive age to collect essential information on contraceptive practices and Zika prevention behaviors from July to November, 2016. More than 3,000 interviews among women 18-49 years old were completed for the CAPRZ survey, and findings were used to inform the emergency response in Puerto Rico.

### ***Zika en Embarazadas y Niños (ZEN)***

CDC is collaborating with Colombia's national public health institute on a prospective cohort study of pregnant women, their male partners, and their children. Pregnant women are recruited into the study during the first trimester and will be followed during pregnancy; children will be followed up to age 4 years. Through this collaboration, we hope to better understand risk factors for Zika virus infection in pregnancy, identify gestational ages during which Zika virus infection causes fetal harm, determine the

duration of viral persistence in body fluids, and identify risk factors for maternal-to-child Zika virus transmission during birth and the postpartum period. Results of this study will be used to guide Colombia and U.S. recommendations for preventing Zika virus infection, to improve counseling of patients about risks to themselves, their pregnancies, their partners, and their infants, and to help agencies prepare to provide services to affected children and families.

#### ***Microcephaly Case Control, Paraiba, Brazil***

CDC and partners in Paraiba, Brazil are working together on a case-control examination of Zika related microcephaly. The specific aims of this project are to: (1) Establish the proportion of infants with microcephaly who have evidence of congenital ZIKV infection; (2) Examine clinical characteristics and outcomes; (3) Establish the AR of microcephaly explained by ZIKV infection; (4) Establish the RR of microcephaly associated with ZIKV infection; and (5) Assess prevalence and duration of RNA in urine/semen during 6 months after acute infection. In this population, infants with microcephaly at follow-up were 22 times as likely as infants without microcephaly to have evidence of recent Zika virus infection. This investigation has improved understanding of the outbreak of microcephaly in northeast Brazil and highlights the need to obtain multiple measurements after birth to establish if an infant has microcephaly and the need for further research to optimize testing criteria for congenital Zika virus infection. [http://www.thelancet.com/journals/lanchi/article/PIIS2352-4642\(18\)30020-8/fulltext](http://www.thelancet.com/journals/lanchi/article/PIIS2352-4642(18)30020-8/fulltext)

#### ***Zika Outcomes and Development in Infants and Children (ZODIAC)***

CDC is collaborating with Brazil's Ministry of Health (MOH) to conduct the first follow-up assessment of babies aged 12-24 months with congenital ZIKV infection in two Brazilian states: Paraíba and Ceará. The ZODIAC project is designed to provide a comprehensive description of the longer term health and development consequences for babies infected with Zika virus before birth. This project investigates the following outcomes, to determine any possible associations: physical growth, birth defects, vision, hearing, and cognitive, social, language, and motor development. The presence of a child with complex medical and developmental needs associated with long-term home care affects the physical and emotional health and well-being of the parents, siblings, and other family members. Therefore, ZODIAC investigators are also assessing family functioning and care needs of the children and families. Data collection began in August 2017 and was completed in October 2017. Knowledge gained will be relevant to families and practitioners coping with and caring for children affected by congenital Zika virus infection in Brazil as well as in the U.S. and other countries. The information from the ZODIAC investigation will be used to help health professionals, and public health and social service agencies understand and prepare for the medical and social service needs of affected children and families. Complete assessments and earlier identification of health and developmental outcomes will allow for more appropriate care, including early intervention services and support for affected children, women, families, and communities.

### **3. DISSEMINATION OF PREVENTION PROGRAMS AND MESSAGES**

### ***Expanding Contraceptive Access through Zika Contraceptive Access Network***

The prevention of unintended pregnancy is a primary strategy to reduce adverse Zika-related pregnancy and birth outcomes. The CDC Foundation, with technical assistance from CDC, and in partnership with a diverse group of stakeholders, established the Zika Contraception Access Network (Z-CAN) in Puerto Rico. Z-CAN was a short-term (May 2016-September 2017) response for rapid implementation of reversible contraceptive services in a complex emergency setting. The goals of the Z-CAN program were to: 1) build a network of health care providers to provide client-centered contraceptive counseling and same-day provision of the full range of reversible contraceptive methods at no cost for women who chose to delay or avoid pregnancy; and 2) to raise awareness among women and families of the role of contraception as a primary prevention measure to reduce Zika-related pregnancy and birth outcomes.

### ***Monitoring and Evaluation of the Z-CAN Project***

CDC, in partnership with the University of Puerto Rico have plans to evaluate the Z-CAN program to monitor and evaluate the implementation and impact of the Z-CAN program. The objectives of the evaluation are to assess women's perceptions of facilitators and barriers to accessing reversible contraception in Puerto Rico; Z-CAN physician and clinic staff perceptions of potential areas for Z-CAN program improvement and sustainability; and contraceptive use patterns and continuation rates, unintended pregnancy rates, and unmet need for services among Z-CAN patients after receipt of services.

### ***Zika Care Connect: Improving Access to Clinical Services for the Management of Zika virus***

CDC, in collaboration with McKing Consulting Corporation and March of Dimes, established Zika Care Connect (ZCC), a resource for pregnant women and families seeking clinical services for the management of Zika, to facilitate coordination of care for families and help improve access to necessary services. Central to ZCC is a network of specialty providers knowledgeable about and dedicated to the care of these patients. Specialties in the ZCC network include maternal-fetal medicine, mental health counseling, pediatric neurology, pediatric ophthalmology, radiology, audiology, developmental pediatrics, infectious disease, endocrinology, and care coordination. Additionally, 20 jurisdictions have enrolled in ZCC: Arizona, California, Florida, Georgia, Illinois, Louisiana, Maryland, Massachusetts, New Jersey, New Mexico, New York, North Carolina, Ohio, Pennsylvania, Tennessee, Texas, Virginia, Washington, Puerto Rico, US Virgin Islands. Zika Care Connect, available both in English and Spanish, can be accessed at <https://www.zikacareconnect.org/>.

### ***Local Health Department Initiative***

To help local health departments respond to the Zika virus outbreak, CDC launched the Zika Local Health Department (LHD) Initiative. The LHD Initiative places field assignees in local health departments responding to Zika virus in order to build the capacity to provide educational outreach about Zika virus to healthcare providers and community members; monitor pregnant women and infants affected by Zika virus; report Zika virus infection data to the appropriate state health agency and CDC; and refer

women, infants, and families affected by Zika virus to additional services, as needed. Field assignees are people with expertise in public health who are placed in the local health department to help respond to local needs regarding Zika virus infection. Since the beginning of the program, field assignees have been placed in:

- **American Samoa:** American Samoa Department of Health
- **AZ:** Maricopa County Department (Dept.) of Public Health
- **CA:** Alameda County Public Health Dept., County of San Diego Health and Human Services
- **DC:** District of Columbia Dept. of Health
- **FL:** Florida Dept. of Health-Orange County, Florida Dept. of Health-Palm Beach County, Florida Dept. of Health-Broward County, Florida Dept. of Health-Miami-Dade County (2)
- **FSM:** Kosrae Dept. of Health Services
- **IL:** Kane County Health Dept., Chicago Dept. of Public Health
- **LA:** New Orleans Health Dept.
- **MS:** Mississippi State Dept. of Health
- **NY:** Metropolitan Area Regional Office in New Rochelle (New York State Dept. of Health), Congenital Malformations Registry in New Rochelle (New York State Dept. of Health), Suffolk County Dept. of Health Services
- **PR:** Dept. of Health of Puerto Rico (4)
- **TX:** City of El Paso Dept. of Public Health, City of Laredo Health Dept., Hidalgo County Health and Human Services Dept., Cameron County Public Health, City of Brownsville Public Health Dept., Corpus Christi-Nueces County Public Health District, Harris County Public Health
- **USVI:** US Virgin Islands Dept. of Health
- **UT:** Salt Lake County Health Dept.
- **VA:** Fairfax County Health Dept.

#### **List of Publications Based on USZPIR Surveillance Data**

##### **May 2016**

Simeone RM, Shapiro-Mendoza CK, Meaney-Delman D, et al. Possible Zika virus Infection Among Pregnant Women — United States and Territories, May 2016. *MMWR Morb Mortal Wkly Rep* 2016;65. DOI: <http://dx.doi.org/10.15585/mmwr.mm6520e1>

##### **July 2016**

Oduyebo T, Igbiosa I, Petersen EE, et al. Update: Interim Guidance for Health Care Providers Caring for Pregnant Women with Possible Zika virus Exposure — United States, July 2016. *MMWR Morb Mortal Wkly Rep* 2016;65:739–744. DOI: <http://dx.doi.org/10.15585/mmwr.mm6529e1>

##### **August 2016**

Russell K, Oliver SE, Lewis L, et al. Update: Interim Guidance for the Evaluation and Management of Infants with Possible Congenital Zika virus Infection — United States,



August 2016. MMWR Morb Mortal Wkly Rep 2016;65:870–878. DOI: <http://dx.doi.org/10.15585/mmwr.mm6533e2>

### **January 2017**

Honein MA, Dawson AL, Petersen EE, et al. Birth Defects Among Fetuses and Infants of US Women With Evidence of Possible Zika virus Infection During Pregnancy. JAMA. 2017;317(1):59–68. doi:10.1001/jama.2016.19006

### **April 2017**

Reynolds MR, Jones AM, Petersen EE, et al. Vital Signs: Update on Zika virus–Associated Birth Defects and Evaluation of All U.S. Infants with Congenital Zika virus Exposure — U.S. Zika Pregnancy Registry, 2016. MMWR Morb Mortal Wkly Rep 2017;66:366–373. DOI: <http://dx.doi.org/10.15585/mmwr.mm6613e1>

### **June 2017**

Shapiro-Mendoza CK, Rice ME, Galang RR, et al. Pregnancy Outcomes After Maternal Zika virus Infection During Pregnancy — U.S. Territories, January 1, 2016–April 25, 2017. MMWR Morb Mortal Wkly Rep 2017;66:615–621. DOI: <http://dx.doi.org/10.15585/mmwr.mm6623e1>

Reagan-Steiner S, Simeone R, Simon E, et al. Evaluation of Placental and Fetal Tissue Specimens for Zika virus Infection — 50 States and District of Columbia, January–December, 2016. MMWR Morb Mortal Wkly Rep 2017;66:636–643. DOI: <http://dx.doi.org/10.15585/mmwr.mm6624a3>

### **July 2017**

Oduyebo T, Polen KD, Walke HT, et al. Update: Interim Guidance for Health Care Providers Caring for Pregnant Women with Possible Zika virus Exposure — United States (Including U.S. Territories), July 2017. MMWR Morb Mortal Wkly Rep 2017;66:781–793. DOI: <http://dx.doi.org/10.15585/mmwr.mm6629e1>

### **October 2017**

Adebanjo T, Godfred-Cato S, Viens L, et al. Update: Interim Guidance for the Diagnosis, Evaluation, and Management of Infants with Possible Congenital Zika virus Infection — United States, October 2017. MMWR Morb Mortal Wkly Rep 2017;66:1089–1099. DOI: <http://dx.doi.org/10.15585/mmwr.mm6641a1>

### ***Consultation with Women’s Health Professionals***

CDC collaborates with local, state, and national governmental and nongovernmental agencies and organizations, professional organizations, academia, health providers, ministries of health, individuals, and others to advance women’s and girls’ health.

### ***CCWH Membership***

CDC OWH is a member of the HHS Coordinating Committee on Women’s Health.

## **Food And Drug Administration (FDA)**

### **Office of Women's Health**

#### ***Establishment of an Office***

In 1994, the FDA's Office of Women's Health (OWH) was established in response to a Congressional mandate.

#### ***Mission***

The mission of the FDA OWH is to further the understanding of women's health by

- Protecting and advancing the health of women through policy, science, and outreach
- Advocating for inclusion of women in clinical trials and analysis of sex/gender effects
- Increasing scientific knowledge through advanced professional training/education in subpopulation analysis

During fiscal years 2015 to 2017, FDA OWH aligned its activities with the FDA Commissioner's 2016 diversity in clinical trials priorities including the ongoing implementation of activities in support of Sec. 907 of the Food and Drug Administration Safety and Innovation Act (FDASIA). FDA OWH's work has resulted in the availability of important new tools and resources to assist FDA's understanding of the safety and effectiveness of FDA-regulated products used by women across the demographic spectrum. Key initiatives focus on the following:

- Women in Clinical Trials and Sex Analyses
- Research into Sex Differences
- Pregnancy
- Education and Training of Health Professionals
- Outreach and Consumer Education

These achievements and others are described below.

#### ***Women in Clinical Trials and Sex Analyses***

#### ***Title IX. The Food and Drug Administration Safety and Innovation Act Section 907 Action Plan***

Section 907 of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA) directed the FDA to publish and provide to Congress an action plan outlining "recommendations...to improve the completeness and quality of analyses of data on demographic subgroups in summaries of product safety and effectiveness data and in labeling; [and] on the inclusion of such data, or the lack of availability of such data, in

labeling; and to improve the public availability of such data to patients, healthcare providers, and researchers” and to indicate the applicability of these recommendations to the types of medical products addressed in section 907. The FDA released the *Action Plan to Enhance the Collection and Availability of Subgroup Data* in August 2014, which outlined 27 specific actions the Agency plans to implement in three priority areas:

1. Quality: Improve the completeness and quality of demographic subgroup data collection, reporting, and analysis.
2. Participation: Identify barriers to subgroup enrollment in clinical trials and employ strategies to encourage greater participation.
3. Transparency: Make demographic subgroup data more available and transparent.

#### ***FDA FDASIA Section 907 Action Plan Activities***

- On February 29, 2016, the Agency held a public meeting, “Progress on Enhancing the Collection, Analysis and Availability of Demographic Subgroup Data”, to present the FDA’s progress in implementing the FDASIA 907 Action Plan and to receive feedback and recommendations from stakeholder groups.
- In June 2016, FDA issued the draft guidance, “Evaluation and Reporting of Race and Ethnicity Data in Medical Device Clinical Studies.” Also undergoing an update is the 2005 “Guidance for Industry Collection of Race and Ethnicity Data in Clinical Trials.”
- To meet the FDASIA section 907 Action Plan’s transparency priority objectives, the FDA continued to publish Drug Trails Snapshots to provide important demographic participation information for clinical trials supporting FDA-approved drugs and biologics. The Snapshots highlight differences in benefits and side effects among sex, race, and age groups.

#### ***OWH Implementation of the FDASIA Section 907 Action Plan***

- ***Women’s Health Research Roadmap***

In January 2016, the FDA OWH released the *Women’s Health Research Roadmap* to provide a strategic plan for addressing research in seven priority areas that are important to FDA regulatory decision making on products impacting the health of women. The Roadmap aims to align women’s health research priorities and leverage resources across the agency while remaining flexible enough to respond to emerging issues. Implementation of the road map is currently ongoing. The *Roadmap* has already been used to guide intramural grants funding processes during FY16 and FY17.

- ***Diverse Women in Clinical Trials Campaign***

FDA OWH launched the *Diverse Women in Clinical Trials* Initiative in collaboration with NIH’s Office of Research on Women’s Health to raise awareness of the importance of the participation of diverse women in clinical trials and to share best practices about clinical research design, recruitment, and subpopulation analyses. The initiative includes three main components: 1) an awareness campaign, 2) scientific webinars and

workshops, and 3) tools for researchers and health professionals. More information on the campaign is provided below under *Outreach and Education*.

- ***Demographics Project***

The FDA OWH is conducting a study to assess the demographics of study participants and the conduct of sex analyses for clinical trials for drugs and biologics approved by the FDA from January 2013 to December 2015. This project examines the participation of women and ethnic/racial groups in all phases of clinical trials as well as the analyses of the effects of sex on efficacy and safety for the FDA-approved New Drug Applications (NDAs) and Biologics License Applications (BLAs). The study was published in the *Journal of Women's Health* and the citation is as follows:

Chen A, Wright H, Itana H, Elahi M, Igun A, Soon G, Pariser A, Fadiran E.  
Demographics of Study Participants in Clinical Trials for New Molecular Entities  
and Original Therapeutic Biologics Approved by FDA CDER from 2013-2015. *J  
Womens Health (Larchmt)*. 2017 Oct 19. [Epub ahead of print].

- ***OWH-Funded Research in Support of FDASIA Section 907***

The FDA OWH-funded projects that involve the use of individual patient data meta-analysis and post-market data analyses for improving subgroup data analysis for cardiac resynchronization (CRT) and transcatheter aortic valve replacement (TAVR) device trials where women's representation in individual trials may not provide appropriate statistical power for subgroup sex analysis.

### ***Research into Sex Differences***

#### ***Intramural Research***

The FDA OWH has established a strategic priority to support research that informs the FDA's regulatory decision-making regarding the safety, effectiveness, or impact of FDA-regulated products for women. In 2015, FDA OWH's Intramural Science Program funded 20 new research projects and continued 38 existing research projects that addressed topics such as sex-based differences in drug-induced heart arrhythmias, digital breast imaging, and toxic shock syndrome. Similarly in 2016, the FDA OWH's Intramural Science Program funded 21 new research projects and continued 45 existing research projects that addressed topics in the areas of assessment of pro-arrhythmias risk in drug therapies; characterizing key mechanical characteristics of surgical meshes used for pelvic organ prolapse repair and treatment of urinary stress syndrome; effects of gender differences in adverse events for integrated fixation spinal implants; and assessment of placental transmission of Zika virus.

From March 2015–September 2016, several articles were produced as a result of the FDA OWH-funded sex differences research. Examples follow.

- Skeletal fragility in post-menopausal women is an important public health issue. The FDA OWH has been funding a project on the effects of gender differences in

adverse events for integrated fixation spinal implants and the interaction between spinal implants and bone quality in women. A publication from this project titled *“Impact of Screw Location and Endplate Preparation on Pullout Strength for Anterior Plates and Integrated Fixation Cages published in The Spine Journal, 15 (11), 2425-2432* found that screw fixation for this spinal device is lower in females. This research finding is useful for industry and regulators in identifying the patient population that can benefit from this class of devices.

- FDA OWH published an overview of the regulatory impact of OWH-funded research projects from 2004 to 2014. The citation for this publication is as follows:

Merina Elahi, Noha Eshera, Nkosazana Bambata, et al. *The Food and Drug Administration Office of Women’s Health: Impact of Science on Regulatory Policy: An Update*. J Women's Health 2016; 25(3):222-234.

### ***Investigation of Inclusion of Women in Cardiovascular Drug Trials***

The FDA OWH spearheaded an effort with the FDA Center for Drug Evaluation and Research to assess the participation of women in clinical trials for drugs for cardiovascular disease. This analysis evaluated 35 drugs approved by the FDA for indications in 6 cardiovascular disease areas between 2005 and 2015. The representation of women in drug trials compared to their representation in the corresponding disease population was evaluated. Where available, screening data were assessed to investigate whether women were disproportionately screened out of participation in cardiovascular drug trials compared to men. Additionally, publically available data on the efficacy of cardiovascular drugs in women compared to men were assessed to discuss the Agency’s evidence base for approval of cardiovascular drugs for use by both genders. A manuscript is pending.

### ***FDA-NIH Zolpidem Project***

Many drugs exhibit sex-specific therapeutic and adverse effects. Zolpidem (i.e. Ambien®) is a drug that is indicated for the treatment of insomnia, characterized by difficulties with sleep initiation. The FDA recommends administering zolpidem at a lower initial dose in females because side effects were more frequent and severe than those seen in males. The pharmacokinetics (PK) of zolpidem is affected by sex based on the results from studies indicating that women clear zolpidem from the body at a lower rate than men<sup>16</sup>. Because of this slower clearance, women experience a higher incidence of motor impairment and/or cognitive performance compared to men. However, because the mechanism for the PK sex differences is poorly understood, the FDA OWH is collaborating with NIH NCI to better understand how zolpidem pharmacokinetics are influenced by sex. A manuscript from this collaboration entitled *“Alcohol and Aldehyde Dehydrogenases Contribute to Sex-Related Differences in Clearance of Zolpidem in Rats”* has been

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<sup>16</sup> *Pharmacol.* 2016; 7:260. doi: 10.3389/fphar.2016.00260.

published in *Front*. A human study is currently under discussion between NIH and the FDA to further this research.

### ***New Publication on Sex Differences Drug Pharmacokinetics***

The FDA OWH, in collaboration with other FDA scientists, authored a chapter in *Medicines for Women* (2015) a clinical textbook dedicated to the health of women. The chapter titled “*Effects of Sex Differences in the Pharmacokinetics of Drugs and Their Impact on the Safety of Medicines in Women*” provides a comprehensive understanding of sex differences in drug pharmacokinetics and of the resulting impacts on drug safety for women.

### ***FDA Workshop on the Influence of Sex on Response to Drugs and Devices***

In May 2016, the FDA OWH presented a half-day workshop to 250 health researchers at The Organization for the Study of Sex Differences (OSSD) Tenth Annual Meeting. This workshop, “Variability in Response to Drugs and Devices: Influence of Sex,” discussed important examples of sex differences in response to drugs and devices; the efforts of the FDA to understand these sex differences; and the endeavors undertaken by the FDA to evaluate and communicate sex differences in response to drugs and devices.

## ***PREGNANCY***

More than 60 percent of women are prescribed medicines during pregnancy for chronic illnesses, such as diabetes, hypertension, and depression, or for conditions that arise during pregnancy. Yet very few drugs are approved for use during pregnancy and many drug labels have little pregnancy related data to help the physicians to make prescribing decisions.

### ***Research***

The FDA OWH funded projects related to pregnancy and the safe use of medications during pregnancy. Examples include the following:

- A project titled “Population-Based Computational Framework for Assessing Xenobiotic Disposition and Interaction Effects in Pregnant Women” involves the development of computational framework for risk assessment using a quantitative data-driven approach to guide regulatory decisions in pregnant women. A manuscript titled “*Quantitative global sensitivity analysis of a biologically based dose-response pregnancy model for the thyroid endocrine system*” by Lument et al in *Front Pharmacol.* 2015; 6: 107. doi: 10.3389/fphar.2015.00107” demonstrated the application of large computational models developed for risk assessment in pregnant women.
- Treating the pregnant patient: pharmacokinetic and mechanistic studies of antiviral Immune Globulin Intravenous (IGIV) preparations at different stages of gestation in an animal model of pregnancy

- Assessment of placental transmission of Zika virus Glycoprotein E Immunogen
- Modulatory effects of progesterone on maternal immunity and their implications in pregnancy-associated susceptibility to avian influenza infections
- Effect of procoagulant impurity on coagulation in plasma from pregnant women

### ***Pregnancy Exposure Registries***

Pregnancy exposure registries collect data on the effects of approved drugs that are prescribed to and used by pregnant women. The pregnancy registries enroll pregnant women who have already been prescribed the drug for therapeutic purposes by their physician. In an effort to increase awareness on availability of pregnancy registry information, FDA OWH launched an updated Pregnancy Exposure Registries web portal to connect health professionals and pregnant women to active registries for over 60 drugs and medical conditions. Currently, there are approximately 100 registries listed on the webpage. The new site features a sortable and searchable list of registries, information for women, and patient education and outreach tools for health professionals.

### ***Birth Control Guide***

In 2016 FDA OWH released a new list of all FDA-approved contraceptive methods (medications and medical devices) that was posted online and distributed throughout the U.S. and Puerto Rico to provide consumers and health care providers with information describing each method and its effectiveness rate.

### ***Resources for You and Your Baby: Consumer Education Initiative***

To educate women about medication use during pregnancy, FDA OWH partnered with text4baby, MotherToBaby (OTIS) and FDA's Center for Food Safety and Nutrition to conduct a pregnancy promotion that disseminated over 189,000 publications in FY16 and 309,650 publications in FY15 to health professionals, WIC programs, state and local service providers, and other community based organizations. In October 2016, OWH also released a new medicine and pregnancy fact sheet and webpage available in English and Spanish.

### ***Educating Health Professionals about Pregnancy and Lactation Labeling Rule***

FDA OWH partnered with FDA's Center for Drug Evaluation and Research Division of Pediatric and Maternal Health (DPMH) to conduct outreach to educate health professionals about the "Pregnancy and Lactation Labeling Rule" (Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling). The PLLR requires changes to the content and format for information presented in prescription drug labeling in the Physician Labeling Rule (PLR) format to assist health care providers in assessing benefit versus risk and in subsequent counseling of pregnant women and nursing mothers who need to take

medication. FDA OWH conducted outreach exhibits with DPMH to educate physicians, nurses, and nurse practitioners about the labeling changes that went into effect in June 2015.

### ***Education and Training of Health Professionals***

#### ***Diverse Women in Clinical Trials Webinar Series in conjunction with The Association of Clinical Research Professionals (ACRP)***

FDA OWH developed two, hour-long continuing education-accredited webinars on the topic of “Diverse Women in Clinical Trials” to advance the mission of increasing diversity in clinical trials by providing clinical research professionals with proven strategies for recruiting and retaining diverse women in research. The webinars were developed with guidance from leading academic experts in clinical trial recruitment of diverse populations. Additionally, FDA OWH coordinated the development of an hour-long continuing education-accredited webinar entitled “FDA BIMO Compliance and Enforcement of Drugs and Devices” to empower clinical research professionals with best practices for preparing for FDA inspections. All three webinars will be available for continuing education credit and viewing online for one year. All employees of the Department of Health and Human Services may access these materials at no cost.

- *“Diverse Women in Clinical Trials Part I: Planning for Diversity,”* presented by Aisha Langford, PhD, MPH, was broadcast Nov. 1<sup>st</sup> 12-1 PM EDT and will be available through October 31, 2017.
- *“Diverse Women in Clinical Trials Part II: Recruitment and Retention,”* presented by Carol Horowitz, MD, MPH, was broadcast Nov. 9<sup>th</sup> 12-1 PM EDT and will be available through November 8, 2017.
- *“FDA BIMO Compliance and Enforcement of Drugs and Devices,”* presented by David Burrow, PharmD, JD, and CDR Tamika Allen, MS, RN, was broadcast on Nov. 16<sup>th</sup> from 12-1 PM, EDT, and it will be available through November 15, 2017.

#### ***OWH Scientific Speaker Series: Exploring Sex and Gender***

FDA OWH established a new CE lecture series for FDA reviewers to provide the latest evidence about sex differences in disease presentation, treatment, and outcomes. Launched in March 2016, the series features scientific developments and regulatory best practices in sex and gender-specific women’s health. Several lectures in this series have been accredited for continuing education for the medical, nursing, and pharmacy professions. Past Scientific Speaker lectures include “Sex Differences in CVD and Stroke” (March 1, 2016), “Sex and Gender: Affecting Scientific Outcomes, Deriving Clinical Value” (July 19, 2016), and “Sex Considerations in the FDA Drug Review Pipeline: The Where, When, and How” (November 1, 2016”). On December 6, 2016, Dr. Karen Parker, Director of the Sexual and Gender Minority Research Office at the National Institutes of Health, presented “Advancing Transgender Health: Closing the



Gaps in Research, Clinical Care, and Public Health.” This lecture was open to all employees of the Department of Health and Human Services.

### ***FDA/NIH Science of Sex and Gender in Human Health Online Series***

- Developed by the National Institutes of Health (NIH) Office of Research on Women’s Health (ORWH), in collaboration with FDA OWH, the online series is offered free of charge, and provides continuing education credit for medicine (CME), nursing (CNE), and pharmacy (CPE) on sex differences.
- The fourth course currently under development will focus on major diseases impacting women such as cardiovascular, neurological, pulmonary and infectious diseases. A 2017 completion is anticipated.
- New publication: *Jennifer L. Plank-Bazinet, Annie Sampson, Leah R. Miller, et al. The Science of Sex and Gender in Human Health: Online Courses to Create a Foundation for Sex and Gender Accountability in Biomedical Research and Treatment. Biology of Sex Differences* 2016, 7(Suppl 1):47. DOI 10.1186/s13293-016-0100-z.

### ***Presentation: National Conference on Women’s Health Research***

The 2016 National Conference on Women’s Health research was organized by the Center for Women’s Health Research at the Anschutz Medical Campus of the University of Colorado and focused on the theme “Sex Differences Across the Lifespan: A Focus on Metabolism. The FDA OWH presented “FDA Commitment for Study of Sex Differences in Drug Development: Update for 2016,” which outlined developments in regulatory science and policy pertaining to the inclusion of women as subjects in biomedical research and the evaluation of sex differences.

### ***Outreach and Consumer Education***

#### ***Diverse Women in Clinical Trials Campaign***

The FDA OWH launched the Diverse Women in Clinical Trials awareness campaign in January 2016. FDA OWH conducted digital and stakeholder outreach throughout the U.S. and Puerto Rico targeting older women, women from racial and ethnic minority groups, women living with disabilities and women with select health conditions (Alzheimer’s disease, Cardiovascular Disease, Diabetes, Depression/ Anxiety, HIV, and Lung diseases). The ongoing campaign has mobilized nearly 300 individual and organizational supporters and disseminated 69,000 consumer fact sheets/ posters and 500 partner toolkits in English and Spanish. The FDA OWH also launched a new webpage: [www.fda.gov/womeninclinicaltrials](http://www.fda.gov/womeninclinicaltrials)

#### ***Women in Clinical Trials Workshop with NIH***

The FDA OWH partnered with the NIH's Office of Research on Women's Health to sponsor the *Meet the Faces of Clinical Research: Beyond Inclusion* workshop during National Women's Health Week in May 2015. The panel featured women who have participated in NIH clinical research and investigators who helped to raise awareness about the importance of women and diversity in clinical research and provided personal perspectives on research participation.

### ***Stakeholder Workshop for Nursing Organizations and Other Health Associations.***

The FDA OWH held two stakeholder workshops in November 2015 to promote dialogue on the participation of diverse women in clinical trials.

### ***College Women's Health Campaign: Ace Your Health College Toolkit***

The FDA OWH continued the Ace Your Health campaign to provide college women with access to FDA health and safety information. More than 160 colleges and universities distributed the FDA OWH's educational materials at their campus health centers and health programs. In August 2016, the FDA OWH released a new college women's health toolkit that includes social media messages, flyers, and other tools that can be used by college health professionals and peer health educators. In March-April 2016, FDA OWH completed a month long Spring Break promotion encouraging college women to make smart choices regarding tattoos, contact lens care, and medication use during Spring break travel. In 2015, the FDA OWH released two new medication safety posters targeting college students. The materials are available at [www.fda.gov/collegewomen](http://www.fda.gov/collegewomen)

### ***Pink Ribbon Sunday Program***

The Pink Ribbon Sunday Mammography Awareness Program works to reduce breast cancer health disparities by providing community leaders with free, mammography educational materials from FDA that they can use to inform African American and Hispanic women about early detection through mammography. The program also educates women about the FDA's role in regulating mammography facilities and setting mammography quality standards. The program disseminated over 506,000 free outreach planning guides, mammography fact sheets in English and Spanish, and mammography outreach cards that direct women to the FDA website where they can search for certified mammography facilities in their area.

- **Mammography Outreach with African American Churches.** In 2016, FDA OWH established a partnership with the Balm in Gilead, Inc. to conduct a Pink Ribbon Sunday promotion with African American churches throughout the U.S. Outreach activities were held on the fourth Sunday in October which was deemed Pink Ribbon Sunday.
- **Mammography Education for Women Living with a Disability.** The Pink Ribbon Sunday program was expanded to include outreach to women living with disabilities.

In October 2016, FDA OWH partnered with the American Association on Health and Disability and the Association of University Centers on Disabilities to disseminate FDA mammography information to women living with a disability. FDA OWH joined AAHD and AUCD for webinar entitled *Health Promotion and Women Living with a Disability* that was hosted by the Friends of NCBDDD.

### ***Take Time to Care Program***

In alignment with FDA's Strategic Priority to promote better informed decisions about the use of FDA-regulated products, FDA OWH conducted outreach and education initiatives to provide print and digital resources to health professionals and consumers including special populations of women such as pregnant women, caregivers, LGBT individuals, minority women, and women with limited English proficiency. FDA OWH disseminated 5.9 million easy-to-read consumer health publications to communicate product safety information and general medication safety tips to women. FDA OWH also disseminated email and social media alerts to inform health care professionals and patients about FDA drug safety communications, product approvals and withdrawals, product labeling changes, and other regulatory information related to sex differences and the treatment of health conditions impacting women.

### ***Safe Medication Use Project for Women with Disabilities***

FDA OWH continued to conduct outreach to disability service providers, health professionals, caregivers, and consumers to disseminate materials promoting the safe use of over-the-counter and prescription medications. FDA OWH made Braille versions of the Use Medicines Wisely brochure available in bulk free of charge through the Federal Citizens Information Center/ USA.gov. FDA OWH also continued to promote an online adapted version of the Use Medicines Wisely brochure for women with intellectual and developmental disabilities.

### ***Heart Health for Women***

- In support of 2015 and 2016 Wear Red Day and American Heart Month, FDA OWH collaborated with USA.gov to disseminate 10,000 Heart Health kits for women. The kits included FDA materials on heart health, sodium consumption, and smoking cessation. The kits also included a flyer from HHS OWH on the signs of heart attack in women from their *Make the Call, Don't Miss a Beat* campaign.
- The FDA OWH also released new foreign language consumer publications to educate women about heart disease in women. Since 2015, the Heart Health for Women fact sheet has been made available on the FDA website in Chinese, Korean, Vietnamese, and French Creole to complement the existing English and Spanish versions.

### ***Summer Safety and Zika Prevention Outreach***

The FDA OWH sponsored a summer safety publication promotion to provide women with resources to help them avoid common medication mistakes, Zika, and other injuries. Confusing sentence: The FDA OWH partnered with the CDC and the Consumer Product Safety Commission to disseminate a kit of materials on safe medication use, grilling and eating outdoors, mosquito bite prevention, pool safety and other tips for parents. The kits were distributed throughout the U.S. and Puerto Rico via the Federal Citizen Information Center/ USA.gov.

### ***Family Caregiver Outreach***

The FDA OWH launched a new Caregivers webpage that provides tips and resources for family caregivers. The resource page includes links to FDA information for caregivers of the elderly, individuals with disabilities, and young children.

### ***Healthy Aging for Women***

The FDA OWH launched a new webpage with healthy aging tips for women over 40. The webpage includes tips and links to FDA and other HHS resources in five areas: 1) healthy eating; 2) avoiding common medication mistakes; 3) managing health conditions; 4) getting recommended health screenings; and 5) being active. The FDA OWH also partnered with the NIH National Institute on Aging to disseminate FDA and NIH materials on safe medication use, health scams, food safety for older adults, and tips on communicating with a healthcare provider. The kits were made available in English and Spanish throughout the U.S.

### ***CCWH Membership***

The FDA's Office of Women's Health is a member of the HHS Coordinating Committee on Women's Health.

## **Health Resources and Services Administration (HRSA)**

### **Office of Women's Health**

#### ***Establishment of an Office***

HRSA fulfilled the requirement set forth in section 713(a) of the Social Security Act, as amended by section 3509 of the Affordable Care Act, which required HRSA to establish an Office of Women's Health within the Office of the Administrator. HRSA previously established an Office of Women's Health (OWH) in 2000 under the Maternal and Child Health Bureau. In October 2011, an amended Statement of Organization, Functions, and Delegations of Authority was published in the Federal Register (Volume 76, No. 202, pp. 64953-64954) that transferred the function of OWH from the Maternal and Child Health Bureau to the Office of the Administrator, as required. HRSA will continue to administer this section of the Affordable Care Act.

#### ***Report on Current Level of Activities***

The mission of HRSA OWH is to improve the health, wellness, and safety of women and girls across the lifespan through policy, programming, outreach and education. HRSA OWH provides ongoing expertise, updates, and reports on a variety of collaborative women's health-related activities to the Office of the Administrator, as required under section 713(b)(1) of the Social Security Act, including the following:

- integration of trauma-informed approaches, and violence prevention education and awareness among HRSA grantees and other stakeholders;
- integration of violence and trauma as social determinants of health into HRSA funding opportunity announcements; and
- outreach and educational information on the HRSA-supported women's preventive services guidelines to consumers and providers.

HRSA OWH and the Bureau of Primary Health Care collaborated on the second phase of a pilot project with the Administration for Children and Families (ACF) to support Intimate Partner Violence (IPV) screening and counseling in ten health centers, including dually funded Ryan White sites. This collaboration took place between September 2015 and August 2016. A health center centric virtual toolkit was developed and distributed to health centers to assist them with developing a comprehensive and sustainable response to IPV, in collaboration with community-based social service organizations. See <http://ipvhealthpartners.org/>

HRSA OWH is leading an agency-wide Strategy to Address Intimate Partner Violence (IPV). Aligned with HRSA goals to strengthen the health workforce and build healthy communities, as well as the Department's health care delivery reform initiative, this comprehensive project will address the public health challenge of IPV. The development and completion of a formal strategic framework document took place in the fall of 2017.

### ***Women's Health-Related Goals and Objectives***

HRSA's mission is to improve health and achieve health equity through access to quality services, a skilled health workforce, and innovative programs. HRSA OWH serves a crosscutting role in support of this mission through coordination, collaboration, information sharing, and program support activities to improve women's health across the lifespan.

HRSA OWH collaborated with the Office of Human Resources to develop an agency Workplace Violence Prevention Training to support the President's April 18, 2012 Memorandum to Heads of Executive Departments and Agencies. In 2015, 91 percent of HRSA staff completed annual violence prevention in the workplace training as part of the agency's policy to address violence prevention in the federal workforce.

### ***Office of Administrative Management***

In collaboration with Federal Occupational Health (FOH), HRSA hosted seminars and events on topics such as domestic violence, elder care, heart health, women's leadership, balancing work and personal life, breast cancer awareness, stress management, and women's cardiac health awareness. FOH offers a dedicated space for lactating mothers returning to the workplace.

### ***Maternal and Child Health Bureau (MCHB)***

#### ***Women's Preventive Services Initiative***

Through a five-year cooperative agreement funded by HRSA's MCHB beginning in March 2016, the American Congress of Obstetricians and Gynecologists (ACOG) is leading the effort to update recommendations for women's preventive healthcare services by creating a coalition of health professional organizations with expertise in women's health across the lifespan to leverage existing partnerships, and facilitate the inclusion of a broad range of expertise. In August 2016 and 2017, ACOG provided updated guidelines that were accepted by the HRSA Administrator.

### ***Title V Block Grant Transformation***

As the nation's public health system for mothers, children, and families, Title V plays an important role in improving women's health before, during, and beyond pregnancy. In FY 2016, MCHB provided continued leadership in the transformation of the Title V MCH Block Grant.

The Title V Block Grant transformation includes a new performance measurement framework with a total of 15 National Performance Measures (NPMs). Each NPM is associated with one of six population health domains. The Maternal/Women's Health domain reflects a renewed emphasis on women's health as a critical factor in improving maternal outcomes. Within this domain, 50 of 59 States and jurisdictions have chosen to address NPM 1, "Increase the number of women who have a preventive medical visit," as part of their State Action Plans for improving MCH outcomes. State strategies related to

NPM 1 include improving access to preconception and interconception care, improving the content and quality of the well woman visit, reducing unintended pregnancies, addressing substance use disorders, and reducing postpartum depression.

### ***Healthy Start Program***

The Healthy Start (HS) Program works to improve pregnancy outcomes. This program targets communities with high rates of infant mortality and poor birth outcomes to improve women's health before, during, and beyond pregnancy. HS staff work with women and their families to empower them to develop health plans. Healthy Start funds 100 competitive grants that reach 200 counties in 37 States and the District of Columbia. In FY 2015, the HS program served over 67,000 clients including more than 26,000 pregnant women. In FY 2016, HRSA MCHB continued to provide a greater focus on improving women's health, perinatal quality and safety, family resilience, collective impact, and program accountability.

HRSA MCHB provided grant funding for the Healthy Start (HS) EPIC Center to assist HS grantees in achieving program goals. The project period is June 1, 2014 – May 31, 2019. The HS EPIC Center helps to strengthen all HS staff skills to implement evidence-based practices in maternal and child health, facilitates grantee-to-grantee sharing of expertise and lessons from the field, enables grantees to conduct ongoing evaluation of activities for effectiveness, and builds program capacity to work with community partners to improve health and social service systems for women, infants, and families.

HRSA MCHB initiated a robust evaluation plan using a scientifically-rigorous design and stratified sample of respondents in Pregnancy Risk Assessment Monitoring System (PRAMS) from Healthy Start and comparison sites. MCHB also worked to ensure that Healthy Start (HS) grantees increased their reach and impact in targeted communities. Based on grantee-reported data, in 2015, HS projects reported serving 44,219 women and 24,706 children. A total of 11,500 men were also involved with project activities.

### ***National CoIIN on Infant Mortality***

In FY 2016, HRSA's MCHB supported the National CoIIN (Collaborative Improvement and Innovation Network) on Infant Mortality. The National CoIIN has accelerated collaborative improvement and innovations across the states, and catalyzed a national movement on infant mortality.

The National CoIIN is built on the successes of the Regions IV and VI CoIIN (started in 2012), which contributed to a 30 percent reduction in early elective delivery in the 13 southern states, translating to approximately 85,000 early elective deliveries averted and a 12 percent reduction in smoking during pregnancy, translating to approximately 18,000 fewer pregnant women smoking across the South.

In 2015, the CoIIN was expanded to all states and territories and focused on several areas including:

- Safe sleep (36 states)

- Smoking cessation (20 states)
- Social determinants of health (22 states)
- Preterm and early term birth (21 states)
- Preconception/Interconception Care (29 states)
- Perinatal Regionalization (14 states)

### ***Home Visiting***

HRSA's MCHB redesigned the Federal Home Visiting Program (formerly known as the Maternal, Infant, and Early Childhood Home Visiting Program) by

- revising the benchmark performance measures system to more accurately capture the performance of the grantees;
- ensuring stability in grantee funding by implementing a new funding allocation;
- clarifying policies related to caseload of family slots, grantee-led evaluation infrastructure expenses, and data collection of participants.

In FY 2016, states reported serving 160,000 parents and children, in 893 counties in all 50 states, the District of Columbia and five territories. More than 3.3 million home visits were provided between 2012 and 2016, including nearly 1 million visits in 2016 alone.

### ***Alliance for Innovation in Maternal Health***

The Alliance for Innovation in Maternal Health (AIM) is a national partnership of organizations poised to reduce severe maternal morbidity by 100,000 events and maternal mortality by 1,000 deaths by 2018. This partnership has produced seven patient safety bundles that include the following: obstetric hemorrhage; severe hypertension; safe reduction of primary Caesarean births, maternal venous thromboembolism prevention; patient, family, and staff support after a severe maternal event; prevention of surgical site infections; and maternal mental health. Ten states have enrolled in the AIM Program to date and include Florida, Illinois, Louisiana, Maryland, Michigan, Mississippi, New Jersey, North Carolina, Oklahoma, and Utah. Each of these states has selected one or two patient safety bundles for implementation. In addition, the Northern Mariana Islands and Malawi have implemented the obstetric hemorrhage patient safety bundle. According to the data submitted by the four states that were implementing the hemorrhage and hypertension bundles in 2015, there has been a decrease in the maternal morbidity rate, ranging from 8.3 to 22.1 percent, bringing the average overall rate of severe maternal morbidity to under 2 percent.

### ***Centers of Excellence in Maternal and Child Health Education***

HRSA's MCHB currently funds 13 Centers of Excellence (CoE) in Maternal and Child Health (MCH) Education. The project period is January 1, 2015 – May 31, 2020. These CoEs are located within Schools of Public Health across the country to support the training of graduate and post-graduate public health professionals. Training is provided in an interdisciplinary setting to prepare future MCH public health professionals, achieve



optimal outcomes, and to advance science, research, practice and policy. Centers of Excellence grantees include the following:

- Boston University School of Public Health
- Emory University School of Public Health
- Harvard University School of Public Health
- Johns Hopkins School of Public Health
- University of Minnesota School of Public Health
- Tulane University School of Public Health and Tropical Medicine
- University of Illinois at Chicago School of Public Health
- University of South Florida College of Public Health
- University of Washington School of Public Health

### ***Maternal and Child Health Pregnancy Related Care Research Network***

The Maternal and Child Health (MCH) Pregnancy Related Care Research Network (PRCRN) is a national research network that conducts multi-site research on critical issues affecting pregnancy-related care and maternal health across the lifespan. Funded by MCHB and previously implemented by ACOG, PRCRN is the only existing national collective of practicing obstetrician-gynecologists (OB-GYNs) recruited to participate in research studies that impact various aspects of the health of women, especially those related to the periods before, during, and after pregnancy. PRCRN also serves the pregnancy-related needs and outcomes of women by developing the skills and capacity of the nation's current and future OB-GYNs. The Network supports evidence-based practice by tracking OB-GYNs' knowledge and clinical practice through survey-based research on a wide range of clinical issues, and comparing existing practice with that supported by evidence-based guidelines through surveys to inform and evaluate ACOG's efforts to provide guidance on clinical practice. Gaps in current practice, training, knowledge among clinicians is determined through a needs assessment questionnaire for professional education. Many of the studies that assess the uptake and compliance with ACOG clinical guidelines are implemented before and after the ACOG guidance is published to provide an assessment of whether additional interventions may be required. The PRCRN disseminates evidence-based guidelines, educational resources, and peer reviewed publications based on identified gaps in uptake and deficits in practice and knowledge to advance improvements in health care for women across the lifespan. PRCRN findings are disseminated in major scholarly journals including *Obstetrics and Gynecology*, the official publication of ACOG.

### ***Intimate Partner Violence Study***

HRSA's MCHB is funding a study on IPV during pregnancy and implications for fetal growth. IPV is a significant public health problem, affecting nearly 30 percent of women in the U.S., with significant health consequences.<sup>17, 18</sup> The study involves a sample of

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17 Campbell JC, Garcia-Moreno C, Sharps P. Abuse during pregnancy in industrialized and developing countries. *Violence Against Women*. 2004;10:770-789.

18 Tjaden P, Thoennes N. Full report of the prevalence, incidence, and consequences of violence against women: Findings from the national violence against women survey. Washington, DC: US Department of Justice; 2000;181867

over 202,000 women to examine: 1) the relation between timing of IPV during pregnancy (i.e., IPV in the year prior to pregnancy, during pregnancy, both time periods) with small for gestational age (SGA); 2) the relation between timing of IPV during pregnancy and SGA in subgroups of racial and ethnic minorities and mothers with concurrent depressive symptoms; and 3) adequacy of prenatal care moderates the association between IPV and SGA.

### ***Study Analyzing the Policy Process to Improve Comprehensive and Coordinated Systems for Breastfeeding Equity***

HRSA's MCHB is supporting a policy study focused on improving comprehensive and coordinated systems for breastfeeding equity. Policymakers will be able to apply the results of this study to improve policies, practices, and environments as part of comprehensive approaches to increasing breastfeeding rates and reducing disparities.

### ***Advisory Committee on Infant Mortality (ACIM)***

ACIM advises the Secretary of Health and Human Services on Department activities and programs that are directed at reducing infant mortality and improving the health status of pregnant women and infants. The Committee represents a public and private partnership at the highest level to provide guidance, and to focus attention on the policies and resources required to address the reduction of infant mortality.

ACIM submits recommendations and reports to the Secretary on infant mortality, including implementation of the Healthy Start program and infant mortality objectives from Healthy People 2020: National Health Promotion and Disease Prevention Objectives. In FY 15, ACIM's charter was renewed through September 30, 2019.

### ***Maternal Child Health Equity Blueprint***

The overarching vision of the "MCH Health Equity Blueprint" is improvement of health equity and elimination of health disparities for the MCH population. It includes strategies on workforce development, performance measurement, and program guidance.

### ***HIV/AIDS Bureau***

HRSA's HIV/AIDS Bureau (HAB) funded the "Enhancing Engagement and Retention in Quality HIV Care for Transgender Women of Color" initiative to promote the development and evaluation of innovative interventions to improve timely entry, engagement, and retention in quality HIV care for transgender women of color living with HIV. Nine demonstration sites and an Evaluation Center received funding for five years (FY2012-FY2016). The Transgender Evaluation and Technical Assistance Center (TETAC) and some of the demonstration sites are currently in a no-cost extension year of funding to complete analysis of the data collected on health outcomes, intervention dosage, client care engagement factors, and cost indicators. The TETAC is also coordinating the publication of the initiative's findings and lessons learned, working in collaboration with the demonstration sites.

Two interventions of the HRSA’s HAB initiative, “Dissemination of Evidence-Informed Interventions to Improve Health Outcomes along the HIV Care Continuum,” are targeted to HIV-positive women of color, and focus on effective strategies to improve linkage and enhance retention of this population in HIV primary health care. This 5-year (FY 2015-FY2019) initiative will replicate, evaluate, and disseminate four adapted linkage and retention interventions from prior initiatives and the Secretary's Minority AIDS Initiative Fund. The goal is to develop best practices for replication of four evidence-informed interventions for linking and retaining newly-diagnosed populations in HIV primary care. The interventions will be evaluated utilizing an implementation science approach to reflect the dynamics of the HIV epidemic under a rapidly changing health care environment.

HRSA’s HAB also has published several data reports and data visualizations that are pertinent women and girls. In December 2015, HAB published its first client-level data report which is located at <http://hab.hrsa.gov/data/data-reports>. Data presented include demographic and socioeconomic variables (e.g., poverty level, health care coverage, housing status). In 2016, several infographics/fact sheets were also released and can be viewed at <http://hab.hrsa.gov/publications/hivaids-bureau-fact-sheets>.

HRSA’s HAB continues to collaborate with the OWH in the development of innovative HIV service delivery models through demonstration projects, including the following.

- The “Use of Social Media to Improve Engagement, Retention, and Health Outcomes along the HIV Care Continuum” (FY2015-FY2019) initiative promotes the development and evaluation of mobile health applications and social media tools to identify, link, and retain HIV-positive, underserved, underinsured, hard-to-reach youth and young adults, including women, between the ages of 13-34.
- The Special Projects of National Significance (SPNS) “Culturally-Appropriate Interventions of Outreach, Access, and Retention among Latino(a) Populations” (FY2013-FY2018) initiative promotes development and evaluation of innovative models of access to care for HIV-positive populations, including Spanish-speaking cisgender and transgender women. The initiative funds ten demonstration sites that are implementing and evaluating innovative strategies to link HIV positive Latinos to care and improve timely entry and retention in care. This initiative assesses the effectiveness of transnationalism, a theoretical approach that transcends Spanish language identification of Latino populations with deeper cultural factors related to country or place of ancestral origin that may affect early entry and retention in HIV care and treatment.

HRSA’s HAB funded– regional AIDS Education and Training Centers (AETC) Program partnered with local agencies in 2016 to conduct education and training on topics related to HIV/AIDS care and treatment for women. This included the annual South Central AETC Women and HIV International Clinical Conference Tour, with the training focusing on women of color and pre-exposure prophylaxis (PrEP) in Washington, D.C., as well as activities to observe National Black HIV Awareness Day, and National Women and Girls HIV Awareness Day.

HRSA's HAB is funding a project that focuses on the integration of workforce capacity building initiatives of relevance to women's health. The SPNS "System-level Workforce Capacity Building for Integrating HIV Primary Care in Community Health Care Settings" (FY2014-FY2018) initiative funds 15 demonstration sites to promote the design, implementation, and evaluation of innovative strategies to increase organizations' workforce capacity in the delivery of HIV care. Strategies include Practice Transformative Models for the delivery of HIV treatment and comprehensive care services to better respond to the changing health care landscape marked by shortages of HIV primary care physicians and the increasing demand for access to quality HIV services.

HRSA's HAB, in collaboration with the Office of the Assistant Secretary for Planning and Evaluation (ASPE), convened a one-day in-person meeting of a 10-member technical expert panel in April 2015. The purpose of this meeting was to discuss models of care and strategies to improve care for women living with HIV who are served by the Ryan White HIV/AIDS Program. The panel discussion was framed around 5 main themes – barriers to care and gaps in care; gender-responsive care as a system-level strategy; trauma-informed care and behavioral health integration as a system-level strategy; provider-level strategies; and patient-level strategies. As a result, HAB produced two publications.

<http://hab.hrsa.gov/sites/default/files/hab/Publications/factsheets/improvingcarewomenhiv.pdf> and  
<http://hab.hrsa.gov/sites/default/files/hab/Publications/factsheets/traumahivconsultation.pdf>

HRSA's HAB released a Secretary's Minority AIDS Initiative funded Federal Opportunity Announcement in May 2016. Entitled "Leadership Training for People of Color Living with HIV Program", this funding supports the development of leadership training programs for people of color, and transgender women of all ages living with HIV. This multiyear project (2016-2019) will enable full, active and engaged participation on planning bodies, medical and support care teams, boards of directors, and other mobilization efforts to address the goals of the *National HIV/AIDS Strategy: Updated to 2020*. This new project was awarded to the National Minority AIDS Council in September 2016 and leadership training activities commenced in October 2016. During Year 1, 31 percent of all participants were women of color, and 18 percent of all participants were transgender women of color.

### ***Bureau of Health Workforce (BHW)***

HRSA's Bureau of Health Workforce (BHW) supported a number of diverse programs that supported women in health professions training including the following.

- In academic year 2014-2015, HRSA-supported 128 nurse-midwife students through the Advanced Education Nursing Traineeship, providing students with an average award of \$2,500.00.
- In academic year 2014-2015, 14 HRSA-supported Area Health Education Centers provided a total of 31 continuing education courses related to women's health on topics such as maternal and child health, breastfeeding, prenatal health, menopause, and sexual assault, reaching 811 practicing professionals.
- In academic year 2014-2015, HRSA-supported Teaching Health Centers Graduate Medical Education grantees funded three OB-GYN residency programs, resulting in the education of 13 OB-GYN residents.
- In academic year 2015-2016, HRSA-supported Regional Public Health Training Centers provided 54 different courses related to women's health on topics such as maternal and child health, breast feeding, contraception, cancer prevention and sexual assault.
- HRSA's National Health Service Corps (NHSC) and NURSE Corps Programs allow up to 35 days of maternity/paternity/adoption leave per service year for purposes of service credit computation for participants without incurring any extension of their service obligation. HRSA OWH also partnered with the NHSC around *National Women's Health Week* activities.
- In FY 2016, 18 students in the NHSC pipeline were training to serve as certified nurse midwives; 80 medical students were training as obstetricians/gynecologists, and 98 as family practice physicians with a specialty in obstetrics; and 3 nurse practitioner students were planning to specialize in women's health.
- In Fiscal Year 2016, there were 158 obstetricians/gynecologists, 98 family practice physicians with a specialty in obstetrics, 83 nurse practitioners and physician assistants specializing in women's health, and 184 certified nurse midwives providing services at NHSC approved sites.
- In Fiscal Year 2016, there were 12 nurse midwives in the NURSE Corps providing services at facilities with a critical shortage of nurses.

### ***Office of Regional Operations (ORO)***

HRSA's Region I Office collaborated with the Region I HHS Office on Women's Health to deliver the Women and Opioids Invitational Symposium on October 24-25, 2016 in Boston, MA. The meeting included facilitated state-specific break-out sessions with

resource experts on women and opioid addiction to allow states to identify key areas for improvement and action steps for change.

HRSA's Region II Chief Medical Officer in San Juan led the Agency's Zika efforts in Puerto Rico in collaboration with other HHS staff and key stakeholders. Activities included meetings with elected officials, the HHS Secretary and the CDC Director addressed the needs of women of reproductive age and pregnant women infected with the Zika virus. Additional efforts focused on CDC Foundation-sponsored trainings for health care providers and other staff on the use of Long Acting Reversible Contraceptives (LARCs).

HRSA's Region VIII Office is working with HHS Regional partners and with the Rocky Mountain Tribal Leaders Council in Billings, MT to develop and implement a Perinatal Drug Exposure pilot initiative to address the drug exposure to pregnant women on one reservation for a period of 18 months. The goal is to integrate HHS programs in a culturally competent manner to address the crisis of perinatal drug exposure. The project will focus on the two areas of prevention and rehabilitation for both mother and baby, and include a model that has been successful on other reservations, with proven outcomes or with interventions that have an evidence base, that is also culturally responsive. Over the course of the pilot, outcomes and lessons learned will be summarized as a possible model for future approaches to tribal funding.

### ***Federal Office of Rural Health Policy***

The Federal Office of Rural Health Policy (FORHP) funds eight rural health research centers that conduct policy-focused health services research on a wide variety of topics. In this work, researchers are encouraged to examine potential health disparities by sex and gender whenever possible. One of the funded projects was a research study conducted through FY2017 to examine the relationship between obstetric unit closures, maternity care, and outcomes of childbirth in rural U.S. counties, including prenatal care, distance to delivery hospital, out-of-hospital births, and infant health outcomes.

### ***Women's Health Projects***

HRSA OWH continued to coordinate and engage in strategic planning and activities with HRSA Bureaus and Offices as well as other federal partners on activities that relate to health care provider training, health service delivery, research, and demonstration projects for issues of particular concern to underserved women to fulfill the requirements in section 713(b)(3) of the Social Security Act. Examples follow:

- The development of a library of short videos in FY16 that featured HRSA female staff sharing in their own words how HRSA programs deliver for women's health.  
<http://bit.ly/2b3RKfH>

- Coordination of National Women’s Health Week activities in 2015 and 2016 that engaged all HRSA Bureaus and Offices to promote women’s health across the lifespan. A set of women’s health-related infographics featured data from HRSA programs. <http://www.hrsa.gov/about/organization/bureaus/owh/nwhw-infographic.pdf>
- Poster presentation at the 2016 HRSA Research and Innovation Symposium on “Improving Health Outcomes through Violence Prevention: Promising Strategies from Community Health Centers”.
- A 2015 Domestic Violence Awareness Month webinar, “Improving Health Outcomes through Violence Prevention: Promising Strategies from Community Health Centers” that highlighted the integration of screening and counseling for IPV at three HRSA-funded health centers in Washington, D.C., Alabama, and West Virginia.
- Two 2016 blog posts on womenshealth.gov that focused on domestic violence and sexual assault. HRSA funded health centers were highlighted.  
<http://womenshealth.gov/blog/sexual-assault-relationships.html>  
<https://www.womenshealth.gov/blog/domestic-violence-your-health.html>
- Mentoring in FY2016 and FY2017 for more than ten students considering careers in public health and interdisciplinary health professionals training programs.

### ***Consultation with Women’s Health Professionals***

In ongoing fulfillment of section 713(b)(4), HRSA OWH consulted with non-federal organizations and consumer groups to seek and provide input on the Administration’s policy to provide culturally appropriate, comprehensive, quality primary care to all women and well as health professions programs and education training opportunities. Examples of these consultations are below.

- HRSA OWH worked with members of the Women and Trauma Federal Partners Committee to organize a national meeting “Building a Trauma-Informed Nation: Transforming the Conversation into Action” at the U.S. Department of Labor in Washington, D.C., September 29-30, 2015. The goal of this event was to bring together stakeholders and facilitate discussion around integrating trauma-informed practices across multiple fields.
- HRSA OWH engaged with other presenters at the 2015 National HIV Prevention Conference and presented an overview of the history and activities of the Interagency Federal Working Group on the Intersection of HIV/AIDS, Violence Against Women and Girls, and Gender-related Health Disparities.
- HRSA OWH engaged with other presenters at the 2016 Academy Health Research Meeting and presented a poster “Highlighting Cardiovascular

Healthcare Disparities Experienced by Women and Men in the United States (U.S.): Findings from the 2014 National Healthcare Quality and Disparities Report.”

***CCWH Membership***

HRSA OWH actively served on the HHS Coordinating Committee on Women’s Health (CCWH) as required in section 713(b)(5) of the Social Security Act.



## **National Institutes of Health (NIH)**

### **Office of Research on Women's Health**

#### ***Establishment of an Office***

The NIH Office of Research on Women's Health (NIH ORWH) was established in September 1990 within NIH's Office of the Director (OD). NIH ORWH was charged with ensuring that research conducted and supported by NIH appropriately addresses issues regarding women's health and that there is appropriate participation of women in NIH-supported clinical research, especially in clinical trials. NIH ORWH was later codified into law on June 10, 1993, in the NIH Revitalization Act of 1993 (P.L. 103-43, section 141), which amended section 486 of the Public Health Service Act (PHSA).

The NIH Reform Act of 2006 (P.L. 109-482) mandated that the NIH ORWH reside within the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), which is located within the OD of NIH. Thus, the Director of NIH ORWH reports to the Director of DPCPSI. However, the Director of NIH ORWH is not precluded from reporting to the Director of NIH. The Patient Protection and Affordable Care Act (P.L. 111-148, section 3509) amended section 486(a) of the PHSA by adding language that the Director of ORWH is a direct report to the NIH Director (as required under section 3509(c)). Section 3509(c) was the only requirement directed to NIH under section 3509.

#### ***Report on Current Level of Activities***

NIH ORWH serves as the focal point for the following:

- coordinating women's health research and research on the influence of sex and gender on health and disease at NIH and in NIH-funded research;
- advising the NIH Director on matters relating to women's health research and research on the influence of sex and gender on health and disease;
- strengthening and enhancing research related to diseases, disorders, and conditions that affect women, and research on the differences and similarities between men and women to strengthen the understanding of health issues impacting women;
- working to ensure that women and minorities are appropriately represented in research studies supported by NIH; and
- promoting recruitment, retention, re-entry, and advancement of women in biomedical careers, and supporting programs aimed at training clinician scientists in research careers in women's health research

NIH ORWH collaborates with the NIH Institutes and Centers (ICs) to increase and enhance women's health research and research on the influence of sex and gender on health and disease. NIH ORWH co-funds basic, preclinical, clinical, and translational studies through grants, contracts, and cooperative agreements. Some funding

opportunities, such as the NIH ORWH signature programs, are developed, implemented, and coordinated by NIH ORWH, with additional funding and grants management provided by the ICs. Other funding opportunities are generated by the ICs or involve investigator-initiated applications identified by IC program staff as candidates for NIH ORWH co-funding.

In accordance with the *NIH Strategic Plan for Women's Health and Sex Differences Research* (<http://orwh.od.nih.gov/research/strategic-plan/>), NIH ORWH facilitates research conducted across NIH to address women's health across the lifespan and in appropriate sociocultural contexts. For instance, NIH ORWH initiatives promote scientific excellence by reinforcing the requirement to include women, minorities, and children as appropriate in NIH clinical research, such that the results of clinical research benefit diverse populations. In addition, NIH ORWH leads the Coordinating Committee on Research on Women's Health (CCRWH), which convenes representatives from all the NIH ICs and program offices and serves as the primary conduit for collaboration and integration of research, program development, and NIH ORWH funding through the ICs.

### ***Coordinating Committee on Research on Women's Health***

Through the CCRWH, the NIH ORWH:

- Identifies research needs through gap analyses and portfolio review across NIH
- Facilitates the integration of women's health research and research on the influence on sex and gender on health and disease perspectives into NIH research
- Supports the development of methodologies related to analysis of sex/gender, race/ethnicity, and age in NIH-supported clinical studies
- Supports the development and expansion of clinical trials on diseases relevant to women
- Promotes women's health research within the IC-specific missions (Sect c. P.L. 103-43, June 10, 1993).

NIH ORWH conducts monthly meetings with the CCRWH and is in regular communication with these IC representatives regarding grants, funding opportunities, relevant publications and upcoming events, and the development and implementation of new research initiatives. Such interactions allow NIH ORWH to strategically collaborate with ICs on women's health research and research on the influence of sex and gender on health and disease. With input from the CCRWH, NIH ORWH constructs a biennial report on NIH ORWH and *NIH Support for Research on Women's Health Issues* that is approved and issued by the Advisory Committee on Research on Women's Health (ACRWH).

### ***Advisory Committee on Research on Women's Health***

ACRWH is a congressionally mandated advisory committee, required by the 1993 NIH Revitalization Act. This committee comprises physicians, scientists, and other health

professionals whose clinical practice, research specialization, or professional expertise includes a significant focus on women's health issues including research, inclusion of women and minorities in clinical research, and fostering of research careers in women's health research areas. ACRWH advises the NIH ORWH Director on appropriate research activities to be undertaken by the NIH ICs and provides recommendations to the NIH ORWH Director on relevant issues addressing women's health research and research on the influence of sex and gender on health and disease.

On Friday, April 10, 2015, the 39<sup>th</sup> meeting of the NIH ACRWH was held at NIH. Presentations included the following:

- *NIH ORWH Director's Report:* Dr. Janine Clayton, Associate Director for Women's Health; Director, Office of Research on Women's Health
- *Update on Inclusion:* Dr. Meredith Temple O'Connor, Ph.D., NIH Inclusion Policy Officer, Office of Extramural Research
- *Discussion of concept ideas for a sex-focused experimental design, methods and statistics course:* Dr. Susan Maier, Ph.D, Associate Director for Special Projects, ORWH
- *Improving Women's Heart Health by Mapping the Gender Gaps in Cardiovascular Care:* Dr. Chloe Bird of the RAND Corporation, Special Advisor to the Director, ORWH
- *Update on the ORWH workshop at the National Academy of Sciences, A National Perspective on Women's Health by ORWH epidemiologist:* Ms. Amy Mistretta, M.P.H., Epidemiologist, ORWH
- *Communications update by ORWH communications director:* Ms. Anne Rancourt, Communications Director, ORWH

On October 20, 2015, NIH ORWH convened the 40<sup>th</sup> meeting of the Advisory Committee on Research on Women's Health. The afternoon portion of the agenda included a celebration of science in honor of NIH ORWH's 25th anniversary. Presentations included the following:

- *NIH ORWH Director's Report:* Dr. Janine Clayton, Associate Director for Women's Health; Director, Office of Research on Women's Health
- *NIH Leadership Presentation:* Dr. Kathy L. Hudson, Ph.D., NIH Deputy Director for Science, Outreach, and Policy, Precision Medicine Initiative Cohort Program (PMI-CP)
- *NIH Legislative Update:* Adrienne Hallett, M.T.S., Associate Director for Legislative Policy and Analysis and Director of the NIH, Office of Legislative Policy and Analysis
- *Building Interdisciplinary Research Careers in Women's Health (BIRCWH):* Dr. Terri Cornelison, M.D., Ph.D., Associate Director for Clinical Research, ORWH
- *Specialized Centers for Research on Sex Differences (SCOR):* Dr. Leah Miller, Ph.D., M.B.A., Research Program Officer, ORWH
- *Introduction of a Film Clip Featuring Sen. Barbara A. Mikulski:* Dr. Lawrence

Tabak, D.D.S., Ph.D., Principal Deputy Director, NIH

- *Panel Discussion: Sex as a Biological Variable*: Dr. David Page, Director, Whitehead Institute, Massachusetts Institute of Technology, Moderator
- *An NIH Outreach Toolkit- How to Engage, Recruit, and Retain Women in Clinical Research*: Ms. Amy Mistretta, M.P.H., Epidemiologist, ORWH

On April 19, 2016, the 41<sup>st</sup> meeting of the NIH ACRWH was held at Natcher Conference Center, NIH, Bethesda, Maryland. Presentations included the following:

- *NIH ORWH Director's Report*: Dr. Janine A. Clayton, Associate Director for Women's Health, Director, Office of Research on Women's Health
- *NIH ORWH Programs to Support Women in Science*: Jennifer Plank-Bazinet, Health Scientist Administrator, ORWH
- *NIH Legislative Update*: Anne Tatem
- *Zika virus: Unraveling the Public Health Emergency*: Catherine Spong, Acting Director, National Institute of Child Health and Human Development (NICHD)
- *Sex Differences in Addiction – Animal Models and the Human Condition*: Jill Becker and George Koob
- *Updates on the Strategic Plan*: Juliana Blome, Associate Director of Science Policy, Planning & Analysis, ORWH
- *Raising the Bar – National Academies of Sciences*: Ms. Amy Mistretta, Epidemiologist, Office of Research on Women's Health
- *Evidence-Based Funding: Thoughts About Extramural Research*: Michael Lauer, Deputy Director for Extramural Research

On September 27, 2016, the 42<sup>nd</sup> meeting of the NIH ACRWH was held at the NIH Main Campus, Bethesda, Maryland. Presentations included the following:

- *NIH ORWH Director's Report*: Dr. Janine A. Clayton, Associate Director for Women's Health, Director, Office of Research on Women's Health
- *Zika virus: A Pandemic in Progress*: Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases
- *The Sexual & Gender Minority Research Office: Overview and SGM Research Activities at NIH*: Dr. Karen Parker, Director, Sexual and Gender Minority Research Office
- *Inclusion in NIH Clinical Research: An Update*: Dr. Meredith Temple O'Connor, Senior Scientific Advisor to the NIH Deputy Director for Extramural Research, Office of Extramural Research
- *Unequal Burdens and Unheard Voices: The Role of Sociodemographic Characteristics on the Pain Care Experience*: Dr. Carmen Green, Associate Vice President and Associate Dean for Health Equity and Inclusion, Professor of Health Management and Policy, Anesthesiology & Obstetrics and Gynecology, University of Michigan Health System, and ACRWH Member
- *Report of the new ACRWH Working Group: Raising the Bar – National Academies of Sciences*: Ms. Amy Mistretta, Epidemiologist, Office of Research

### ***Biennial Report***

The NIH ORWH biennial report is a congressionally mandated document that is written by NIH ORWH and approved by the ACRWH. The previous report published in 2015, *National Institutes of Health - Report of the Advisory Committee on Research on Women's Health, Fiscal Years 2013–2014: Office of Research on Women's Health and NIH Support for Research on Women's Health* is available at [https://orwh.od.nih.gov/resources/pdf/ORWH\\_Biennial\\_Report\\_WEB\\_508\\_FY-15-16.pdf](https://orwh.od.nih.gov/resources/pdf/ORWH_Biennial_Report_WEB_508_FY-15-16.pdf). Work on the FY 2015 – FY 2016 report began in October 2016 and is complete and available at <https://orwh.od.nih.gov/research/reports/>.

### ***Improving the Health of Women in the United States Workshop and Summary***

On September 25, 2015, NIH ORWH sponsored a workshop, convened by the National Academy of Sciences Committee on Population, entitled Raising the Bar: The Health of Women in America. This workshop was developed in response to a 2013 report “U.S. Health in International Perspective: Shorter Lives, Poorer Health” by the National Research Council and the Institute of Medicine, which documented the poor health of U.S. women relative to those in 16 peer countries (Australia, Austria, Canada, Denmark, Finland, France, Germany, Italy, Japan, Norway, Portugal, Spain, Sweden, Switzerland, the Netherlands, and the United Kingdom). While the U.S. spends more money on health care than any other country, Americans die sooner and experience more illness. For many years, people in almost all peer countries have had longer life expectancy than Americans and for the last three decades, particularly for women, the difference in life expectancy has been growing. Additionally, The U.S. has the highest rate of adolescent pregnancies, infant mortality, and obesity. The workshop brought together experts in demography, public health, epidemiology, and statistics to discuss the original report's findings, identify current and future challenges, and help inform a research strategy to improve the relative health of women in America. The workshop was held at the National Academy of Science's Keck Center, Washington, D.C.

The objective of the workshop was to highlight a challenge - that the health of women in the United States is significantly worse than the health of women in 16 peer countries. The workshop reached across sectors, disciplines, and areas of expertise to highlight what is known and what needs to be learned. It served to identify key factors at the system, federal, state, patient, and provider levels that might explain the comparative deficiency of the health of women in the United States. The workshop identified key research areas to decrease mortality and morbidity for both the short and long term. It also identified some areas in which small interventions that are relatively inexpensive could have large effects. The challenge now is to communicate, educate, disseminate information to journal editors and colleagues, and to get the word to all women in the United States. When the health of women in the United States improves with decreases in chronic diseases such as diabetes and obesity and lower rates of infant and maternal mortality, the overall health of the United States improves.

## *Response to the Zika Epidemic in the United States*

The whole-of-government response to the potential Zika pandemic by HHS, NIH, and NIH ORWH has been robust, forceful, and comprehensive. NIH, led by the National Institute of Allergy and Infectious Diseases (NIAID) under Dr. Anthony Fauci, MD, and by NICHD, “is working with its partners in government, academia, and the pharmaceutical and biotechnology industries to better understand Zika virus, the disease it causes, and ways to combat it. Specifically, NIAID is accelerating research in areas such as the natural history of the disease, basic research on the Zika virus, how it causes disease (called pathogenesis), diagnostics to rapidly determine if someone is or has been infected with Zika and to distinguish from other flaviviruses, as well as treatments and vaccines.”<sup>19</sup>

NIH ORWH has contributed to the effort to battle Zika by co-sponsoring and participating in the Workshop “Bridging Knowledge Gaps to Understand How Zika virus Exposure and Infection Affect Child Development,” held September 22-23, 2016. The goals of the workshop follow.

- To develop research strategies on how to appropriately assess, evaluate, and monitor the neonate/infant/child affected by Zika virus in utero based on available clinical guidelines
- To identify research strategies to improve evaluation for new/emerging complications of in utero Zika virus exposure and infection and to understand the prospective impact of these complications on the developing child
- To use available information from other vertically transmitted pathogens to provide recommendations for assessment, evaluation, and management
- To outline the research needs for treatment and rehabilitation approaches that optimize cognitive and physical function for Zika-affected children
- To evaluate and expand on treatment options currently offered<sup>20</sup>

The topic of Zika virus infection has been an important topic presented at the last two meetings of the ACRWH. At the 41<sup>st</sup> session of the ACRWH on April 19, 2016, Dr. Catherine Spong, MD, then Acting Director, NICHD, presented “Zika virus: Unraveling the Public Health Emergency.” Most recently, at the 42<sup>nd</sup> session of the ACRWH on September 27, 2016, Dr. Anthony Fauci, MD, Director, National Institute of Allergy and

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<sup>19</sup> National Institute of Allergy and Infectious Diseases. Zika virus. *National Institute of Allergy and Infectious Diseases*. 2016.

<sup>20</sup> National Institute of Child Health and Human Development. NICHD/Bridging Knowledge Gaps to Understand How ZIKV Exposure and Infection Affects Child Development. 2016.

Infectious Diseases, presented “Zika virus: A pandemic in progress.” These two presentations and the robust discussions between committee members should inform and enhance NIH ORWH involvement in the response to the Zika epidemic going forward.

### ***Human Heredity and Health in Africa (H3Africa)***

H3Africa aims to facilitate a contemporary research approach to the study of genomics and environmental determinants of common diseases with the goal of improving the health of African populations. To accomplish this, the H3Africa initiative aims to contribute to the development of the necessary expertise among African scientists, and to establish networks of African investigators. NIH ORWH is supporting H3Africa by participating in two FOAs (Research Projects (U01), RFA-RM-16-015; and Collaborative Centers (U54), RFA-RM-16-016).

### ***Knockout Mouse Phenotyping (KOMP) Project***

The KOMP Project is a trans-NIH initiative that aims to generate a comprehensive and public resource comprised of mice containing a null mutation in every gene in the mouse genome. The project is supported by the International Mouse Phenotyping Consortium (IMPC), European Union, Wellcome Trust, Canada, and the Texas Enterprise Fund. ORWH is participating in project. ORWH is participating in this project because there are sexual dimorphisms in knockout mouse models. More information is available at <https://commonfund.nih.gov/komp2>.

### ***Immunity in Neonates and Infants (RFA-AI-16-001)***

NIH ORWH supports research to advance current knowledge of the developing immune system during the first year of life (neonates: 0-28 days; infants: 29 days - 12 months) and to encourage innovative approaches to understand the distinctive characteristics of neonatal/infant immune responses. The ultimate goal of this program is to expand our understanding and knowledge of early immune system development, which will provide foundational information for future studies to improve immune health and vaccine efficacy in this critical age group.

### ***NIH Autoimmune Disease Coordinating Committee (ADCC)***

National Institute of Allergy and Infectious Diseases (NIAID) chairs the NIH Autoimmune Disease Coordinating Committee (ADCC), which was established in 1998 at the request of Congress. NIH ORWH participates on this committee, the purpose of which is to facilitate coordination of research across the NIH, federal agencies, professional societies, and patient and advocacy organizations with an interest in autoimmune diseases. Reporting of autoimmune disease research is now included in Chapter 3 of the NIH Biennial Report. The most current report, as well as past reports, are available through the Research Portfolio Online Reporting Tool (RePORT).

### ***NIH Sexual and Gender Minority Research Office***

The NIH Sexual & Gender Minority Research Office (SGMRO), established in 2015 in the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), coordinates sexual and gender minority (SGM) research and related activities, including work focused on SGM women, by working directly with the NIH Institutes, Centers, and Offices. NIH ORWH is represented on the NIH SGM Research Coordinating Committee (SGM RCC), and has been a participating Office in the Administrative Supplements for Research on Sexual and Gender Minorities, in addition to other Funding Opportunity Announcements in this area of research. The SGM RCC (previously the trans-NIH Lesbian, Gay, Bisexual, and Transgender (LGBT) Research Coordinating Committee, established by the NIH Director in 2011) helps coordinate NIH's efforts in SGM health. In 2015 the SGM RCC developed the NIH SGM Strategic Plan. In October of 2016, the National Institute for Minority Health and Health Disparities announced the official designation of sexual and gender minorities as a health disparity population for research; this designation will encourage researchers to collect and analyze SGM-related data in order to better understand differences and/or disparities between SGM subpopulations and other populations of interest. This enhanced knowledge will hopefully lead to better care for SGM populations, including SGM women.

### ***NIH Office of AIDS Research***

The NIH Office of AIDS Research (NIH OAR), located within DPCPSI in the NIH OD, coordinates the scientific, budgetary, legislative, and policy elements of NIH HIV/AIDS research. NIH OAR, established in 1988 to coordinate the NIH response to the HIV/AIDS epidemic, has the authority to plan, coordinate, and evaluate AIDS research, to set scientific priorities, and to determine the budgets for all NIH Institutes and Centers HIV/AIDS research projects. NIH represents the largest public investment in AIDS research in the world. Women and girls HIV research is a cross-cutting portfolio that includes basic, translational, clinical, behavioral, and social sciences components.

NIH OAR identifies emerging scientific opportunities and public health challenges that require focused attention; manages and facilitates multi-Institute and trans-Institute activities to address those needs; fosters research by designating funds and supplements to pilot program areas; sponsors reviews or evaluations of research programs; facilitates international AIDS research and training; and supports initiatives to enhance the dissemination of research findings to researchers, physicians, institutions, communities, constituency groups, and patients.

NIH OAR supports HIV/AIDS activities focused on women and girls, including the following current and recent activities:

- Annual evaluation of the NIH HIV/AIDS research portfolio to ensure that current research issues related to women and girls living with or at risk for HIV/AIDS are addressed.
- Development of the annual Trans-NIH Strategic Plan for HIV Research that also addresses the issues of women and girls. NIH OAR organizes Trans-NIH HIV Research Coordinating Committees, with representatives from all NIH ICs and Offices to develop the Strategic Plan. The purpose of these committees is to provide input during the annual planning process and in the development of special initiatives. NIH ORWH actively participates on these committees.



- NIH OAR coordinates monthly meetings of the NIH AIDS Executive Committee (NAEC) with representatives from all ICs and Offices, including NIH ORWH, to address research issues and foster collaboration among ICs and Offices on HIV research including women's research.
- Support for conferences and workshops to determine research gaps and new approaches to advance scientific investigation, including sex differences research across the spectrum of basic, translational, clinical, behavioral, and social sciences research. NIH OAR supported the biennial Centers for Aids Research (CFAR) Research Conference on Women and HIV, participated in the scientific planning for the annual International Conference on HIV and Women, presented data on the intersection between violence and HIV risk for the NIH ORWH Research Symposium at the Annual Academy of Women's Health Conference, and supported the NIH workshop that outlined the relationship between adolescence, mucosal injury, and HIV susceptibility. This workshop resulted in a FOA, funded by multiple ICs and Offices, to define the relationship between genital injury and HIV risk in youth.
- Defining opportunities for collaboration between HIV and non-HIV scientists that advance the understanding of HIV issues in women and girls. NIH OAR supported CFAR research supplements to better understand the biologic relationship between sexual violence, genital tract immunology, and HIV risk across the lifecycle, and the Creative and Novel Ideas in HIV Research (CNIHR) Program that has strategies for women's prevention. This program resulted in new use of nanotechnology to develop intravaginal prevention strategies.
- Collaborating with other U.S. Governmental agencies to better address HIV risk, prevention, treatment, and management: NIH OAR collaborated with HHS OWH, SAMHSA, and CDC to outline research and program gaps for older women living with HIV.
- Funded, coordinated, and developed specific approaches to HIV prevention in women such as research in vaccines, microbicides and pre-exposure prophylaxis (PrEP); multi-purpose prevention technologies (MPTs) to prevent HIV and pregnancy or other sexually transmitted infections; mucosal immunology and the female genital tract microbiome that form the foundation for the understanding of HIV risk and prevention in women; and behavioral and social sciences to address how women's place in society can affect HIV risk and prevention.
- Ensuring that new and existing areas of investigation, such as research towards a cure and HIV treatment also address sex-differences. NIH OAR is participating in the scientific planning of the Women's Research Institute meeting on HIV research toward cure in women.

- The dissemination of research information, including trial results and other learnings from basic, translational, clinical, behavioral, and social sciences research, by coordinating and managing the NIH conference exhibit displayed at major conferences including the International AIDS Conference in Durban, South Africa.

### ***Environmental Influences on Child Health Outcomes Program (ECHO)***

Over the past year, NIH ORWH staff in collaboration with other Institutes and Offices, have been actively involved in the strategic planning for the Environmental Influences on Child Health Outcomes Program (ECHO). ECHO will address the longitudinal impact of pre-, peri-, and post-natal environmental exposures on pediatric development and health outcomes with high public health impact. The ultimate goal is to identify critical periods of development that are impacted by multi-level exposures, and identify opportunities to mitigate risk of disease and maximize health. The NIH Associate Director for Research on Women's Health (also the NIH ORWH Director) served as a co-chair for ECHO from 2015-2016.

### ***New NIH ORWH Website***

NIH ORWH has developed an exciting, brand-new website. The updated site features an engaging, user-friendly design that functions across desktops, tablets, and phones. The website provides important NIH ORWH content along with new prominent spotlights, including the Raising the Bar report, the Women of Color Health Data Book, and the newly revised Sex and Gender courses. The new website can be found at <https://orwh.od.nih.gov/>.

The NIH ORWH website features a new resource, the NIH Outreach Toolkit: How to Engage, Recruit, and Retain Women in Clinical Research. In order to address challenges and promote creativity in addressing barriers to recruitment and retention of women in clinical trials, the site provides several important resources. Information is available regarding NIH inclusion policies, and recruitment and retention best practices. A series of case reports demonstrates real-life clinical research scenarios with suggested actions to meet the needs of researchers and research participants. Also provided was a review of the literature germane to the topic of clinical trials recruitment and retention. A useful hand-out card was also developed to aid in dissemination of information at meeting and gatherings, which has been well received.

### ***Women's Health-Related Goals and Objectives***

NIH ORWH is charged with advising the NIH Director on the future direction and planning of research in mission areas. NIH ORWH develops the NIH strategic plan for women's health and sex differences research through a comprehensive strategic planning process. The NIH ORWH strategic plan for women's health and sex differences research, *Moving into the Future with New Dimensions and Strategies: A Vision for 2020 for Women's Health Research*, has been widely distributed, presented at multiple venues, and has been acknowledged in a Senate resolution. The full strategic plan, including the complete text of the 37 working group reports and the entirety of the written public testimony, is posted on the NIH ORWH website. (<https://orwh.od.nih.gov/research/strategic-plan/>)

The core of the NIH ORWH mission for more than 20 years is promoting women's health research and research on the influence of sex and gender on health and disease, increasing the number of women's health researchers, supporting women's careers in biomedical science, and reinforcing the requirement to include women and minorities as appropriate in clinical research. Although the following efforts were not initiated in specific response to the Affordable Care Act, they support the intent of section 3509. Specifically, they are consistent with the stated goal of HHS OWH to "establish short-range and long-range goals and objectives within the U.S. Department of Health and Human Services and, as relevant and appropriate, coordinate with other appropriate offices on activities within the Department that relate to disease prevention, health promotion, service delivery, research, and public and health care professional education, for issues of particular concern to women throughout their lifespan" (42 U.S.C. 237a).

In Fiscal Years 2015 and 2016, NIH ORWH supported 190 and 162 high quality research-related projects, respectively. These important projects included grants and contracts with 24 IC partners across NIH, for a wide range of extramural and intramural collaborative projects related to women's health and sex differences research. Projects are generally funded through the NIH ORWH Strategic Research Planning process or through one of several NIH ORWH Signature programs.

### ***Strategic Research Planning Program***

The NIH ORWH Strategic Research Planning program (SRP) encourages IC partners to propose to NIH ORWH a variety of extramural and intramural research projects and other projects at any stage of development. Proposals can include opportunities for meetings, conferences, or other forms of collaboration. Research projects can be proposed during early conceptual development, at the protocol phase, or near initiation. NIH ORWH provided support in Fiscal Years 2015-2016 for a broad range of relevant projects. Examples follow.

### ***The BRAIN Initiative***

The Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative is a Presidential initiative aimed at revolutionizing our understanding of the human brain. NIH is one of several public and private partners involved in the BRAIN Initiative. Planning for the NIH component of the BRAIN Initiative is guided by the long-term scientific plan, "BRAIN 2025: A Scientific Vision," which details seven high-priority research areas and calls for a sustained federal commitment of \$4.5 billion over 12 years. NIH ORWH has provided support to the NIH BRAIN Initiative from its initial awards in FY14 through FY16 totaling almost \$3.4M.

The first awards included in the ground-breaking neuroscience initiative pilot include ones that consider sex as a biological variable in rigorous scientific research. In FY16, the *Consideration of Sex as A Biological Variable* (NOT-OD-15-102) policy is in its first year of Trans NIH implementation as a portion of the overarching policy *Enhancing Reproducibility through Rigor and Transparency* (NOT-OD-15-103). The NIH BRAIN Initiative continues to spearhead and pilot award and funding announcement language in support of sex as a biological variable and the NIH ORWH mission through FY17.

### ***HPV Vaccine Trial in Costa Rica***

In this blinded, randomized, phase III clinical trial, the National Cancer Institute (NCI) collaborates with investigators in Costa Rica to evaluate the efficacy of a bivalent HPV-16/18 virus-like particle (VLP) vaccine. NIH ORWH provided support for this trial in FY2014. The vaccine used in the trial was developed by investigators at NCI and other research institutions and is manufactured by GlaxoSmithKline Biologicals. The trial was initiated in 2004 and there were 7,466 women enrolled upon completion of enrollment in 2005. This study was designed to evaluate vaccine efficacy, immunological correlates of long-term vaccine success and failure, and other factors of immunological and etiological interest. Data from the trial demonstrated that three doses of the HPV vaccine may not be necessary, as similar vaccine efficacy against cervical HPV-16/18 infection was observed among women who received two, and even a single dose, of the HPV vaccine after four years of follow-up. This trial is an ongoing activity, where a decade of follow-up is now underway to complete evaluation of the long-term impact of this important public health intervention. NIH ORWH has consistently supported this trial, and in FY 2015 and FY 2016 provided support for the ongoing participant follow-up and analysis.

### ***National Person-Centered Assessment Resource (PCAR)***

Investigators propose to refine and sustain a research resource infrastructure that will educate and enable researchers and other interested health professionals on the use and interpretation of person-centered health outcomes. Person-centered health outcomes are those that are reported or performed by an individual research participant or patient, and that have importance to the quality of life of that participant. In FY 2015 (5-U2C-CA-186878-02) and FY 2016 (5-U2C-CA-186878-03), NIH ORWH co-funded this project with the NCI to bring all four of these person-centered outcome measures together and then educate, equip and enable researchers and clinical providers to use them correctly and effectively.

### ***A Multi-omic Analysis of the Vaginal Microbiome during Pregnancy***

NIH ORWH provided support in FY 2015 (3-U54-HD-080784-02S1) for the Human Microbiome Project (a Common Fund initiative) to support the collection of data on the vaginal microbiome and immune properties of pregnant women. This project focuses on preterm birth and will provide an unparalleled integrated dataset of biological properties of the microbiome with host properties in order to evaluate the role of the vaginal microbiome in preterm birth.

### ***Chronic Overlapping Pain Conditions***

NIH ORWH co-sponsors research groups with interests in bridging expertise in pain mechanisms with translational and clinical expertise to address important unresolved questions about overlapping pain conditions, in collaboration with the National Institute of Neurological Disorders and Stroke (NINDS), the National Institute of Dental and

Craniofacial Research (NIDCR), and the NIH Pain Consortium. NIH ORWH support encourages investigators to address the sex differences in pain disorders and etiology. This funding opportunity announcement was a direct result of the NIH ORWH co-sponsored the Workshop on Chronic Overlapping Pain Conditions in 2012 that outlined a coordinated research strategy and a comprehensive approach for diagnosing and addressing chronic overlapping pain conditions. NIH ORWH continues to support this effort, with the most recent workshop held in September 2015.

### ***Diabetes Prevention Program Outcomes Study Follow-up***

The purpose of this Limited Competition Funding Opportunity Announcement (FOA), 5U01DK048489-24, is to continue follow-up of the Diabetes Prevention Program Outcomes Study (DPPOS) cohort through a cooperative agreement. The Diabetes Prevention Program (DPP) was a multi-center controlled clinical trial examining the efficacy of treatments to prevent or delay the development of type 2 diabetes in a population at high risk. The DPP demonstrated that either lifestyle change or the drug metformin could reduce the development of type 2 diabetes by 58 percent and 31 percent, respectively, compared with placebo. Following the end of DPP, the DPP cohort was enrolled in the DPPOS to determine the long-term effects of the DPP interventions on further diabetes development and microvascular complications. The primary purpose of this FOA is to continue follow-up of the DPPOS cohort to examine the effectiveness of early metformin treatment on the development of cardiovascular disease and cancer.

### ***Pediatric Chronic Fatigue Syndrome (CFS) in a Community-Based Sample***

The first generation of adult chronic fatigue syndrome (CFS) prevalence studies recruited samples from treatment settings and concluded that patients with CFS affected primarily Caucasian, middle-to-high-income groups.<sup>21</sup> This notion led to the inappropriate attribution of CFS being a flu-like illness.<sup>22</sup> Almost all we know about pediatric CFS is based on patients from primary and tertiary care settings, and these youth might not be representative of pediatric CFS in the general population. Biased sampling methods to identify pediatric cases of CFS have impeded efforts to understand the true prevalence of this illness as well as the nature of the condition, similar to what occurred with the first generation of adult CFS epidemiologic studies.

The proposed study (5-R01-HD-072208-05) will determine the prevalence of pediatric CFS by studying a community-based, demographically diverse sample of participants, unbiased by illness, help-seeking behaviors, or differential access to the health care system. Major strengths of this grant application are the diversity of the population, identification of cases from the community, and comparing these samples with community controls. The specific aim of the project is to determine the prevalence of pediatric CFS in a community-based sample, as well as the relative frequency of CFS among various groups (e.g., different age groups, genders, racial/ethnic groups).

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<sup>21</sup>Reyes et al., 1997.

<sup>22</sup> Johnson, 1996.

### ***Single Cell Mapping of Developmental Trajectories Underlying Health and Disease***

Multicellular organisms develop from a single cell that undergoes many stages of proliferation and differentiation that result in the vast array of progenitor and terminal cell types. While dogma defines development as a series of discrete steps, it is actually a continuous process, characterized by transitional stages and intermediate cell types that have yet to be described. The study (1-DP1-HD-084071-01) proposes reframing development in terms of branching trajectories. The study will develop computational algorithms that use high-dimensional single cell data to map each individual cell into a lineage tree representing the chronological order of development. Rather than grouping cells into nodes of this tree (cell types), single cells will fill in the branches in a continuum ordered according to their developmental chronology. Thus, each branch is a developmental trajectory that represents all the transitional stages between cell states. Combining single cell technologies with sophisticated computation will allow researchers to construct a complete and detailed map of normal development. This map will provide both a full catalog of all cell types in our body, as well as the developmental relations between them. The detailed resolution of the resulting map will empower developmental studies, help elucidate how and where development is derailed in disease, and guide the next generation of regenerative medicine. The public health relevance is to develop methods that will enable the construction of complete atlas that maps out in full detail how our bodies develop from a single embryonic cell. This atlas will become an invaluable reference for the progression of many cancers, as well as developmental disorders such as Rett syndrome, Fragile X syndrome, autism spectrum disorders and autoimmunity. In addition, the tools developed, and the insights gleaned from these tools could play a crucial role in advanced therapeutic applications of regenerative medicine.

### ***Alcohol Use, Relationship Factors, Minority Stress and Psychological Wellbeing: A Daily Process Exam among Young Adult Same-sex Couples.***

This renewal (2-R15-AA-020424-02) builds upon the investigators' earlier research on how daily interactions among Lesbian couples (N=150 couples) contribute to alcohol use and abuse.

### ***NIH Office of Intramural Training & Education (OITE) Pedagogy, Mentoring, Leadership and Communication Training***

The project supports a comprehensive series of workshops and courses to teach mentoring, pedagogy, management, and leadership skills to intramural trainees. All of the trainings supported by this funding were developed at the NIH, by expert staff in the NIH OITE, and have been evaluated by outside experts and by participants. The mission of the OITE is to help trainees performing internships and fellowships in NIH research labs (intramural trainees) develop the skills needed to be leaders in the biomedical workforce. The OITE shares their resources with colleagues, universities, and research centers across the U.S. and abroad. The work described in this report was developed and disseminated at NIH and used in workshops outside of NIH. The series of workshops and courses

funded through this appropriation are focused on the development of leadership, management, mentoring, and teaching skills.

The project directly addresses Goal Six of the NIH ORWH strategic plan: employ innovative strategies to build a well-trained, diverse, and vigorous women's health research workforce. The project also seeks to provide training that addresses poor mentorship in research groups and impedes the progress of women and under-represented groups in the scientific workforce (Sub-aims 6.2 and 6.3). The biomedical workforce at early educational stages is more diverse and includes more women (~50% of the training workforces) than the permanent STEM workforce. The goal is for the permanent biomedical research workforce to mirror this diversity. More women and people of color in leadership positions in the biomedical workforce will drive a greater focus on research relevant to women and diverse communities.

By providing pedagogy training to over 100 trainees annually, the proposal seeks to enhance the design and delivery of educational materials that lead to an improvement in women's health (Sub-aim 6.5). The philosophy is to empower trainees to seek the career development resources and mentorship they need to be successful during their training and beyond. Over 100 current or future faculty participated in pedagogy training with the goal of improving their ability to teach. Most of the participants currently teach, or will soon teach, STEM students at the college or graduate level. We strongly believe that improvements in their ability to teach STEM disciplines will translate into more students enjoying STEM coursework. This will enhance women's health because more students will gain an appreciation for important concepts in women's health. We welcome students with very diverse educational experiences who wish to learn more about the biomedical sciences and biomedical research. Our trainees include researchers, physicians, nurses, pharmacists, mathematicians, computer scientists, engineers, etc. The word trainee is broadly used to mean an individual performing an internship or fellowship at NIH and who is exploring, or committed to, a STEM and health-related career. The program helps these trainees develop a greater awareness of self, a deeper understanding of their communication, learning and work styles, the ability to work with colleagues who have different styles, an appreciation of how diversity and difference enhances the workplace, and an understanding of the principles of emotional intelligence. The project also promotes a culture that focuses on self-care, wellness and resiliency.

These trainings also lay the foundation for broader impact in two ways: 1) participants who leave the NIH and take leadership positions in other employment sectors will have basic training in these important concepts, and 2) we use strategic partnerships with professional societies and specific universities to offer these trainings in the extramural community. While offerings vary for different trainee populations, NIH ORWH support allows the applicant to provide offering in the following categories: assertiveness, leadership, wellness, and mentoring.

### ***Specificity and Validity of Oxidative Stress Model of Chronic Fatigue Syndrome***

The applicants proposed to examine the oxidative stress model for pathology of chronic fatigue syndrome (CFS) using blood, urine and brain biomarkers compared to controls with depression in hopes of validating objective markers of CFS that has been shown in other research. The chosen awardee from Weill Cornell Medical College is expanding a pilot study of patients with CFS, major depressive disorder (MDD), and normal controls using neuroimaging to evaluate glutathione (GSH), ventricular cerebrospinal fluid (CSF) lactate, and regional cerebral blood flow (rCBF). The pilot study showed a deficit in GSH, increased ventricular CSF, lactate, and decreased rCBF in patients with CFS compared to controls, which suggested increased oxidative stress as a pathophysiological model of CFS. Since similar findings were present in those with MDD, but showed a trend difference, the expanded study with more participants hopes to be able to differentiate between the two. CFS is a debilitating disorder for which little is known; one of the goals of this grant (1R01MH100005-01) is to improve diagnosis, as well as further our basic understanding of CFS.

### ***Lower urinary tract symptoms (LUTS) Prevention in Adolescent Girls and Women across the Lifespan***

The purpose of the study is to identify risk factors for LUTS at each of four life-stages of interest; synthesize existing epidemiological literature; and identify patient, provider, and structural barriers to LUTS prevention across the lifespan. The project will provide an evidence base to initiate further prevention and intervention studies.

Because urinary incontinence and other lower urinary tract symptoms are common in women, NIH, specifically NIDDK and ORWH, undertook a program to create a Bladder Health/Prevention initiative in 2014. An RFA was issued in August 2014 to invite competitive research applications to establish a Prevention of Lower Urinary Tract Symptoms (LUTS) in Women – Bladder Health, ([RFA-DK-14-004](#)). Scientific reviews were completed and grant awards were made in mid-2015. From 2015-2017, the grantees have been focusing on the identification and evaluation of risk and protective factors for LUTS, and to plan for future primary and secondary prevention intervention research as the evidence is established. All research work is progressing well, and on target.

### ***NIH ORWH Signature Program***

NIH ORWH provided support in Fiscal Years 2015-2017 and continues to fund two ongoing interdisciplinary programs: Building Interdisciplinary Research Careers in Women's Health (BIRCWH) and the Specialized Centers of Research (SCOR) on Sex Differences. These unique programs address human health concerns through sex differences research and interdisciplinary scientific collaborations. The programs also provide important support for early career scientists, with an emphasis on mentoring and collaboration, to increase the number of investigators pursuing women's health and sex differences research. Please see below for more details on each of these programs.

### ***Building Interdisciplinary Research Careers in Women's Health (BIRCWH)***



ORWH and the NIH institutes and centers created the BIRCWH program in 1999 in order to train young investigators to conduct women's health research. BIRCWH is funded by an institutional mentored career development grant program, which awards federal grants on a competitive basis to educational institutions across the United States. These grants provide protected research time for junior faculty (known as BIRCWH scholars) who work closely with senior investigators in an interdisciplinary mentored environment to learn research methodologies, scientific content areas, and skills essential for career development. Therefore, a key goal of BIRCWH is to support the next generation of researchers studying women's health research and research on the influence of sex and gender on health and disease. BIRCWH scholar research areas cover various topics, including diabetes, cancer, depression, cardiovascular health, HIV/AIDS, arthritis/musculoskeletal health, mental health, substance abuse, intimate partner violence, reproductive health, and health disparities. Since the program's inception in 2000, NIH ORWH and other NIH co-sponsors have awarded 81 grants to 41 institutions supporting more than 600 junior faculty members, 80 percent of whom were women. There are currently 20 active BIRCWH programs nationwide. NIH ORWH funding level for the BIRCWH program in FY 2017 was \$8.5 million. NIH monitors the success of the BIRCWH program through the success of the Scholars who have completed their training and received extramural grant support to undertake independent research. These grants can come from NIH, and other sources such as private foundations.

As part of the evaluation of the BIRCWH program undertaken in 2015 to 2016, an updated analysis of scholar success in successful application for NIH funding was performed for the period between FY 2010 to FY 2015. For this time period, 52 percent of the Scholars who applied for individual NIH-Career Development awards such as the K01 were successful. For research grants such as the R01, 36 percent of the Scholars were successful in obtaining funding. Men and women had similar person funding rates, but women had higher success rates for R01 awards. These findings suggest that the BIRCWH program has been successful in helping scholars establish independent research funding, advancing their careers. Another metric of success are the 2,539 peer-reviewed publications that were generated between FY 2000 through April 2016.

As part of career development for the BIRCWH Scholars, annual meetings are held to present scientific findings from Scholar-related research, to provide mentoring opportunities by the NIH institute and center research staff, and share important advances in career development programs across the NIH. The most recent meeting was held on October 25, 2017, at NIH, where over 150 people were in attendance. The prior year's meeting was held on June 7, 2016, which featured a panel of principal investigators (PIs) who have BIRCWH grants and a poster session for BIRCWH Scholars.

On July 14, 2016, the new BIRCWH RFA ([RFA-OD-16-013](#)) was published in the NIH Guide. The application due date was October 6, 2016. Ten BIRCWH applications were selected for FY 2017 funding based on their competitive scientific review scores. NIH ORWH has committed an additional \$5 million to fund these 10 awards for five years; several institutes, centers, and offices (ICOs) joined the RFA. Each grantee will be permitted to have three scholars each. These scholars are at the junior faculty level.

### ***Specialized Centers on Research on Sex Differences (SCOR)***

The NIH ORWH SCOR program uses a P50 mechanism and funds research centers that integrate basic, preclinical, clinical, and translational research to facilitate innovative, interdisciplinary studies on sex differences and major medical problems affecting women's health. NIH ORWH provided support in Fiscal Years 2015-2016, and currently funds SCORs include research on substance abuse, the urinary tract, musculoskeletal diseases, birth injuries, stress, and pain. The majority of SCOR funding is provided by NIH ORWH, with additional support from NIH IC partners and the United States Food and Drug Administration (FDA) Office of Women's Health. In FY2016, NIH ORWH funded 11 P50-SCOR programs across NIH totaling approximately \$9.5 million, which explored sex and gender differences in musculoskeletal diseases, vascular dysfunction and cognitive decline, substance use, pain, tobacco dependence, and urinary tract and reproductive health.

On June 8, 2016, NIH ORWH convened the SCOR meeting at the Natcher Conference Center. The theme for the SCOR meeting was: Forging Ahead. The SCOR PIs provided updates of their research programs and there was a discussion on "Challenges and Strategies for Considering Sex as a Biological Variable in Preclinical Research and Challenges and Advantages of an Interdisciplinary Research Approach."

On July 5, 2016, SCOR Program Director Dr. Emeran Mayer, investigator on brain gut microbiome interactions, released his book *The Mind-Gut Connection*, published by Harper Collins.

SCOR Program Director Dr. Sherry McKee (Yale SCOR), President of the American Psychological Association's (APA) Society of Addiction Psychology (SoAP), recently wrote a column entitled, "Incorporating sex and gender into addiction research and practice—the time has come", and made her presidential address entitled, "Factoring Sex and Gender Differences into Precision Medicine for Addiction Science and Treatment" at the most recent APA conference.

### ***NIH ORWH Administrative Supplements***

NIH ORWH began in 2013 a new initiative, the Administrative Supplement program, to bolster the research NIH IC grantees to encourage sex/gender comparisons in preclinical and clinical studies. This investment encourages researchers to study females and males, and is a catalyst for considering sex as a fundamental biological variable in research. A survey of almost 2,000 animal studies revealed a male bias in 8 out of 10 biological disciplines, most pronounced in neuroscience (5.5 males to 1 female), pharmacology (5 males to 1 female) and physiology (3.7 males to 1 female).<sup>23</sup> The current overreliance on male subjects in preclinical research can obscure key findings related to sex that could guide the planning and development of clinical studies<sup>24</sup>. This progressive approach has resulted in greater awareness of the need to study both sexes, demonstrate how research can incorporate sex, and reinforce the value of taking sex into

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<sup>23</sup> Zucker and Beery. Males still dominate animal studies. *Nature*, 2010, June 10, 465, page 690

<sup>24</sup> Clayton and Collins. Policy: NIH to balance sex in cell and animal studies. *Nature*, 2014, May 15 509, page 282

account as these studies yield results. The funded supplement projects span a wide array of science, including basic immunology, cardiovascular physiology, neural circuitry, and behavioral health.

NIH ORWH provided support in Fiscal Years 2015-2016 for a wide range of projects that supported missions for both NIH ORWH and ICs. In FY 2016, NIH ORWH appropriated \$5 million to support 50 administrative supplements for research on sex/gender differences (PA-16-066). The scientific community responded enthusiastically and NIH ORWH received 261 applications across the NIH. All the applications were administratively reviewed and ranked by the ICOs for their scientific content, followed by a second level of review by the NIH ORWH scientific staff for office mission and programmatic priorities. Additional funding was approved by ORWH leadership allowing for an overall success rate of 23.4 percent (\$6.02 million to fund 61 applications).

### ***NIH ORWH R56 Research Grant Program***

The NIH ORWH R56 Research Grant Program functions to support high-priority, short-term research projects that satisfy the strategic goals of NIH ORWH and IC partners. The R56 program, supported by NIH ORWH in Fiscal Years 2015-2016 and continuing into FY 2017, enables innovative potentially high-impact research that falls outside of NIH ICO pay lines but which, if implemented successfully could significantly advance knowledge of women's health and/or sex/gender influences on human health and disease. R56 is a DPCPSI initiative involving NIH ORWH, the Office of Dietary Supplements and Office of AIDS Research. The program operates mechanistically under an NIH internal solicitation for applications; only institutes can apply through their project officers. The FY 2017 Internal Solicitation for Applications went out in October 2016.

In FY 2017, 12 projects were supported with \$3.6 million. Topics included essential and timely subjects such as the following:

- Nanoparticle Transport Through Tissue
- Nanosensor-Based Phenotypic Screening for Precision Therapy of Cancer Stem Cells
- Biomimetic Nanovesicles to Overcome Multiple Physiological Barriers for Primary and Metastatic Triple Negative Breast Cancer Therapy
- Integrated Nano -Therapeutics to Overcome Tumor Plasticity and Resistance
- Effects of Inhaled Nicotine on Vascular miR-24 Activity and AAA Formation
- Role of Hofbauer Cells in Fetal Infection/Inflammation
- Cytoplasmic Maturation in Mouse Oocytes
- The Genetics of Primary Ovarian Insufficiency
- Ovarian Ultrasonography for the Clinical Evaluation of Polycystic Ovary Syndrome
- Social-Moral Processing in Female Stimulant Abuse and Psychopathy
- E-Cigarette Use as a Smoking Cue
- Analysis of MyD88-Mediated Immune Activation in Sjogren's Syndrome Pathogenesis

It is anticipated that many of these will go on to obtain R01 funding and make substantive contributions to women's health science. Monitoring will be conducted regularly as part of the oversight process. The projects are evaluated yearly based on submitted Research Performance Progress Reports (RPPR) by program staff at issuing ICs.

In FY 2016, 14 projects were supported with \$4.13 million. Topics included important and timely subjects such as the following:

- Psychological effects of helping behavior in older adults
- Tunable polymer-graphene oxide composite for single-cell analysis of breast cancer CTCs and CSCs
- Understanding beliefs, concerns, and needs of pregnant patients who use marijuana
- Regulation of craving under stress: novel model and neural mechanisms
- Comparing novel strategies for reducing drug abuse in male and female Rhesus monkeys
- Proteins, microRNAs and genes associated with TMD and overlapping pain conditions
- Phthalates and ovarian toxicity
- BPA and phthalates: effects on inflammatory markers in the breast and breast density in young women
- FSH and IGF1R signaling crosstalk in ovarian GCs
- Interactions of 17-beta estradiol and ketamine on depression-like behavior, hippocampal synaptic function, and cognition in ovariectomized rats
- Pain management for older adults living in nursing homes
- Sex differences in angiotensin-induced vascular disease
- Impact of supportive policies on minority stress, drinking and health among women
- Ovarian-specific transcription networks regulated by the TFIID subunit TAF4b

Fifty-seven percent of the R56 grantees from 2016 went on to obtain R01 funding for subsequent years, either on the same or a closely related topic. Sixty-three percent of those resulted in publications. Some examples include:

- Zhou C, Gao L, Flaws JA. Prenatal exposure to an environmentally relevant phthalate mixture disrupts reproduction in F1 female mice. *Toxicol Appl Pharmacol.* 2017 Mar 1;318:49-57 – This study tested the hypothesis that prenatal exposure to an environmentally relevant phthalate mixture adversely affects female reproduction in mice. The results indicated that prenatal exposure to the phthalate mixture significantly increased uterine weight and decreased anogenital distance on postnatal days 8 and 60, induced cystic ovaries at 13 months, disrupted estrous cyclicity, reduced fertility-related indices, and caused some breeding complications at 3, 6, and 9 months of age. These data suggest that prenatal exposure to an environmentally relevant phthalate mixture disrupts aspects of female reproduction in mice.

- Convissar S, Armouti M, Fierro MA, Winston NJ, Scoccia H, Zamah AM, Stocco C. Regulation of AMH by oocyte-specific growth factors in human primary cumulus cells. *Reproduction*. 2017 Dec;154(6):745-753 – “The purpose of this study was to determine the role of the oocyte-secreted factors, growth differentiation factor 9 (GDF9) and bone morphogenetic protein 15 (BMP15), on AMH production in primary human cumulus cells.... These findings show for the first time that AMH production is regulated by oocyte-secreted factors in primary human cumulus cells. Moreover, our novel findings establish that the combination of GDF9 + BMP15 potently stimulates AMH expression.”
- Hunnicutt JN, Chrysanthopoulou SA, Ulbricht CM, Hume AL, Tjia J, Lapane KL. Prevalence of Long-Term Opioid Use in Long-Stay Nursing Home Residents. *J Am Geriatr Soc*. 2017 Sep 21 – “Overall and long-term opioid use among older adults have increased since 1999. Less is known about opioid use in older adults in nursing homes (NHs).... One in seven NH residents was prescribed opioids long-term. Recent guidelines on opioid prescribing for pain recommend reducing long-term opioid use, but this is challenging in NHs because residents may not benefit from nonpharmacological and nonopioid interventions. Studies to address concerns about opioid safety and effectiveness (e.g., on pain and functional status) in NHs are needed.”

In FY2015, 11 projects were supported with \$3.3 million. Similarly, topics included the following:

- Immune modulation of hypertension
- Impact of prenatal hypoxia on mitochondrial function of offspring hearts
- The interaction of varenicline, ethanol, and CNS development
- Stress and decision making in older persons: toward a neurobehavioral phenotype
- Circulating microRNAs and TLR8 activation in chronic pain
- The female urinary microbiome and urinary incontinence
- Improving heart transplant allocation to reduce high waitlist mortality in women
- Neurodevelopmental features of sexual dimorphism in pediatric psychopathology
- Altering the physical microenvironment and enhancing lipid availability for in vitro follicle and oocyte development
- Mitochondrial function and insulin sensitivity in African American women
- Estradiol and hippocampal development

Seventy-three percent of the R56 grantees from 2015 went on to obtain R01 funding for subsequent years, either on the same or a closely related topic. Of those, 63% of the projects produced findings reported in publications. Some examples include:

- Arnold, Arthur P; Cassis, Lisa A; Eghbali, Mansoureh; Reue, Karen; Sandberg, Kathryn. Sex Hormones and Sex Chromosomes Cause Sex Differences in the Development of Cardiovascular Diseases. *Arterioscler Thromb Vasc Biol*. 2017 May;37(5):746-756 – “This review summarizes recent evidence concerning hormonal and sex chromosome effects in obesity, atherosclerosis, aneurysms, ischemia/reperfusion injury, and hypertension. Cardiovascular diseases occur and

progress differently in the 2 sexes, because biological factors differing between the sexes have sex-specific protective and harmful effects.... Gonadal hormones, especially estrogens and androgens, have long been found to account for some sex differences in cardiovascular diseases, and molecular mechanisms mediating these effects have recently been elucidated. More recently, the inherent sexual inequalities in effects of sex chromosome genes have also been implicated as contributors in animal models of cardiovascular diseases, especially a deleterious effect of the second X chromosome found in females but not in males.”

- Thompson LP, Pence L, Pinkas G, Song H, Telugu BP. Placental Hypoxia During Early Pregnancy Causes Maternal Hypertension and Placental Insufficiency in the Hypoxic Guinea Pig Model. *Biol Reprod.* 2016 Dec;95(6):128 – “This animal model of placental HPX identifies several aspects of abnormal placental development, including increased TB proliferation and decreased migration and invasion of TBs into the spiral arteries, the consequences of which are associated with maternal hypertension and fetal growth restriction.”
- Mueller, Elizabeth R; Wolfe, Alan J; Brubaker, Linda. Female urinary microbiota. *Curr Opin Urol.* 2017 May;27(3):282-286 – “Clinical laboratories can modify traditional standard urine culture methods to enhance detection of uropathogens. However, given the existence of the female urinary microbiota, the simple presence of bacteria in the lower urinary tract should not be taken as evidence of infection.”
- Raeisi-Giglou, Pejman; Rodriguez, E Rene; Blackstone, Eugene H; Tan, Carmela D; Hsieh, Eileen M. Verification of Heart Disease: Implications for a New Heart Transplantation Allocation System. *JACC Heart Fail.* 2017. – “This study sought to determine the accuracy of the pre-transplantation clinical diagnosis of heart disease in the United Network for Organ Sharing (UNOS) database.” It found that “[t]here is high concordance between clinical and pathologic diagnosis, except for sarcoidosis and genetic diseases. Few misclassifications result in disadvantages to patients based on the new allocation system, but rare diseases like sarcoidosis remain problematic. To improve the UNOS database and enhance outcome research, pathology of the explanted hearts should be required post-transplantation.”

### ***Sex as a Biological Variable***

The NIH Office of Research on Women’s Health, under the leadership of Dr. Janine A. Clayton, MD, NIH Associate Director for Women’s Health and Director of NIH ORWH, has aggressively pursued the goal of implementation of the recent NIH Sex as a Biological Variable policy. The Office has worked, and continues to work, on implementation, dissemination, education and training, publication, and monitoring of the policy. These efforts are elaborated upon in the next several sections below.

### ***Implementation and Dissemination***

- On May 18, 2015, the NIH ORWH Director presented to the Advisory Council to the Center for Scientific Review, and discussed recent NIH and NIH ORWH efforts to enhance consideration of sex as a biological variable.

- On May 20, 2015, in coordination with the Office of Extramural Research, NIH ORWH released a summary report on responses to a Request for Information on Consideration of Sex as a Biological Variable in Biomedical Research (NOT-OD-14-128). The report is posted on the NIH ORWH website and joint blogs were published.
- On June 9, 2015 the Office of Extramural Research released two notices to the NIH Guide clarifying NIH expectations regarding rigor and transparency (NOT-OD-15-103) and consideration of sex as a biological variable (NOT-OD-15-102). These notices announced updates to application instructions and review criteria, pending OMB approval. In conjunction with the notice publication, Dr. Janine Clayton published a blog post, NIH ORWH published additional guidance, and OER published a FAQ webpage that includes questions and answers regarding consideration of sex as a biological variable.
- On June 30, 2015, the NIH Associate Director for Women's Health participated in a conference call with members of Senator Patty Murray's staff. The Director discussed the use of sex as a biological variable in research, including the use of male and female animals. Other participants in the call included Office of Extramural Research (OER) and Office of Legislative Policy and Analysis (OLPA) staff.
- On July 10, 2015, the NIH Associate Director for Women's Health participated in a congressional briefing entitled Maximizing the Benefits of Biomedical Research: A Tale of Mice and Men- Why We Need to Balance the Study of Males and Females. The briefing was co-sponsored by the Endocrine Society and the Society for Women's Health Research, to educate new congressional staff and other advocacy groups on the importance of studying both sexes in preclinical and clinical research. The Director gave a progress update on NIH policy change. Other presenters included:
  - Phyllis Greenberger, MSW, President and CEO, Society for Women's Health Research
  - Teresa Woodruff, PhD, Thomas J. Watkins Memorial Professor of Obstetrics and Gynecology, Northwestern University, Past President of the Endocrine Society
  - Marsha Henderson, MCRP, Assistant Commissioner for Women's Health, U.S. Food and Drug Administration

### ***NIH ORWH Roadshows on Sex as a Biological Variable***

Implementation of the Sex as a Biological Variable (SABV) NIH policy is crucial to development of the best science to support improvements in women's health. Training and encouragement of scientific review officers, peer reviewers, applicants, and grantees plays an important role in effectively implementing the policies.

NIH ORWH liaisons to each IC have, or will soon provide instructional lectures to IC staff on why and how to implement SABV policies. By the end of calendar-year 2016, lectures were given to the majority of ICs. In addition, similar but targeted and customized lectures have been given to several interested and affected outside organizations, including but not limited to the American Physiological Society, American Association for Laboratory Animal Science, and the American Heart Association. Additional activities highlighting SABV include The American Academy of Child & Adolescent Psychiatry (panel discussion on Advancing Sex- and Gender-Based Research to Understand Mechanisms and Developmental Trajectories of Depression) October 2017, The Mayo Clinic: Mayo Clinic's Celebration of Women's Health Research Symposium (October 2017) and a poster presentation on "Considering Sex As a Biological Variable (SABV) in Research: A Primer for Neuroscience Investigators for the 47th Annual Meeting of the Society for Neuroscience, Washington, DC, Nov. 11-15, 2017.

### ***Trans-NIH Research Highlights***

Other entities at NIH have done tremendous work, and there are far too many projects and publications to list them comprehensively. The following is a list of only some of the highlighted projects and publications that address women's health and to which NIH ICs have contributed.

### **National Institute of Aging (NIA)**

#### *Sex Differences in Cognitive Trajectories in Clinically Normal Older Adults*<sup>25,26</sup>

"A recent observational study by Dr. Anna C. McCarrey and colleagues in NIA's Intramural Research Program showed that cognitive ability in some, but not all, domains declines at a steeper rate for men than for women. NIA researchers followed participants in the Baltimore Longitudinal Study of Aging up to nine years on average. Participants ranged in age from 50 to 96, and were free of cognitive impairment throughout the course of the study. Participants periodically took memory and other cognitive tests that assessed mental status, visuospatial ability, verbal learning and memory, perceptuomotor speed and integration, and other cognitive skills. Initially, men outperformed women on the two tests of visuospatial ability, and women did better than men on several other cognitive tests. Men showed overall steeper rates of cognitive decline in areas of mental status, perceptuomotor speed and integration, and visuospatial ability. None of the measures showed significantly steeper declines for women. This suggests that women have a greater resilience to age-related cognitive decline than do men. The researchers note that societal changes may contribute to these sex differences as they have resulted in greater improvements in cognitive stimulation, financial prosperity, and health for women. In addition, sex differences in cognitive aging may be affected by differences in brain structure and function, which tend to show more favorable outcomes for women at

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<sup>25</sup> McCarrey AC, An Y, Kitner-Triolo MH, Ferrucci L, Resnick SM. Sex differences in cognitive trajectories in clinically normal older adults. *Psychology and aging*. 2016;31(2):166-175.

<sup>26</sup> National Institute on Aging. Age-related cognitive decline: Women are more resilient than men. *National Institute on Aging*. 2016.



advanced ages. Further research is needed to link longitudinal brain changes to cognition in older men and women.”<sup>27</sup>

### **Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)**

#### ***NIH Invests \$46 million in Technologies to Monitor Placental Health***<sup>28</sup>

"The National Institutes of Health has announced \$46 million in research awards for the Human Placenta Project, an initiative to revolutionize understanding of the placenta. The awards will fund technology development and testing to assess placental function throughout pregnancy, with the ultimate goal of improving pregnancy outcomes and lifelong health. People usually take the placenta for granted. But when it doesn't work the way it should, it can put the entire pregnancy at risk—along with the health of mother and fetus," said Catherine Spong, M.D., deputy director of NIH's Eunice Kennedy Shriver National Institute of Child Health and Human Development, which is leading the initiative. NIH's Human Placenta Project aims to revolutionize understanding of a critical, but poorly understood, organ. The placenta is a critical organ that shuttles blood, oxygen, and nutrients from mother to fetus and clears harmful waste like carbon dioxide. It also produces hormones to help sustain the pregnancy and regulate the immune system so that mother and fetus can coexist. Many problems of pregnancy — such as preeclampsia, preterm birth, and even stillbirth — can occur because of problems with the placenta. If researchers can develop tools to monitor the placenta from the earliest stages of pregnancy, physicians may one day be able to identify problems sooner and intervene more quickly. NIH has funded 19 projects, totaling approximately \$46 million in this fiscal year. The awards will support development of safe, noninvasive methods to monitor the placenta in real time, throughout all stages of pregnancy. The funds also will support research on environmental factors that may affect placental function."<sup>5</sup>

#### ***A Longitudinal Study of Depression and Gestational Diabetes in Pregnancy and the Postpartum Period***<sup>29, 30</sup>

"Researchers at the National Institutes of Health have discovered a two-way link between depression and gestational diabetes. Women who reported feeling depressed during the first two trimesters of pregnancy were nearly twice as likely to develop gestational diabetes, according to an analysis of pregnancy records. Conversely, a separate analysis found that women who developed gestational diabetes were more likely to report postpartum depression six weeks after giving birth, compared to a similar group of women who did not develop gestational diabetes. ... The researchers analyzed pregnancy

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<sup>27</sup> Ibid.

<sup>28</sup> National Institute of Biomedical Imaging and Bioengineering. NIH invests \$46 million in technologies to monitor placental health. *National Institute of Biomedical Imaging and Bioengineering*. 2015.

<sup>29</sup> Hinkle SN, Buck Louis GM, Rawal S, Zhu Y, Albert PS, Zhang C. A longitudinal study of depression and gestational diabetes in pregnancy and the postpartum period. *Diabetologia*. 2016.

<sup>30</sup> National Institutes of Health. Depression in early pregnancy linked to gestational diabetes, NIH study finds. *National Institutes of Health (NIH)*. 2016.

records from the NICHD Fetal Growth Studies-Singleton Cohort, which tracked the progress of thousands of pregnancies, to understand the patterns of fetal growth. The study enrolled 2,334 non-obese and 468 obese women in weeks eight to 13 of pregnancy. The women responded to questionnaires on symptoms of depression when they enrolled in the study, again between the 16th and 22nd week of pregnancy, and then six weeks after giving birth. The researchers also reviewed the women's records to identify who had developed gestational diabetes. 'Of particular note, persistent depression from the first to second trimester set women at even greater risk for gestational diabetes.' ... The researchers also found a higher risk for postpartum depression among the women who had gestational diabetes. Of the women who developed gestational diabetes, nearly 15 percent experienced depressive symptoms after birth, which was more than four times that of women who had not had gestational diabetes."<sup>7</sup>

### **National Center for Advancing Translational Sciences (NCATS)**

#### *Modeling the Female Reproductive Tract in 3-D: The Birth of EVATAR™<sup>8</sup>*

"Too often, laboratory and animal tests used by scientists in the early phases of research fail to predict a therapy's effectiveness or potential side effects in humans. Use of inaccurate models can result in many years and millions of dollars being wasted while patients wait for effective treatments. Researchers need scientifically valid alternatives for predicting treatment effectiveness and safety. Another issue is consideration of sex as a biological variable. Although women now comprise roughly half the participants in NIH-funded clinical trials, the same is not true for pre-clinical research. More often than not, pre-clinical research conducted to date has involved mostly male-derived cells and male animals<sup>31</sup>. These practices have resulted in a lack of information about female physiology and women's health. To address these and other drug development challenges, NCATS, along with the Defense Advanced Research Projects Agency and the Food and Drug Administration, developed the Tissue Chip for Drug Screening program. Program funding is used to support scientists developing 3-D platforms with living human tissues and cells, called tissue chips or organs-on-chips. These devices are designed as accurate models of the structure and function of human organs and systems, such as the lung, liver, heart and, in this case, female reproductive tract."<sup>32</sup>

### **National Institute of Mental Health (NIMH)**

NIHM issued in 2015 notice that they were prioritizing certain areas of research related to women's mental health during pregnancy and the postpartum period.<sup>33</sup>

### **National Institute on Alcohol Abuse and Alcoholism (NIAAA)**

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<sup>31</sup> Zucker and Beery. Males still dominate animal studies. *Nature*, 2010, June 10, 465, page 690.

<sup>32</sup> National Center for Advancing Translational Sciences. Modeling the Female Reproductive Tract in 3-D: The Birth of EVATAR™. *Feature Stories*. 2015.

<sup>33</sup> National Institute of Mental Health. NOT-MH-15-013: Notice of Information: NIMH High-Priority Areas for Research on Women's Mental Health During Pregnancy and the Postpartum Period. *NIH Guide*. 2015.

### ***Fetal Alcohol Spectrum Disorders***<sup>34</sup>

NIAAA “has a large research program on fetal alcohol spectrum disorders (FASD) that sponsors projects on preventing prenatal alcohol exposure, treating women with alcohol use disorder, improving the diagnosis of FASD, establishing more precise prevalence estimates of FASD in the United States, increasing our understanding of the effects of alcohol on the unborn child, and developing effective interventions to mitigate the health effects on individuals prenatally exposed to alcohol. Annually, NIAAA expends about 8 to 9 percent of its extramural research and training budget, or roughly \$30 million, toward its portfolio of FASD-related grants. This portfolio is comprised of approximately 90 grants, including research project grants, cooperative agreements, training grants, center grants, fellowships, and career development awards, that collectively address FASD prevention, diagnosis, treatment, and etiology. In addition, NIAAA funds a conference grant that supports the annual meeting of the FASD Study Group (see [www.fasdsg.org](http://www.fasdsg.org)). ”<sup>35</sup>

### **National Institute of Drug Abuse (NIDA)**

NIDA has a large portfolio including numerous programs that include and study women.

### ***Sex Differences in Smoking Cessation Pharmacotherapy Comparative Efficacy: A Network Meta-analysis***<sup>36,37</sup>

"A meta-analysis of smoking cessation therapies, funded by the National Institute on Drug Abuse (NIDA), showed that clinicians should strongly consider varenicline as the first treatment option for women who are trying to quit smoking. Varenicline, a prescription medication used to treat nicotine addiction, was about 1.4-fold more effective than bupropion or the nicotine patch for women, compared to men. The meta-analysis of several studies compared the success rates of the nicotine patch versus the prescription medications varenicline and bupropion. Women treated with varenicline were 41 percent more likely to quit smoking after six months, compared to women treated with the nicotine patch, and were 38 percent more likely to quit than women treated with bupropion. Among men, the advantage of varenicline over these two medications was not statistically significant. When compared to the placebo, women and men achieved similar outcomes when treated with varenicline. The authors also discussed how the effectiveness of particular smoking cessation therapies might relate to the sex of the person. For example, research has shown that women metabolize nicotine at a faster rate than men; and fast metabolizers have poorer smoking cessation outcomes

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<sup>34</sup> National Institute on Alcohol Abuse and Alcoholism. Fetal Alcohol Spectrum Disorders. *Major Initiatives*.

<sup>35</sup> Ibid.

<sup>36</sup> Smith PH, Weinberger AH, Zhang J, Emme E, Mazure CM, McKee SA. Sex Differences in Smoking Cessation Pharmacotherapy Comparative Efficacy: A Network Meta-analysis. *Nicotine & Tobacco Research*. 2016.

<sup>37</sup> National Institute on Drug Abuse. Smoking cessation success linked to sex difference. *Science Spotlight*. 2016.

with the nicotine patch."<sup>38</sup> Research into the effects of nicotine replacement in relation to nicotine metabolism and sex continue. For example, an international study from the University of Lausanne, University of Madrid, and University of Geneva found that women and normal nicotine metabolizers may benefit more from varenicline over nicotine replacement<sup>39</sup>. Researchers at Vanderbilt University and the University of Toronto conducted a pilot study to see if “metabolism-informed care” could improve smoking cessation by matching normal metabolizers with non-nicotine medications such as varenicline and slow metabolizers with NRT patch. They found that broad implementation of “metabolism-informed care” will improve drug efficacy in normal metabolizers and can minimize side effects in slow metabolizers<sup>40</sup>.

### **National Heart, Lung, and Blood Institute (NHLBI)**

In addition to their classic cardiac, pulmonary, and hematology portfolios, NHLBI houses the National Center on Sleep Disorders Research. A prominent example of funded ongoing research pertinent to women, in collaboration with NICHD, follows.

#### ***Sleep Disordered Breathing sub study of the Nulliparous Pregnancy Outcomes Study Monitoring Mothers-to-be (nuMoM2b)***<sup>41</sup>

The objective of the Sleep Disordered Breathing sub study of the Nulliparous Pregnancy Outcomes Study Monitoring Mothers-to-be (nuMoM2b) is to determine whether sleep disordered breathing during pregnancy is a risk factor for adverse pregnancy outcomes. NuMoM2b is a prospective cohort study of 10,037 nulliparous women with singleton gestations that was conducted across 8 sites with a central Data Coordinating and Analysis Center. The Sleep Disordered Breathing sub study recruited 3,702 women from the cohort to undergo objective, overnight in-home assessments of sleep disordered breathing. The primary pregnancy outcomes to be analyzed in relation to maternal sleep disordered breathing are preeclampsia, gestational hypertension, gestational diabetes mellitus, fetal growth restriction, and preterm birth. Objective data were obtained at visit 1 on 3261 women, which was 88.1 percent of the studies that were attempted and at visit 3 on 2511 women, which was 87.6 percent of the studies that were attempted. The sub study was designed to address important questions regarding the relationship of sleep-disordered breathing on the risk of preeclampsia and other outcomes of relevance to maternal and child health.<sup>42</sup> Analyses published in January 2017 showed an independent

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<sup>38</sup> Ibid.

<sup>39</sup> Glatard, A., Dobrinas, M., Gholamrezaee, M., Lubomirov, R., Cornuz, J., Csajka, C., & Eap, C. B. (2017). Association of nicotine metabolism and sex with relapse following varenicline and nicotine replacement therapy. *Experimental and Clinical Psychopharmacology*, 25(5), 353-362.

<sup>40</sup> Wells QS, Freiberg MS, et al. Nicotine Metabolism-informed Care for Smoking Cessation: A Pilot Precision RCT. *Nicotine Tob Res*. 2017 Oct 14

<sup>41</sup> Facco FL, Parker CB, Reddy UM, et al. NuMoM2b Sleep-Disordered Breathing study: objectives and methods. *Am J Obstet Gynecol*. 2015;212(4):542.e541-127.

<sup>42</sup> Ibid.

association between sleep-disordered breathing and preeclampsia, hypertensive disorders of pregnancy, and GDM<sup>43</sup>.

## ***Women's Health Research Projects***

### **NIH ORWH Activities**

#### ***To Support and Increase the Number of Women in Biomedical Careers***

The NIH Director and the NIH ORWH Director co-chair the *NIH Working Group on Women in Biomedical Careers* (Working Group). This trans-NIH initiative was established in 2007 to develop novel strategies and tangible actions to promote the sustained advancement of women in biomedical research careers, within the NIH intramural community and throughout the extramural research community. Through the Working Group, NIH ORWH collaborates with NIH leadership, scientists, and staff to implement programs and policies to support female scientists at all stages of their careers. Recent Working Group and additional NIH activities to promote careers of women in biomedical research and to implement programs and policies include the following.

- **Casual Factors Research:** The Working Group, funding ICs, and awardees of the Request for Applications (RFA GM-09-012) on Research on Causal Factors and Interventions that affect the careers of women in biomedical and behavioral sciences and engineering, are maximizing the impact of the results from the initial NIH-funded investigations and focusing on effective institutional change strategies and organization, structural, and cultural factors that inhibit the success of women in science. The Working Group provided staff support for this ongoing effort in FY2015 and FY2016. As of May 2015, the grantees funded through this endeavor published 62 manuscripts and gave over 160 presentations on this topic.
- **Conference on Evidence-Based Innovations to Support Women in Biomedical Research Careers, June 2016:** Speakers included grantees funded through RFA-GM-09-012 and topics of discussion were retention and predictors of academic success, institutional culture and climate, evidence-based change to support women in biomedical careers, and the intersection of gender and race/ethnicity. Over 500 participants registered for the conference and more the 350 individuals viewed the live or archived videocast.
- **Research Supplements to Promote Re-Entry into Biomedical and Behavioral Research Careers, May 2016:** The NIH announced the continuation of the program for administrative supplements to research grants to support individuals with high potential to re-enter an active research career after an interruption for family responsibilities or other qualifying circumstances. The purpose of these supplements

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<sup>43</sup> Association Between Sleep-Disordered Breathing and Hypertensive Disorders of Pregnancy and Gestational Diabetes Mellitus. Facco FL, Parker CB, Reddy UM. *Obstet Gynecol.* 2017 Jan;129(1):31-41.

is to encourage such individuals to re-enter research careers within the missions of all the program areas of NIH. This program will provide administrative supplements to existing NIH research grants for the purpose of supporting full-time or part-time research by these individuals to update their existing research skills and knowledge.

- **Revised Parental Leave Policy for Ruth L. Kirschstein National Research Service Awards**, June 2016: The new policy allows trainees on institutional research training grants or individual research training fellowships to receive stipends for up to 60 calendar days of parental leave per year for the adoption or the birth of a child, regardless of whether individuals in comparable training positions at the grantee organization have access to the same level of paid leave.
- **Poster presentation at the 2016 NIH Research Festival Outlining Programmatic Efforts of the NIH Working Group on Women in Biomedical Careers**, September 15, 2016: NIH ORWH presented a poster at the NIH Research Festival highlighting the continuous efforts of the Working Group including: 1) “Advances and Insights: The Women in Science Newsletter” that showcases abstracts of scholarly peer-reviewed articles, features women researchers, and spotlights institutions with innovative programs supporting women 2) “The Women of Color Research Network” that promotes collaborations and sharing of resources among diverse groups of women 3) family-friendly policies that help employees manage work-life integration 4) educational conferences to help women establish rewarding independent research careers and 5) systematic efforts to increase the visibility of women scientists by nominating exceptional candidates for lectureships and awards. Approximately 10 scientists who are women of color were nominated in 2016 for awards given by scientific societies. One nominee was selected for the 2016 AACR Minorities in Cancer Research Award. The greatest impact of the nominations was not the number of awardees, but in providing scientists/societies with new individuals that can be invited for speaking engagements. Our successful nominee was Dr. Wortia McCaskill-Stevens <https://prevention.cancer.gov/news-and-events/news/dr-wortia-mccaskill-stevens>. Approximately 10 prominent women scientists were nominated and selected for the NIH Director’s Wednesday Afternoon Lecture Series for the 2015-2017 lecture years. This is a competitive and prestigious lecture series that is open to the public and broadly attended across the NIH.

### ***To Promote Women’s Health Research and Research on the Influence of Sex and Gender on Health and Disease***

In 2014, NIH leadership and the NIH ORWH Director stated an intention to develop and implement policies requiring applicants to consider sex as a biological variable in the design and analysis of NIH-funded research involving animals and cells (see Nature. 2014 May 15;509(7500):282-3.). This will lead to a stronger foundation upon which to build clinical research and clinical trials. To inform the development of these policies, NIH has formed a *Trans-NIH Sex as a Biological Variable Working Group*. The group is jointly co-chaired by the Director of the Office of Extramural Research (OER) and the Director of NIH ORWH. Members of the working group include senior scientists from NIH Institutes and the NIH Intramural Research Program, who are assisted in their

activities by science policy staff from OER and NIH ORWH. The charge of the working group is to develop and implement a policy requiring the consideration of sex as a biological variable in NIH-funded research. The NIH announced the new policy in October 2014 (NOT-OD-15-102) and expects that sex as a biological variable will be factored into research designs, analyses, and reporting in vertebrate animal and human studies. Strong justification from the scientific literature, preliminary data, or other relevant considerations must be provided for applications proposing to study only one sex. A subsequent guide notice (NOT-OD-16-0110) indicated that consideration of sex as a biological variable must be considered in most research grant applications submitted for due dates on or after January 25, 2016. The Trans-NIH Working Group continues to meet quarterly to develop approaches for successful implementation of the policy and dissemination of helpful resources.

NIH ORWH staff members participate actively in numerous trans-NIH and trans-federal committees germane to women's health research and research on the influence of sex and gender on health and disease, especially those involved in developing new research initiatives.

NIH ORWH plays a central role in preparing, reviewing, and clearing official reports related to women's health research and research on the influence of sex and gender on health and disease within NIH and on behalf of NIH in response to Departmental, Congressional, or other requests. For example, NIH ORWH recently reviewed the CDC's Cervical Cancer Prevention Fact Sheet. The Vital Signs Fact Sheet is a call-to-action, focusing public attention on what specific steps various key groups, especially healthcare providers, could take to ensure that all women receive the proper screening and HPV vaccination and testing appropriate for their age.

NIH ORWH staff members served on the *White House Working Group on Gender-based Violence*, which aimed to improve the collecting, analyzing, and using of data and research to enhance prevention and response efforts for gender-based violence. While not currently active, the working group released a report titled "Addressing Gender-based Violence and Empowering Women and Girls through Gender Equality" in 2016 that is available on the U.S. Department of State's website. NIH ORWH also serves on the HHS Violence Against Women (VAW) Steering Committee and works with key members of CCRWH to coordinate NIH research relevant to VAW.

## **ACTIVITIES BY NIH INSTITUTES, CENTERS, OFFICES, AND COMMITTEES**

Most centers have instituted programs that are designed to improve and promote diversity in the biomedical workforce, including for women and other minorities. Below is a sampling of activities intended to support enhancements for women and girls in biomedical careers.

- National Institute of Biomedical Imaging and Bioengineering *Programs Help Girls Consider Science Careers*<sup>44,45</sup>

"A SMART Scholars Workshop at NC State during the first weekend in August drew more than 100 girls interested in science. The foundation that helped create the program, called the Brilliant and Beautiful Foundation, was co-founded by Tiffani Bailey Lash, who earned her doctorate in chemistry at N.C. State University and is with the National Institutes of Health. Read more at the Raleigh News & Observer."

- Workshop on Advancing Women in Independent Positions (sponsored by the NIH Committee on Advancing Women in Independent Positions (CAWIP), which is part of the NIH Working Group on Women in Biomedical Careers)

On July 25, 2016, NIH ORWH convened a workshop in collaboration with Dr. Judith Greenberg, deputy director, National Institute of General Medical Sciences. The goal of the workshop was to bring together representatives from professional societies and other organizations and explore lessons learned related to the advancement of women who have already attained independent positions in the biomedical workforce.

### ***Consultation with Women's Health Professionals***

NIH ORWH actively disseminates information to the scientific community and members of the public through developing, producing, and distributing print and electronic materials. The NIH ORWH houses information related to the policy like Question-and-Answer documents, links to Requests for Information, and blog posts on the topic from NIH officials. The site also contains resources for scientists like lists of sentinel journal articles on studying sex. The website also highlights NIH ORWH programs and co-funded research on women's health and sex/gender differences at NIH. NIH ORWH also engages daily with the public on Twitter, and the NIH ORWH Director also maintains a Twitter presence with her own handle.

NIH ORWH participated in several meetings around the topic of women's cardiovascular health. The Society of Women's Health Research session on big data was held May 2016 in Washington, D.C. *WomenHeart: The National Coalition for Women with Heart Disease* held a Key Opinion Leaders' meeting in September 2016, and NIH ORWH participated in the breakout session on recruitment and retention in clinical trials.

NIH ORWH creates and manages various other online resources on women's health and sex/gender differences. NIH ORWH maintains and monitors its three-part online course, [The Science of Sex and Gender in Human Health](#), designed to educate researchers, clinicians, and students in the health professions on how to integrate knowledge of

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<sup>44</sup> The Editorial Board. Programs help girls consider science careers. *newsobserver*. 2015.

<sup>45</sup> National Institute of Biomedical Imaging and Bioengineering. Programs help girls consider science careers. *National Institute of Biomedical Imaging and Bioengineering*. 2015.



sex/gender differences and similarities into their research and practice. All courses are accredited and provide continuing education credits (CMEs, CPEs, CNEs, and CEUs) to visitors who complete the course. These courses are a collaborative effort between NIH ORWH and FDA OWH. (<http://orwh.od.nih.gov/resources/cme.asp>)

NIH ORWH, in collaboration with other NIH Institutes and the National Medical Association, is continuing the effort to encourage and support diversity in academic medicine by sponsoring the 2015-2016 NIH-NMA Travel Awards Program. The program provides the opportunity for travel awards to residents and fellows to attend the NMA's Annual Convention and Scientific Assembly and a special one and one-half day NIH Workshop on Career Development in Academic Medicine. The purpose of the program is to prepare minority post-graduate, resident and fellow trainees for careers in academic medicine and encourage research in areas that could positively affect and impact the health of minorities and those in underserved communities. The NIH ORWH Director presented during the workshop and the NIH ORWH program director for minority health/health disparities both were integral members of the planning committee. NIH ORWH has participated on an annual basis.

NIH ORWH leads NIH efforts to annually recognize and celebrate *National Women's Health Week* (NWHW). NIH ORWH staff members serve on the HHS planning committee for NWHW and coordinate activities across NIH. Events throughout the week include a scientific symposium on a relevant women's health topic and various workshops on safety, prevention, and wellness. On May 10, 2016, NIH ORWH hosted the Inaugural Vivian W. Pinn Seminar as part of the 17th annual National Women's Health Week, May 8 to May 14, 2016. The seminar honored Vivian W. Pinn, M.D., the first and former director of NIH ORWH, and featured a keynote address from Lauren V. Wood, M.D., Senior Clinical Investigator at the National Cancer Institute. The 2016 NWHW Vivian W. Pinn Seminar will continue to be viewed as an archived video cast on both the NIH and NIH ORWH websites. In addition, NIH ORWH created an online interactive visual slideshow showcasing research successes in women's health and sex differences research across the NIH ICs over the past 25 years.

## **PRESENTATIONS TO STAKEHOLDER ORGANIZATIONS**

- NIH ORWH sponsored a Pre-Conference Workshop in advance of the 23rd Women's Health Congress on Thursday, April 16 from 2:30-5:00 pm at the Grand Hyatt, Washington, D.C. The workshop, "The Health of Women of Color: A Critical Intersection at the Corner of Sex/Gender and Race/Ethnicity" featured the research of NIH intramural and extramural investigators. Topics included cancer disparities in women of color, advances and challenges in the clinical translation of therapeutic cancer vaccines, cardiovascular risk and treatment at the intersection of race/ethnicity and sex, genome-wide analysis of carotid intima-media thickness among African Americans, sexual violence and the biomedical risk for HIV infection in women, and disability outcomes: data from the Health, Aging, and Body Composition Study. This year, with over 200 registrants, marked the largest pre-congress workshop for the NIH ORWH.

- On April 7, 2015, the NIH Associate Director for Research on Women's Health participated in an HHS Public Health Reports webinar entitled "Progress in Women's Health: 1985-2015". The Director spoke about the history of NIH's Office of Research on Women's Health, ongoing NIH ORWH activities to improve our understanding of women's health across the research spectrum, and NIH ORWH public resources on women's health.
- On April 21, 2015, the NIH Associate Director for Research on Women's Health presented as part of the Presidential Symposium at the annual meeting of the Organization for the Study of Sex Differences in Palo Alto, CA. The Director's talk was entitled "Sex as IS a Biological Variable", and she discussed efforts to enhance the study of sex and gender across the biomedical research spectrum. She also participated in a Stakeholder's Forum at the meeting, organized by Canadian Health Institutes for Research Institute for Gender and Health Director Dr. Cara Tannenbaum. The forum included discussion of key elements essential to consideration of sex as a biological variable in preclinical research. The NIH ORWH Director also participated in a panel discussion on women's health organized by the Stanford University Medical Center Women's Heart Health Center.
- On April 23, 2015, the NIH Associate Director for Research on Women's Health presented the keynote address at the 2015 Annual Conference on the Neurobiology of Learning and Memory at the University of California, Irvine. The Director discussed the study of sex and gender in human health and disease, NIH efforts to enhance the study of both sexes, and the relevance of these issues for research on brain and behavior.
- On May 14, 2015, NIH ORWH co-sponsored, with the FDA's Office of Women's Health, a panel discussion during National Women's Health Week entitled "Meet the Faces of Clinical Research: Beyond Inclusion" at Lipsett Amphitheater, Building 10, NIH. The panel featured speakers from NIH and FDA as well as several former NIH clinical research participants. Panelists discussed what is involved in participating in a study, ethical issues and protections, and challenges surrounding clinical trials.
- On May 22, 2015, the NIH Associate Director for Research on Women's Health presented to the Spring Meeting of the National Primate Research Center Directors in Bethesda MD. The Director discussed NIH and NIH ORWH efforts to enhance the study of sex and gender across the biomedical research spectrum.
- On May 27, 2015, the NIH Associate Director for Research on Women's Health participated in the meeting of the NIH-PEPFAR Prevention of Maternal to Child Transmission (PMTCT) Implementation Science Alliance in Washington, D.C. The Director discussed NIH ORWH activities around global maternal and child health, and priorities for the future.
- On August 1, 2015, the NIH Associate Director for Women's Health participated in

an NIH-National Medical Association Career Development Workshop at the National Medical Association Annual Meeting, Detroit, MI. This panel discussion focused on careers in academic research, with an audience of early career MDs.

- On August 11, 2015, the NIH Associate Director for Women's Health spoke at the Partnership for Public Service Excellence in Government Fellows Program. The Director's presentation focused on her career trajectory, leadership skills, and advice for fellows.
- On September 17, 2015, the NIH Associate Director for Research on Women's Health presented to the Advisory Council of the National Institute on Alcohol Abuse and Alcoholism. The Director discussed recent NIH policy initiatives to enhance the study of both sexes and consideration of sex as a biological variable.
- On September 22, 2015, the NIH Associate Director for Research on Women's Health presented to the annual meeting of the International Society for Gender Medicine in Berlin, Germany. The Director discussed recent NIH policy initiatives to enhance the study of both sexes and consideration of sex as a biological variable.
- On September 29, 2015, Women's Policy, Inc. sponsored a lunch briefing, in cooperation with Representatives Kristi Noem, Doris Matsui, Susan Brooks, and Lois Frankel of the Congressional Caucus on Women's Issues, celebrating the 25th anniversary of the NIH Office of Research on Women's Health. Speakers included current Members of Congress Barbara A. Mikulski, Doris Matsui, Lois Frankel, Nita Lowey, Louise Slaughter, Jaime Herrera Beutler, Ambassador and former Member of Congress Connie Morella, former NIH ORWH Director Vivian W. Pinn, and current NIH ORWH Director Janine A. Clayton.
- On October 30, 2015, the NIH Associate Director for Research on Women's Health provided opening remarks at NIH Workshop entitled *Multiple Approaches to Understanding and Preventing Elder Abuse and Mistreatment*.
- On November 17, 2015, the NIH Associate Director for Research on Women's Health presented to the annual meeting of the American Association of Ophthalmology, discussing the role of cultural competence in obtaining informed consent for clinical research.
- On November 18, 2015, the NIH Associate Director for Research on Women's Health provided remarks at the launch of a report by the Lancet Commission on Women and Health, held at the University Of Pennsylvania School Of Nursing. The report, titled "Women and Health: The Key to Sustainable Development", was co-authored by Dr. Afaf Meleis, Dean of the University of Pennsylvania School of Nursing and member of the NIH Advisory Committee on Research on Women's Health. Dr. Clayton discussed the role of sex and gender in global health and disease, and NIH strategies to improve the health of women.

- On November 18, 2015, the NIH ORWH Associate Director for Clinical Research participated in a stakeholder group meeting with the FDA's Office of Women's Health, addressing NIH efforts to ensure diversity of women participating in clinical trials.
- On November 19, 2015, the NIH Associate Director for Research on Women's Health presented to the American Physiological Society's conference Cardiovascular, Renal, and Metabolic Diseases: Physiology and Gender. The Director discussed recent NIH policy initiatives to enhance the study of both sexes and consideration of sex as a biological variable.
- On November 30, 2015, the NIH Associate Director for Research on Women's Health participated in a follow-up stakeholder group meeting with the FDA's Office of Women's Health, addressing NIH efforts to ensure diversity of women participating in clinical trials.
- On November 30, 2015, the NIH Associate Director for Research on Women's Health spoke with members of the United Nations Working Group on Discrimination against Women in Law and Practice at a meeting convened by the Department of Health and Human Services (HHS) Office of Global Affairs (OGA). Dr. Clayton discussed NIH's role in enhancing research on women's health, promoting health equity, and facilitating women in biomedical careers. Other HHS attendees at the meeting included Carol Jimenez (Deputy Director, Office Minority Health, HHS), Marylouise Kelley (Director, Family Violence Prevention & Services Program, Administration for Children and Families), Nancy Lee, Director, Office of Women's Health, HHS), Shawndell Dawson (FYSB), Maeve McKean (HHS OGA), Lena Marceno (HHS Office of Minority Health), and Seema Zeya (FYSB). Working Group attendees included Eleonora Zielinska, Frances Raday, Alda Facio, Hannah Wu, and Bernadette Ardit.
- On December 8, 2015, the NIH Associate Director for Research on Women's Health, participated in a study panel on "The Future of Sex Difference Research in Neuropsychopharmacology" at the annual meeting of the American College of Neuropsychopharmacology. Dr. Clayton discussed recent implementation of NIH policy to enhance consideration of sex as a biological variable in research with vertebrate animals and humans.
- On February 8, 2016, an NIH ORWH medical officer and an NIH Office of Extramural Research program officer presented to the American Heart Association Research Committee via Webinar. The topics were "Studying Both Sexes in NIH-Funded Preclinical Research" and "NIH Grants Policy on Sex as a Biological Variable."
- On February 10, 2016, *A Fix for Gender-Bias in Animal Research Could Help Humans* aired on National Public Radio's (NPR's) All Things Considered. The NIH Associate Director for Research on Women's Health was interviewed for the story by

NPR reporter Rae Ellen Bichell on November 20, 2015. The 4-minute story addressed changes that NIH's 2016 "Sex as a Biological Variable" guidelines are expected to bring, and what cases in the past have shown that accounting for sex as a biological variable is a requirement for good science. The story also covered the contradistinction between NIH ORWH publications on the issue and a recent paper that was critical of the policy. The piece was formatted for both radio and web, with the accompanying web post on NPR's health blog, *Shots*.

- On February 29, 2016, the NIH Associate Director for Research on Women's Health participated in a panel discussion entitled "Challenges and Solutions" at the FDA Safety and Innovation Act (FDASIA) Public Meeting: "Progress on Enhancing the Collection, Analysis, and Availability of Demographic Subgroup Data." The Director discussed the importance of diversity in clinical studies; the NIH Revitalization Act of 1993 inclusion policy; and success strategies for enrolling women and minorities in clinical studies.
- On March 3, 2016, the NIH Associate Director for Research on Women's Health was invited to speak with Dr. Ellen Stofan, Chief Scientist, National Aeronautics and Space Administration (NASA), on how the SABV policy was developed, challenges faced, and the road ahead. NASA is considering implementing its own policy on SABV modeled after the NIH policy.
- On March 18, 2016, the NIH Associate Director for Research on Women's Health spoke with the American Psychological Association's Council of Editors at the Annual APA Journal Editors meeting on how the policy on sex as a biological variable can be championed by journal editors to ensure uptake of the policy in publications.
- On April 6, 2016, the NIH Associate Director for Research on Women's Health delivered the Tulane Building Interdisciplinary Research Careers in Women's Health (BIRCWH) Distinguished Lecture. The lecture was to recognize leaders in women's health research and sex differences research, and to inform the community about advances and opportunities in these fields. The event was part of the Tulane Health Sciences Days, which showcased the diversity of health science-related research at Tulane.
- On April 14, 2016, NIH ORWH sponsored a Pre-Conference Workshop in advance of the 24th Women's Health Congress, Crystal City Marriott, Arlington, Virginia. The workshop, "Transforming Women's Health: From Research to Practice" featured the research of five NIH scientists. Topics included polycystic kidney disease, cellular responses following AIDS vaccination, gender differences in adolescent mood and behavior, sex/gender differences in drug addiction, and cardiovascular risk and outcomes.
- On April 19, 2016, the 41st meeting of the NIH Advisory Committee on Research on Women's Health (ACRWH) was held at Natcher Conference Center, NIH, Bethesda,

Maryland. Presentations included: NIH ORWH Director's Report; Women's Health Initiative; Zika virus; Sex as a Biological Variable (SABV) and Alcohol; and Updates on Inclusion, Mid-point Strategic Plan, Raising the Bar – National Academies of Sciences, Building Interdisciplinary Research Careers in Women's Health (BIRCWH), and Specialized Centers of Research (SCOR) on Sex Differences.

- On April 26, 2016, the NIH Associate Director for Research on Women's Health participated at the Uniformed Services University 2016 Military Women's Health Research Conference. The Associate Director was on the *Unity of Effort Leadership Panel* along with other VIP leaders from the Uniformed Services University, Walter Reed National Military Medical Center, John P Murtha Cancer Center, National Institutes of Health, Defense Medical Research & Development Program in the Office of Force Health Protection and Readiness Programs, Department of Veterans Affairs, and US Department of Health and Human Services.
- On May 10, 2016, NIH ORWH hosted the Inaugural Vivian W. Pinn Seminar as part of the 17th annual National Women's Health Week, May 8 to May 14, 2016. The seminar honored Vivian W. Pinn, M.D., the first and former director of NIH ORWH, and featured a keynote address from Lauren V. Wood, M.D., Senior Clinical Investigator at the National Cancer Institute.
- On May 18, 2016, the NIH Associate Director for Research on Women's Health visited the Weill Department of Medicine as the 2016 Lila A. Wallis, M.D. Distinguished Visiting Professor in Women's Health. She presented on the importance of studying both sex and gender.
- On May 24, 2016, the NIH Associate Director for Research on Women's Health presented an overview of the path to the development of the policy on Sex as a Biological variable at the Organization for the Study of Sex Differences 2016 Conference Presidential Symposium titled "Getting Basic Scientists to Think about Sex." The Director also chaired a panel discussion following the talk.
- On June 15, 2016, the NIH Associate Director for Research on Women's Health presented an overview of the path to the development of the policy on Sex as a Biological variable at the National Hispanic Science Network 16th Annual International Conference. Dr. Clayton was invited to speak in an interdisciplinary panel on Sex and Gender Differences in Substance Use and Health.
- On July 15, 2016, the NIH Associate Director for Research on Women's Health participated in a Health Roundtable on the impact of gender/sex on innovation and novel technologies (iGIANT), an initiative developed by the White House Office of Science and Technology Policy and hosted by HHS OWH. The purpose of the roundtable was to help establish a common dialog about best practices and to inspire participants to serve as ambassadors for innovation.

- On September 8, 2016, the NIH Associate Director for Research on Women's Health delivered the address for the 6<sup>th</sup> Claes H. Dohlman Conference at the 8<sup>th</sup> International Conference on the Tear Film & Ocular Surface (TFOS): Basic Science and Clinical Relevance, held in Montpellier France. Her topic was "Studying Both Sexes: A Guiding Principle for Ophthalmology." This conference was designed to assess the current knowledge and 'state of the art' research on the structure and function of the tear film and ocular surface in health and disease. The TFOS conference promoted an international exchange of information that was of value to basic scientists involved in eye research, to clinicians in the eye care community, and to companies with an interest in the diagnosis and/or treatment of tear film and ocular surface disorders. There were over 300 oral and poster presentations at this conference and over 600 attendees.
- On October 19, 2016, an NIH ORWH medical officer and NHLBI program officer presented to the American Physiological Society's Animal Care & Experimentation Committee in Bethesda, Maryland. The topic was "What you need to know to apply the Sex as a Biological Variable (SABV) policy: We're all in this together!"

### ***CCWH Membership***

NIH ORWH serves as the NIH liaison to HHS OWH on women's health research across HHS through membership on the HHS Coordinating Committee on Women's Health (CCWH).

### ***Additional Activities***

In addition to the activities listed here, please see the 2015 *National Institutes of Health - Report of the Advisory Committee on Research on Women's Health, Fiscal Years 2013–2014: Office of Research on Women's Health and NIH Support for Research on Women's Health* at <https://orwh.od.nih.gov/research/reports/2013-2014-report/>. The Advisory Committee on Research on Women's Health, in collaboration with NIH ORWH and the NIH Coordinating Committee on Research on Women's Health (CCRWH), submitted this biennial report to the Director of NIH. The report, although not a totally comprehensive listing of all NIH research on women's health, does provide a summary of notable accomplishments over a two-year period. The 2015-2016 version of this report is underway and should be completed by September 2017.

### ***Additional Publications***

Barfield WL, Plank-Bazinet JL, Austin Clayton J. Advancement of Women in the Biomedical Workforce: Insights for Success. *Academic medicine : journal of the Association of American Medical Colleges*. 2016.

Blehar MC, Spong C, Grady C, Goldkind SF, Sahin L, Clayton JA. Enrolling pregnant women: issues in clinical research. *Womens Health Issues*. 2013;23(1):e39-45.

- Brooks BP, Thompson AH, Bishop RJ, et al. Ocular manifestations of xeroderma pigmentosum: long-term follow-up highlights the role of DNA repair in protection from sun damage. *Ophthalmology*. 2013;120(7):1324-1336.
- Clayton JA. Studying both sexes: a guiding principle for biomedicine. *Faseb j*. 2016;30(2):519-524.
- Clayton JA, Brooks C, Kornstein SG. Toward more individualized medicine: introducing the Women of Color Health Data Book, Fourth Edition. *Journal of women's health (2002)*. 2014;23(10):781-782.
- Clayton JA, Collins FS. Policy: NIH to balance sex in cell and animal studies. *Nature*. 2014;509(7500):282-283.
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## **Substance Abuse and Mental Health Services Administration (SAMHSA) Office of Women's Health**

### ***Associate Administrator for Women's Services***

The Substance Abuse and Mental Health Services Administration (SAMHSA) was established in 1992 within HHS. SAMHSA's mission is to reduce the impact of substance abuse and mental illness on America's communities. Through its centers and offices, SAMHSA seeks to improve the delivery and financing of prevention, treatment, and recovery support services for mental and/or substance use disorders in the United States, improving health and reducing health care and other costs to society.

SAMHSA fulfilled its statutory requirement under section 3509(d) of the Affordable Care Act and section 501(f) of the Public Health Service Act [42 U.S.C. 290aa(f)], by appointing an Associate Administrator for Women's Services (AAWS). In further compliance with the requirement of section 3509(d), the AAWS reports directly to the Assistant Secretary for Mental Health and Substance Use.

The AAWS established the *SAMHSA Women's Coordinating Committee* (SWCC). Its purpose is to identify substance use and mental health needs and to coordinate the provision of behavioral health services for women through SAMHSA's Center for Mental Health Services, Center for Substance Abuse Prevention, Center for Substance Abuse Treatment, and Center for Behavioral Health Statistics and Quality. The SWCC is legislatively mandated 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 women's services; 3) encourage support from all agencies in the Administration to support women's services; and 4) ensure the unique needs of minority women are recognized and addressed within SAMHSA.

SAMHSA's Advisory Committee for Women's Services (ACWS) is statutorily mandated. Its functions follow: 1) Advise the Assistant Secretary for Mental Health and Substance Use and AAWS on appropriate activities to be undertaken by SAMHSA, regarding women's substance abuse and mental health services; 2) Develop plans to standardize and enhance the collection of data on women's health; 3) promote the allocation of sufficient resources for women's services within each SAMHSA Center; 4) Oversee the conduct of appropriate evaluation of women's services; and 5) Monitor SAMHSA's recruitment and hiring of women in senior positions. ACWS members include physicians, practitioners, treatment providers, other health professionals, and consumers. Members have the clinical practice, specialization, or professional expertise that includes a significant focus on women's substance use and mental health conditions.

### ***Report on Current Level of Activities***

SAMHSA identified six strategic initiatives between 2015-2017 that meet the agency's mission of reducing the impact of substance abuse and mental illness on America's communities, including those specifically related to women and girls.

1. Prevention of Substance Abuse and Mental Illness
2. Health Care and Health Systems Integration
3. Trauma and Justice
4. Recovery Support
5. Health Information Technology
6. Workforce Development

Given that these initiatives are customer-centric, SAMHSA's approach to the strategic initiatives includes the use of a gender-specific lens and gender responsive approaches.

SAMHSA undertook the following list of projects and activities to address the behavioral health needs of women during the reporting period March 2015-2017.

### ***Women's Health-Related Goals and Objectives***

SAMHSA provided technical assistance to support a broad range of publicly funded systems, SAMHSA grantees, consumer organizations, and peer-run organizations serving women and girls, including mental health, substance use, developmental disabilities, primary health care, and criminal and juvenile justice. Technical assistance in 2015 and 2016 included in-depth trainings ranging from one to two days, onsite consultation, coaching, and virtual learning communities focused on implementation of trauma-informed, gender-responsive approaches to meet the needs of women and girls impacted behavioral health conditions, violence and abuse. For instance, in 2015, SAMHSA provided training to project officers and grantees in the Targeted Capacity Expansion Minority Women and AIDS grant program on SAMHSA's concept of trauma and guidance for a trauma-informed approach. In addition, on-site consultation and follow-up as well as long-distance coaching was provided to the Mental Health Transformation Grant program on building, supporting, and sustaining the peer workforce, and providing trauma-informed services and supports to women.

From January 2015 to August 2015, and from September 2015 to May 2016, SAMHSA sponsored two Women's Addiction Services Leadership Institute (WASLI) cohorts. WASLI is a comprehensive leadership program that fosters the growth of emerging leaders in women's behavioral health services and strengthens their capacity to serve women with substance use and co-occurring disorders; it includes leadership assessments and in-person Immersion and Enhancement trainings. The WASLI program in 2015 focused on emerging leaders; the 2016 cohort centered primarily on State Women's Services Coordinators.

In 2016, SAMHSA published the *Guidance Document for Supporting Women in Co-ed Settings*, which offers best practices for treating women with substance use disorders in

co-ed treatment and recovery settings. It was important to address supporting women with substance use disorders (SUDs) in these settings because most women receiving treatment for SUDs are served in treatment and recovery centers that serve both men and women. In addition, it is important to support women with SUDs in co-ed settings because men usually outnumber women in these centers. The purpose of this document is to articulate principles and practices that co-ed centers can easily use to assess and improve their programs and practices to serve women more effectively.

In 2016, SAMHSA published a guidance document entitled “*A Collaborative Approach to the Treatment of Pregnant Women with Opioid Use Disorders.*” This guidance publication supports efforts of states/tribes, as well as local communities, to address the needs of pregnant women with opioid addictions, as well as their infants and families. In addition, SAMHSA offers a program of in-depth technical assistance for state teams working to address the needs of opioid dependent pregnant women and their infants.

On February 7-8, 2017 in Baltimore, Maryland, SAMHSA and the Administration on Children, Youth, and Families (ACYF) through the National Center on Substance Abuse and Child Welfare convened a State Policy Academy composed of cross-systems partners to enhance capacity to meet the needs of pregnant and postpartum women with opioid use disorders, their infants born with and affected by prenatal exposure and other family members or caregivers. The Policy Academy supported teams to create a state-specific policy agenda and Action Plan and strengthen collaboration across systems to address the multiple and complex needs of this population.

In FY 2015 and 2016, SAMHSA’s Center for Substance Abuse Treatment (CSAT) funded the creation and maintenance of an Addiction Technology Transfer Center (ATTC) Center of Excellence on Behavioral Health for Pregnant and Postpartum Women and Their Families (ATTC CoE-PPW). Its purpose is to develop and maintain a comprehensive online toolkit and conduct trainings to support the work of behavioral health and medical professionals, policymakers, and other stakeholders serving pregnant and postpartum women (PPW) and their families. The ATTC CoE-PPW provides the first national clearinghouses on a family-centered approach to treatment and recovery. The ATTC CoE-PPW’s dynamic toolkit is updated on an ongoing basis and provides the infrastructure to feature resources and developments from the field. Key toolkit features include: downloadable free or low-cost training curricula (e.g., webinettes), a program resources library with over 100 tools of the latest research and practical application guides, connections to other programs in order to learn about innovative approaches, and funding, policy, and program evaluation resources available for PPW programs. To learn more about the ATTC CoE-PPW, please visit [www.attcppwtools.org](http://www.attcppwtools.org).

On July 27-29, 2016, SAMHSA’s CSAT convened a Pregnant and Postpartum Women (PPW) Family-Centered Summit titled, “Moving Towards Family-Centered Care.” The Summit was designed to elicit recommendations from experts in the area of women’s substance use disorder services and family-centered care to inform the expansion of CSAT’s PPW program to incorporate a wider range of family-centered services for pregnant and postpartum women and their minor children. This includes the expansion of

treatment modalities to include not just residential treatment but also intensive outpatient treatment with or without housing components (i.e., sober living homes).

The goal of the Summit was to reach consensus regarding effective strategies for implementing a family-centered approach to support substance use disorder prevention, treatment, and recovery services for pregnant and postpartum women and their families in various residential and outpatient settings. This included the identification of: the key elements of a well-coordinated; integrated system of care that promotes improved family functioning, economic stability; quality of life and supports sustained recovery; financing strategies to fund essential and adjunct services; outcome measures that could be used to evaluate the effectiveness of family-centered program models; and the types of technical assistance and support the field needs to implement a family-centered approach.

The intended outcomes of the Summit follow:

1. Define the evidence-based core and adjunct services critical to a family-centered approach.
2. Identify successful strategies for identifying and establishing effective, sustainable partnerships with community stakeholders to support the delivery of family-centered care.
3. Provide concrete examples of how existing funding streams can be used to sustain an integrated and flexible continuum of care by de-categorization, pooling, blending, braiding, refinancing or using wraparound funding.
4. Determine the quality indicators that should be used to evaluate the effectiveness of family-centered care and how to measure change in practice and outcomes from a systems perspective.
5. Gather recommendations for the content to be included in a toolkit/technical assistance document to guide states and communities in the implementation of a family-centered approach.

Sixty-four experts from the field attended the Summit. Participants included; program developers, directors and managers, clinical directors, financial managers, nationally recognized consultants to the field, university faculty, PPW grantees, researchers, evaluators and technical assistance providers. SAMHSA is reviewing recommendations from the Summit and taking them into consideration in determining the future direction of the PPW Program, including the development of service requirements for the PPW program expansion effort to support wide-scale adoption of the family-centered approach. SAMHSA is working with the Addiction Technology Transfer Center (ATTC) Center of Excellence on Behavioral Health for Pregnant and Postpartum Women and Their Families (ATTC CoE-PPW) to disseminate information from the Summit to the field.

During the reporting period, SAMHSA continued support for the Residential Treatment for Pregnant and Postpartum Women (PPW) grant program. The purpose of this program is to expand the availability of comprehensive, residential substance abuse treatment, prevention, and recovery support services for pregnant and postpartum women and their minor children, including services for non-residential family members of both the women and their children. The populations of focus are low-income (according to federal poverty guidelines) women, age 18

and over, who are pregnant, postpartum (the period after childbirth up to 12 months), and their minor children, age 17 and under, who have limited access to quality health services. SAMHSA has also identified traditionally underserved populations, especially racial and ethnic minority women, as a population of focus. In FY 2015, six new PPW grants were awarded. In FY 2016, two new PPW grants were awarded. Per SAMHSA's publicly available forecast, 18 new PPW grants are anticipated in FY 2017. Additionally, the State Pilot Grant Program for Treatment for Pregnant and Postpartum Women was initiated with the purpose to enhance flexibility in the use of funds designed to: 1) support family-based services for pregnant and postpartum women with a primary diagnosis of a substance use disorder, including opioid disorders; 2) help state substance abuse agencies address the continuum of care, including services provided to women in nonresidential-based settings; and 3) promote a coordinated, effective and efficient state system managed by state substance abuse agencies by encouraging new approaches and models of service delivery.

In FY 2014, SAMHSA initiated a campaign to inform the public about the child trauma efforts and resources available through the *National Child Traumatic Stress Initiative* (NCTSI). This *Helping Kids Recover and Thrive* campaign has now reached television and radio audiences with over 600 million impressions nationwide, through PSAs in Spanish and English that have aired over 150,000 times. The online web resources located at [samhsa.gov/child-trauma](http://samhsa.gov/child-trauma), highlight the impact of childhood trauma and provide the public with key information on recognizing traumatic stress and ways to access support.

For example, a SAMHSA's NCTSI program grantee (The Village Collaborative Trauma Center in Hartford, CT) sponsored the Annual "Girl Within" Event in December 2015. This event celebrates over 100 years of helping young women and girls who have experienced abuse and neglect make sustainable progress toward recovery and independence. The featured speaker was Mia Fontaine, author of New York Times bestseller *Come Back: A Mother and Daughter's Journey Through Hell and Back*, who told her story of being abused by her father and her journey through drug addiction and to healing and recovery. She showed how change is possible and how trauma and pain can strengthen and empower survivors to become healthy adults and powerful advocates for improved services for children and families. There was also a presentation by one of our former group home residents, who shared her story about struggle from trauma, and her journey of healing. There were 440 in attendance for this event.

In FY 2015- 2016, and in partnership with the Centers for Medicare and Medicaid Services, the program collaborated to initiate a mechanism for child trauma (complex trauma) to be an allowable condition for inclusion in CMS supported Health Homes, creating opportunity for thousands more children with serious trauma exposure to receive evidence supported assessment and intervention.

In FY 2016, SAMHSA funded the Targeted Capacity Expansion-HIV: Substance Use Disorder Treatment for Racial/Ethnic Minority Women at High Risk for HIV/AIDS grant program and funded 23 grantees, for three years, with an average award of \$500,000. The purpose of this program is to expand substance use disorder (SUD) treatment, behavioral

health, and HIV/AIDS services for high risk women of African American, Hispanic/Latina, and other racial/ethnic minority groups, including heterosexual, lesbian, bisexual, transgender, previously incarcerated women, and their significant others, who have substance use or co-occurring substance use and mental disorders and are living with or at risk for HIV/AIDS. The grant will fund programs that provide integrated services of behavioral health treatment and HIV medical care.

Between 2015-2017, SAMHSA developed and presented two webinar series to expand workforce qualifications in serving women and girls. In 2015, SAMHSA presented *Women Matter! An Introduction to Women, Addiction, and Recovery*, a five-part webinar series to expand awareness and workforce qualifications in serving women and girls. Topics included: co-occurring disorders, families and relationships, health, wellness and recovery, serving women in co-ed settings and services for women involved with the criminal justice system. SAMHSA also developed and held the first two webinars of the five-part *Relationship Matters!*: a webinar series on women's behavioral health. These series featured research, best practices, and critical thinking about key areas that professionals working with women and girls who are experiencing mental health and substance abuse issues need to know. SAMHSA maintained access to recorded sessions as well as the 2014 *Girls Matter!* series on the programs and campaign webpage on Women, Children and Families.

SAMHSA developed the *Training Tool Box for Addressing the Gender-Specific Service Needs of Women with Substance Use Disorders*, which was released in March 2017. The Tool Box is a resource to help trainers educate the workforce about the gender-specific needs of women with substance use disorders. The Tool Box enables clinical supervisors, program directors, and advocates to customize workforce learning for providers, clinicians, and peers in diverse settings across the addiction continuum. It equips users with PowerPoint slides, talking points, activities, case studies, resources, and references to train staff and others on gender-responsive, trauma-informed approaches to SUD services and make a compelling case for effective interventions for women.

### ***Collaboration with HHS Agencies and Offices***

- SAMHSA continues to collaborate with HHS and Department of Justice (DOJ) agencies on initiatives that promote the health and well-being of women and girls. During the reporting period, SAMHSA actively participated as a member of the HHS Working Group on the Intersection of HIV/AIDS, Violence Against Women and Gender-related Health Disparities.
- SAMHSA also participated in the development of the Interagency Federal Working Group Report addressing this intersection and the related action steps.
- SAMHSA is collaborating with the Office of Women's Health on a three-year initiative to strengthen the coordination of mental health services for women

through a comprehensive public health system approach. The overarching goal of the initiative is to improve mental health among women and girls through a gender-based approach.

- SAMHSA staff serves as members of both the HHS Steering Committee on Violence against Women and the HHS Workgroup on Health Considerations in the Federal Strategic Action Plan for Services for Victims of Human Trafficking.
- In conjunction with HHS OWH, NIDA, ACF, and other HHS agencies and offices, SAMHSA staff helped to plan and participate in the implementation of the HHS Research Symposium on Interpersonal Violence (IPV) Screening and Brief Counseling.
- Practice and policy initiatives were supported through collaboration with the State Women's Services Coordinators/Women's Services Network (WSN), which is a specialty network of the National Association of State Alcohol and Drug Abuse Directors (NASADAD) under the auspices of the National Treatment Network and in collaboration with the National Prevention Network.

## PUBLICATIONS

SAMHSA supports a website that contains data from SAMHSA's survey and related analyses at <http://www.samhsa.gov/data/topic.aspx>. This site contains many reports on women and girls. During the reporting period, the following reports were produced that include breakdowns of gender related data: National Mental Health Services Survey; Data on Mental Treatment Facilities, National Survey on Drug Use & Health (NSDUH), Mental Health Client-Level Data, and Uniform Reporting System

- Center for Behavioral Health Statistics and Quality (CBHSQ). (2016). *Spouses and Children of U.S. Military Personnel: Substance Use and Mental Health Profile from the 2015 National Survey on Drug Use and Health*. Rockville, MD: Substance Abuse and Mental Health Services Administration.
- Center for Behavioral Health Statistics and Quality (CBHSQ). (2016). *Women of Childbearing Age and Opioids*. Rockville, MD: Substance Abuse and Mental Health Services Administration.
- Training Tool Box for Addressing the Gender-Specific Service Needs of Women with Substance Use Disorders (2016). This Training Tool Box was developed to facilitate development and delivery of customized trainings and presentations on addressing the unique needs of women with substance use and co-occurring disorders. <https://www.samhsa.gov/women-children-families/trainings/training-tool-box>



- Guidance Document for Supporting Women in Co-Ed Settings (2016). Guide for clinicians, which focuses on best practices for treating women who have substance use disorders (SUDs) and are being served in co-ed treatment and recovery settings. The document highlights gender differences related to SUDs, gender-responsive services, trauma-informed care, cultural sensitivity, and developing healthy relationships.
- Depression in Mothers: More Than The Blues (2016) This toolkit equips providers with information about depression, and offers strategies in working with mothers who may be depressed. The toolkit includes resources, referrals and handouts for depression, and screening tools for more serious depression. <https://store.samhsa.gov/product/Depression-in-Mothers-More-Than-the-Blues/SMA14-4878>
- SAMHSA maintains a website on women's mental health and substance abuse treatment issues, including information on training, publications, and links to other federal government resources on women (<http://www.samhsa.gov/women-children-and-families>).

### ***Stakeholder Outreach and Education***

- By helping and partnering with states, territories, tribes, and communities to prevent illness and promote recovery, SAMHSA strives to improve the lives of those it serves by providing a range of support to meet unique needs across diverse levels of society. SAMHSA, together with many partners, has demonstrated that prevention works, treatment is effective, and people recover from mental and substance use disorders.
- SAMHSA co-sponsored two webinars to the public offered through the Federal Partners Intergovernmental Committee on Women and Trauma. One webinar focused on the work of the Committee and the other on the intersection of mental illness, addictions disorders, and trauma for women and girls. Average participation for each webinar was over 2,000 participants.
- SAMHSA partnered with the DOJ Office of Justice Programs' National Resource Center on Justice-Involved Women to create a taskforce charged with drafting guiding principles and a best-practices statement to reduce the use of restraints among pregnant incarcerated women. SAMHSA provides ongoing technical assistance and training on implementing Trauma-Informed Care and Reduction of Seclusion and Restraints to justice-related institutions serving women and girls.
- SAMHSA's National Center for Trauma Informed Care (NCTIC) is a five-year TA Task Order that provides technical assistance and consulting to publicly-funded systems, including justice-related institutions serving women and girls. The contract is in its second year of its and is focused on implementation of SAMHSA's guidance for a trauma informed approach: priorities for this option year are crisis response, peer empowerment, and trauma-informed inquiry, assessment, and response in primary and other health care settings.
- SAMHSA modified the monitoring protocol for Mental Health Block Grant (MHBG)

to include gender specific and gender responsive service delivery, data and evaluation, state agency system development and stakeholder collaboration.

- SAMHSA provided on-site technical assistance for state and tribal government on MHBG monitoring visits to integrate human trafficking policies, protocols and data collection.
- SAMHSA provides a grant to fund The State Women's Services Coordinators work together as the Women's Services Network, a specialty network of the National Association of State Alcohol and Drug Abuse Directors (NASADAD) under the auspices of the National Treatment Network and in collaboration with the National Prevention Network.
- SAMHSA is in the planning stages for webinars and trainings on human trafficking for tribal, state, and local governments.

### ***CCWH Membership***

SAMHSA is an active participant on the HHS Coordinating Committee on Women's Health.

#### **IV. OTHER HHS AGENCIES AND OFFICES**

Although section 3509 of the Affordable Care Act does not have specific requirements for other HHS federal agencies and offices, the section specifies that AHRQ, CDC, HRSA, and FDA consult with health professionals on policies. The section also requires that the HHS CCWH include senior-level representatives from each HHS agency and office.

The following HHS agencies and offices contributed to or supported efforts under section 3509, including but not limited to serving as members of the HHS Coordinating Committee on Women's Health.

The activities described below reflect the progress of each agency and office on their agency- and office-specific requirements in the reporting period of March 23, 2015–March 23, 2017, which is two years after the third annual report was submitted on March 23, 2015, as required by section 3509.

## **IV. Other HHS Agencies and Offices**

### **Administration for Children and Families (ACF)**

The Administration for Children & Families (ACF) promotes the economic and social well-being of families, children, individuals, and communities with funding, strategic partnerships, guidance, training, and technical assistance. ACF has 19 offices, including the Office of Regional Operations, which represents 10 regional offices around the country. Each office is specialized in its mission, supporting initiatives that empower families and individuals and improve access to services in order to create strong, healthy communities.

ACF administers more than 60 programs, which fund a variety of projects from Native American language preservation to refugee resettlement to child care. By partnering with states and communities, ACF funding provides critical assistance to vulnerable populations and helps families achieve prosperity and independence. ACF-funded programs find safe and supportive families for abused children, help parents find jobs, support individuals with developmental disabilities, and work with troubled teens to leave the streets and find a path toward hope and opportunity.

#### ***Office of Trafficking in Persons***

ACF and OWH partnered in 2014 to design and pilot a training program for health care providers to identify victims of human trafficking. Victims of trafficking are disproportionately women (84.9 percent of cases documented by the National Human Trafficking Resource Center) and can often present a wide-range of physical and psychological health issues and social service needs. This training is designed to equip these professionals with resources and tools to increase the number of potential victims identified and appropriately responded to in their work settings. It also reflects a shift towards a public health framework that is rooted in victim-centered and trauma-informed care.

Informed by the feedback and recommendations on the initial design throughout 2015 and 2016, ACF and OWH leveraged the expertise of trafficking survivors, social service providers, and health care professionals through the 2016 SOAR Technical Working Group. It resulted in the production of the 2016 *SOAR to Health and Wellness Training*. Across 17 sessions, more than 770 individuals were trained.

Approximately 84 percent of training registrants indicated that their area of expertise aligned with the four intended audiences: health care professionals, social service providers, public health professionals, and behavioral health professionals. Many registrants were already working with and providing services to multiple, overlapping, vulnerable populations, including those individuals who suffer from mental illness; victims of intimate partner violence (IPV) and sexual assault; lesbian, gay, bisexual,

transgender, queer/questioning (LGBTQ) individuals, domestic victims of human trafficking; individuals with disabilities; and non-refugee ethnic minorities.

### *Administration for Children, Youth, and Families Family and Youth Services Bureau*

## **FAMILY VIOLENCE PREVENTION AND SERVICES ACT PROGRAM**

Domestic violence is a health care problem of epidemic proportions. Domestic violence can result in immediate trauma and can have a long-term impact on a survivor's or victim's health and often limits the individual's ability to manage other chronic illnesses such as diabetes and hypertension. Despite these facts, a critical gap remains in the delivery of health care to victims of domestic violence. For over 16 years, the Family Violence Prevention & Services Program, a division of the Family & Youth Services Bureau (FYSB) in ACF which administers the Family Violence Prevention & Services Act (FVPSA), has supported national training and technical assistance to address the short-term and long-term health impacts of domestic violence.

FVPSA is the primary federal funding source dedicated for organizations that work to end domestic violence by

- providing emergency shelter and supportive services to victims of domestic violence; and
- preventing domestic violence through advocacy, public awareness, education, and outreach.

FVPSA funds States and Territories (70%), Tribes (10%), State Domestic Violence Coalitions (10%), National and Special Issue Resource Centers (6%), Discretionary Programs (1.5%) and Program Evaluation, Monitoring, and Administration (2.5%).

The FVPSA Program has spent years building partnerships with federal agencies and grantees to address the pervasive impact of domestic violence, dating violence, and trauma across the lifespan for survivors of domestic violence and their children.

### **Intimate Partner Violence (IPV) Workgroup with State Domestic Violence Coalitions**

FYSB's FVPSA Program has established, and continues to steer, an IPV workgroup among state domestic violence coalitions connecting domestic violence stakeholders and health care practitioners. The workgroup advocates the development of IPV tools specifically designed for advocates; identifies implications of enhanced screening and counseling in health settings; surveys local programs for barriers, successes, and challenges; and informs FVPSA Program efforts through feedback on the development of resources for health care screening.

### **Promoting Technical Assistance through the National Health Resource Center on Domestic Violence**

FYSB's FVPSA Program supports ongoing capacity building by National Health Resource Center on Domestic Violence (HRCDV) to provide training and technical assistance on IPV prevention, intervention, and response within healthcare settings through the expertise of practice-area and culturally-specific resource centers and institutes. The HRCDV, a project of Futures Without Violence, has been funded by the FVPSA Program for over 16 years. Collaboration between domestic violence advocates and health professionals is the cornerstone of all FVPSA-supported HRCDV programs and resources. Each year the HRCDV trains over 4,600 providers and distributes hundreds of thousands of patient and provider education materials to over 22,000 professionals nationwide. It also provides in-depth individual technical assistance to more than 1,500 people a year.

As a FVPSA-funded resource center, the HRCDV addresses the health care response to victims of domestic violence. In the past year, the HRCDV provided education to over **10,000** people through **70** trainings and **30** webinars. Moreover, HRCDV staff have disseminated over **1,000,000** patient/provider education tools nationwide to help providers screen and provide brief counseling. The HRCDV also featured information about the ACA and DV at its 7<sup>th</sup> Annual National Conference on Health and Domestic Violence which was attended by **1000** participants and included a keynote speech by Vice President Biden, <http://nchdv.org/>.

The HRCDV has safety cards that can be given to patients or placed in the clinic or other health care setting. In addition, HRCDV's website has other training resources and e-learning CME modules on the overview of domestic violence, preparing your practice, primary care, and confidentiality. Training resources have also been developed on specific settings and specialties such as mental health, reproductive health, urgent care, pediatrics, adolescent health, STI/HIV, and home visitation.

### ***Collaborations and Consultation***

#### **Intimate Partner Violence Screening and Counseling Pilot Project**

Through an interagency collaboration with the Health Resources and Services Administration (HRSA) Bureau of Primary Health Care (BPHC) and the HRSA Office on Women's Health, the FVPSA Program partners with BPHC to provide intimate partner violence and trauma-informed training and technical assistance for HRSA-funded primary health clinics through the *Intimate Partner Violence Screening and Counseling Pilot Project*. This collaboration includes intensive technical assistance and domestic violence program partnership building, offered by the HRCDV, a FVPSA-funded resource center, to 9 health clinics.

As a result of the above-mentioned pilot project, two online toolkits were developed and published for use to increase and sustain partnerships by health care providers and advocates working to end intimate partner violence.

#### **Health Cares About IPV Toolkit**

FYSB's FVPSA Program and the HRCDV maintains an online toolkit entitled the *Health Cares About IPV Screening and Counseling Toolkit*, <http://www.healthcaresaboutipv.org>. This toolkit aims to help health care providers and advocates learn more about how to help women be healthy and safe, using fact sheets, archived webinars, and tools and resources related to the Affordable Care Act. For example, this toolkit includes fact sheets for advocates and health care providers to help them understand the new health policy changes specific to domestic violence; two frequently asked questions about the new Affordable Care Act IPV screening and counseling guidelines; a basic 101 memo on the Marketplaces and how to get health insurance; and a list of the Marketplaces, by state. The website receives approximately 1,000 views per month. Relevant HRC blogposts entitled *Survivors of Domestic Violence Can Now Get Access to Health Coverage at Any Time* and *What Domestic Violence Survivors Need to Know About Affordable Health Coverage* have received over 5200 views.

### **IPV Health Partners Toolkit**

IPVHealthPartners.org is an online toolkit for establishing and expanding partnerships between community health centers and local domestic violence/sexual assault (DV/SA) agencies. This toolkit was developed in partnership with twenty programs that participated in the *Improving Health Outcomes through Violence Prevention Project* and federal partners in FVPSA and HRSA. The toolkit offers easily adaptable tools making it the go-to resource for community health centers and DV/SA agencies partnering to improve the health and safety of survivors of DV/SA. This online toolkit was launched in tandem with [ipvhealth.org](http://ipvhealth.org). Access the online toolkit via the link, <http://ipvhealthpartners.org/>.

### **Interagency Workgroup on Violence Against Women**

FYSB's FVPSA Program Director serves as member of this Workgroup. In this capacity, she collaborates on projects and strategic planning advancing women's health as it relates to the prevention of gender-based violence and support services as well as the development and dissemination of resources for victims of intimate partner violence. This group continues to meet via phone on a monthly basis with quarterly in-person meetings.

### **Interagency Workgroup on Women and Trauma**

FYSB's FVPSA Program staff are members of the Women and Trauma Federal Partners Committee, which was launched in April 2009. In 2014, FYSB's FVPSA Program served as the coordinator of the Women and Trauma Committees national webinar series that reached more than 2,000 individuals. As of March 2017, this groups meets as needed or on a bi-monthly basis.

### **HHS Steering Committee on Violence Against Women**

FYSB's FVPSA Program Director Co-chairs this Steering Committee which coordinates Department-wide efforts to build the capacity of health and human service agencies and

programs to prevent and respond to violence against women and girls. The Steering Committee works to raise public awareness of the health impacts of abuse, ensuring that all HHS components consider the effects of violence against women and girls on health and wellbeing. This group meets semi-monthly in-person and via phone.

### **The Domestic Violence Evidence Project**

An initiative of FYSB's FVPSA Program grantee, the National Resource Center on Domestic Violence, the DV Evidence Project is designed to respond to the growing emphasis on identifying and integrating "evidence-based practice." It combines what is known from research, evaluation, practice, and theory to inform critical decision-making by domestic violence programs, <http://www.dvevidenceproject.com/publications/>. The DV Evidence Project enhances the domestic violence field's knowledge to better serve survivors and their families in four focus areas: Services to Adult Victims, Children's Services, Prevention, and Reducing Abusive Behavior, including development of the Theory of Change Model for domestic violence service providers.

### **Promising Futures: Best Practices for Serving Children, Youth, and Parents Experiencing Domestic Violence**

Developed by FYSB's FVPSA Program grantee, Futures Without Violence, Promising Futures is an online resource center of best practices for serving children, youth, and parents experiencing domestic violence, <http://promising.futureswithoutviolence.org/>. This website is designed for advocates, domestic violence programs, and others seeking to enhance their services to support healing for children, youth, and their mothers experiencing domestic violence. This resource website was created to provide information on evidence based interventions and promising practices that are trauma informed, developmentally and culturally relevant, and strengthen the mother-child relationship. Manual hard copies of two guides were also developed and made available via the website: *Building Promising Futures: Guidelines for Enhancing Response of Domestic Violence Programs to Children and Youth* and *Developing Outcome Measures for Domestic Violence Programs' Work with Children and Youth*.

### **Stakeholder Outreach and Education**

#### **FVPSA Annual Grantee Meeting**

FYSB's FVPSA Program holds an Annual Formula Grantee Meeting for State Domestic Violence Coalition Directors and FVPSA State Administrators. The meeting brings together representatives from Coalitions, State agencies, FVPSA training and technical assistance providers, and presenting experts from the domestic violence field as well as cross-cutting fields such as women's health, HIV/Aids, trafficking, sexual assault, mental health and substance abuse. The 2015 and 2016 meetings included plenaries and workshops on housing options for survivors, survivor-defined and voluntary services, services for culturally-specific communities, best practices for serving people with disabilities, gender-equitable relationships, language access, intersection of child welfare and domestic violence, strengthening relationships with tribes and tribal coalitions, and supporting male victims of domestic violence.



## **Webinar: Open Enrollment: How the Affordable Care Act Can Help Patients Experiencing Domestic and Interpersonal Violence**

On November 19, 2015, FYSB's FVPSA Program grantee, the National Health Resource Center on Domestic Violence, held a webinar entitled *Open Enrollment: How the Affordable Care Act Can Help Patients Experiencing Domestic and Interpersonal Violence*. This webinar provided a basic overview of the coverage requirements in the Affordable Care Act and the U.S. Preventive Services Task Force's "B" recommendation for screening and intervention for domestic violence. Speakers discussed who will be able to access these services, what is required in terms of screening and brief counseling, and referred to tools on addressing domestic violence safely and effectively as well as billing for these services. They also discussed the IRS regulations on financial aid for domestic violence as well as information about how survivors can access a "hardship" exemption to avoid paying penalties if they are not able to enroll this year. This webinar reached 834 people.

## **Domestic Violence Home Visitation Program Training & Curriculum**

FYSB's FVPSA Program grantee, the National Health Resource Center on Domestic, developed a training and curriculum for home visitation providers to better respond to domestic violence. The curriculum supports states and their home visitation programs in developing a core competency strategy, ensuring that all home visitation programs are equipped to help women and children living in homes with domestic violence, <http://www.healthcaresaboutipv.org/specific-settings/home-visitation-programs/>. In November 2016, Futures trained nearly 400 home visitors in Allegheny County, PA, engaging home visitors and early childhood providers from across the state focused on building community partnerships with DV programs and health clinics. Additionally, two webinars were facilitated for military personnel (Navy and Marines) stationed both domestically and overseas. These webinars concentrated on barriers to disclosure within the military and the importance of implementing a universal education approach to address the barriers.

## **CCWH Membership**

ACF is a member of the HHS Coordinating Committee on Women's Health.

## **Administration for Community Living (ACL)**

The Administration for Community Living (ACL) was created around the fundamental principle that all people, regardless of age or disability, should be able to live where they choose, with the people they choose, and fully participate in their communities. To help meet this vision, ACL works with states, localities, tribal and non-profit organizations, businesses, and families to maximize the independence, well-being, and health of older adults and those with disabilities, and the families and caregivers of both communities. It works to ensure that their interests are reflected in the design of public policies and programs; promotes individual self-determination and control of individual independence, well-being, and health; and enables their access to needed long-term services and supports.

ACL's programs work collaboratively to enhance access to health care and long-term services and supports for all individuals while also promoting inclusive community living policies and initiatives nationwide. Activities related to improving the health of women, especially older women and women with disabilities, include the following programs.

### ***The Older American Act Home and Community-Based Services and Nutrition Programs***

For over 50 years, the Older Americans Act (OAA) has provided home- and community-based services (HCBS) and nutrition services to millions of Americans aged 60 and over. OAA programs are targeted to those in greatest social or economic need, with particular attention to low-income individuals, minority individuals, those residing in rural communities, individuals with limited English proficiency, and those at risk of institutional care.

Services provided through the HCBS program include: access services such as transportation; case management and information and referral; in-home services such as personal care, chore, and homemaker assistance; and community services such as adult day care and physical fitness programs.

While age alone does not determine the need for these long-term care supports, statistics show that both disability rates and the use of long-term supports increase with advancing age. Among those aged 85 and older, 56 percent are unable to perform critical activities of daily living (ADLs) and require long-term support.<sup>46</sup> OAA programs serve older women with limitations in the ability to perform ADLs at a much higher rate, with 70 percent of the women served age 85 and older unable to perform at least one ADL<sup>47</sup>.

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<sup>46</sup> Centers for Medicare & Medicaid Services, The characteristics and perceptions of the Medicare population. Data from the 2013 Medicare Current Beneficiary Survey. [data tables 2.5a and 2.6a]. <http://www.cms.gov/ResearchStatistics-Data-and-Systems/Research/MCBS/Data-Tables-Items/2013CNP.html>. Accessed 2 January 2018

<sup>47</sup> ACL/Administration on Aging, FFY 2016 State Program Report

Data also show that 92 percent of older Americans have at least one chronic condition and 76 percent have at least two.<sup>48</sup> Women who received OAA case management, home-delivered meals, or transportation services experience much higher percentages of chronic illness with 97 percent having two or more.<sup>49</sup> Providing a variety of supportive services that meet the diverse needs of these older individuals is crucial to enabling them to remain healthy and independent in their homes and communities, and therefore to avoiding unnecessary, expensive nursing home care.

Nationally, nearly 30 percent of women age 60 and older live alone.<sup>50</sup> Older women who receive OAA services are much more likely to live alone (e.g., 59 percent congregate nutrition, 50 percent case management services and 67 percent home-delivered nutrition)<sup>51</sup>. Living alone is a key predictor of nursing home admission, and HCBS services are critical for enabling them to remain at home, especially for those who do not have an informal caregiver to assist with their care.

OAA nutrition programs provide meals and related nutrition services to older adults in a variety of community settings, including senior centers and via home-delivery to those who are homebound due to illness, disability or geographic isolation. Annually, nearly 1.6 million older adults are served around 80 million meals in congregate settings; while over 868,000 older adults are served more than 145 million meals via home delivery.<sup>52</sup> Moreover, during this time an additional 35,600 older adults received individual nutritional counseling from local registered dietitians.<sup>53</sup> Nearly two-thirds of those served were women.<sup>54</sup>

Over half of the women participating in the home-delivered nutrition program have difficulty going outside of their home, thus limiting their ability to shop for groceries ( 57 percent) and nearly half report difficulty preparing meals (47 percent).<sup>55</sup> The vast majority of women participating in the program report that the meals help them to eat healthier (82 percent); the meals improve their health (84 percent); and help them to continue living in their own homes (92 percent).<sup>56</sup> Women who participate in the congregate nutrition program are more likely than men to live alone (51 percent versus 39

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<sup>48</sup> Centers for Medicare & Medicaid Services, The characteristics and perceptions of the Medicare population. Data from the 2013 Medicare Current Beneficiary Survey. [data tables 2.5a and 2.6a]. <http://www.cms.gov/ResearchStatistics-Data-and-Systems/Research/MCBS/Data-Tables-Items/2013CNP.html>. Accessed 2 January 2018.

<sup>49</sup> 2017 National Survey of Older Americans Act Participants. <https://agid.acl.gov/>.

<sup>50</sup> Administration for Community Living. <https://agid.acl.gov/CustomTables/ACS/Year/>. *Custom Tables: American Community Survey (ACS) Public Use Microdata Sample (PUMS) 1-Year Files (2015)*, Accessed 11 January 2018.

<sup>51</sup> 2017 National Survey of Older Americans Act Participants. <https://agid.acl.gov/>.

<sup>52</sup> ACL/Administration on Aging, FFY 2016 State Program Report.

<sup>53</sup> Ibid.

<sup>54</sup> Ibid.

<sup>55</sup> 2017 National Survey of Older Americans Act Participants. <https://agid.acl.gov/>

<sup>56</sup> Ibid.

percent).<sup>57</sup> Nearly two-thirds of women report that their social opportunities have increased since receiving services (61 percent).<sup>58</sup> Approximately three-quarters of the women report that they eat healthier due to the program (73 percent), and the majority report that the program helps them to continue living in their own homes (56 percent).<sup>59</sup>

### ***The National Family Caregiver Support Program (NFCSP)***

Family caregiving is an issue impacting more than 43.5 million people in the U.S.<sup>60</sup> with 34.2 million providing care for an adult over age 50.<sup>61</sup> National Alliance for Caregiving research indicates family caregivers are predominantly women (60 percent). Research shows more negative physical effects of caregiving for women (e.g., sleep problems, elevated blood pressure, poorer immune system).<sup>62</sup> In addition to experiencing more stressors from caregiving, women often bear more financial burden than do male caregivers by providing monetary assistance to the care recipient.<sup>63</sup> The literature suggests that women, especially unmarried women, might have fewer options when trying to balance the responsibilities of personal life, caregiving, and work.<sup>64</sup> Workplace compromises are more common among women engaged in informal caregiving and include decreasing working hours; arriving late, leaving early, or both; and retiring early.<sup>65</sup> Costs associated with caregiving for women often include lost wages and reduced retirement and Social Security benefits.<sup>66</sup>

The NFCSP provides essential services and support to family caregivers as they endeavor to care for their loved ones at home. Since 2000, ACL has made significant accomplishments in serving family caregivers. Recently released evaluation results demonstrate the value of the NFCSP as a catalyst for states and localities to develop a comprehensive range of supportive services for family caregivers.<sup>67</sup>

Annually, the NFCSP helps more than 740,000 family caregivers locate and receive essential services. For example, in 2016, the most recent year for which service data is publicly available, more than 62,000 family caregivers receive respite services, and more

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<sup>57</sup> Ibid.

<sup>58</sup> Ibid.

<sup>59</sup> Ibid.

<sup>60</sup> National Alliance for Caregiving and AARP Public Policy Institute. *Caregiving in the US, 2015. Focused Look at Caregivers of Adults Age 50+.*

<sup>61</sup> Ibid..

<sup>62</sup> Gibson, Gander, & Jones, 2014; Lee, Colditz, Berkman, & Kawachi, 2003; National Alliance for Caregiving & AARP, 2015; Rosso et al. 2014; Spencer, Goins, Henderson, Wen, & Goldberg, 2013.

<sup>63</sup> MetLife Mature Market Institute, 2011.

<sup>64</sup> Feinberg & Choula., Fact Sheet: Understanding the Impact of Family Caregiving on Work. AARP Public Policy Institute. No. 271. October 2012

<sup>65</sup> Ibid.

<sup>66</sup> MetLife Mature Market Institute, 2011.

<sup>67</sup> Process Evaluation of the Older Americans Act, Title III E: National Family Caregiver Support Program: Final Report (March 2016). Prepared for The Administration for Community Living by The Lewin Group, Inc. See: [Final Report](#)

than 120,000 caregivers received counseling, training and support group services to help enhance their skills and confidence.<sup>68</sup> Over sixty percent of program participants are women, many of whom are older adults themselves (56 percent are age 60 and over) and one-fifth of these caregivers are age 75 years or older.<sup>69</sup> Many of the women caregivers report their own health as fair to poor (29 percent). Nearly one-fifth of female caregivers report high levels of physical strain; close to 25 percent report high levels of emotional strain. Nearly three-quarters (74%) of all caregivers served by the NFCSP report that they felt less stress, while 83 percent found it was easier to provide care as a result of the services received.<sup>70</sup> The NFCSP also annually provides services to nearly 37,000 grandparents and other relatives raising children, 77 percent of whom are women.<sup>71</sup>

### ***Services for Native Americans***

Native American Nutrition and Supportive Services provides grants to eligible tribal organizations to promote the delivery of Nutrition and Home and Community-Based Supportive Services to Native American, Alaskan Native, and Native Hawaiian elders. An estimated 895,000 persons age 60 and over identify themselves as Native American or Alaska Native alone or in combination with another racial group.<sup>72</sup> Over 520,000 of those elders identify as Native American or Alaska Native with no other racial group. Fifty four percent of the American Indian and Alaska Native population 60 years and over are female. Annually, the OAA Native American nutrition program provides more than 2.5 million congregate meals and 2.5 million home-delivered meals.<sup>73</sup> Additionally, over 1,050,000 rides are provided to Native American elders for essential appointments such as doctors' visits and grocery shopping. In addition to providing healthy meals and access to health services, these person-centered supports provide critical social contacts that help reduce risk of depression and isolation and offer connections to cultural and wellness programs.

### ***Eldercare Locator***

The *Eldercare Locator* is the only nationwide service that connects older persons and their caregivers with local support and resources on an array of aging issues. For over 25 years, the Administration on Aging has supported the *Eldercare Locator* as a critical tool for assisting older adults and those who love them to navigate the broad array of health and human service choices that exist for our aging population. Through its call center and website, the *Eldercare Locator* serves as a trusted gateway for older adults and caregivers searching for aging assistance. In 2016, the *Eldercare Locator* call center received over 308,000 requests for assistance with more than 73 percent of the calls from women. In addition to the call center, the *Eldercare Locator* website also provides a variety of

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<sup>68</sup> ACL/Administration on Aging, FFY 2016 State Program Report.

<sup>69</sup> 2017 National Survey of Older Americans Act Participants. <https://agid.acl.gov/>

<sup>70</sup> Ibid.

<sup>71</sup> ACL/Administration on Aging, FFY 2016 State Program Report.

<sup>72</sup> U.S. Census Bureau, Population Division, Annual Estimates of the Resident Population by Sex, Single Year of Age, Race Alone or in Combination, and Hispanic Origin for the United States: April 1, 2010 to July 1, 2016 Released June 2017, accessed January 2018.

<sup>73</sup> ACL/Administration on Aging, FFY 2016 Title VI Program Performance Report.

resources, including fact sheets and brochures that help consumers better understand aging issues and options.

### ***Long-term Care Ombudsmen Programs***

Long-Term Care Ombudsmen are advocates for residents of nursing homes, board and care homes, assisted living facilities and similar adult care facilities. They work to resolve problems of individual residents and to bring about changes at the local, state and national levels that will improve residents' care and quality of life. Research by the Centers for Disease Control, *Long-Term Care Providers Services and Users in the United States*, (2013-2014) shows that the users of long-term care services and supports are overwhelmingly women, with residential care communities having the highest proportion (70 percent), closely followed by residents of nursing homes where 67 percent of all residents are women. Annually, the OAA Long-Term Care Ombudsman Programs work to resolve nearly 200,000 complaints with or on behalf of residents of long-term care facilities, which include nursing homes and residential care communities such as assisted living, and board and care homes. Examples of complaints addressed by Long-Term Care Ombudsman Programs include concerns about poor care, improper discharge planning and eviction and quality of life issues.

### ***Elder Justice and Adult Protective Services***

Elder abuse disproportionately affects women. The higher number of female victims is not only a reflection of the fact that there are more women than men over the age of 60, but also indicates that as women age, they are more vulnerable to abuse, and experience the health consequences of violence with greater severity. In addition, women with disabilities experience much higher rates of abuse, especially sexual violence. ACL's Office of Elder Justice and Adult Protective Services, established in 2014, provides federal leadership and coordination for state and local programs working to combat the problem.

### ***Elder Justice Coordinating Council***

Pursuant to the Elder Justice Act, ACL chairs the Elder Justice Coordinating Council, to coordinate activities related to elder abuse, neglect, and exploitation across the federal government. The Elder Justice Act also names the Attorney General (AG) of the U.S. as a permanent member of the Council. In addition to the Secretary of Health and Human Services and the AG, the statute provides for inclusion as Council members the heads of each federal department, agency, or governmental entity identified as administering programs related to abuse, neglect, or financial exploitation. The purpose of the Council is to make recommendations to the Secretary of HHS on the coordination of elder justice activities within HHS, the Department of Justice (DoJ), and other federal, state, and local entities. The Council was initially convened on October 11, 2012, and currently is comprised of 12 federal agencies.

### ***Older Americans Act Formula Grants***

The Prevention of Elder Abuse and Neglect program provides formula grants to states for training and education and promoting public awareness of elder abuse. The program also supports state and local elder abuse prevention coalitions and multi-disciplinary teams.

#### *National Center on Elder Abuse (NCEA)*

ACL funds the National Center on Elder Abuse (NCEA) ([www.ncea.acl.gov](http://www.ncea.acl.gov)). The NCEA provides relevant information, materials, and support to enhance state and local efforts to prevent and address elder mistreatment. The NCEA makes available news and resources; collaborates on research; provides consultation, education, and training; identifies and provides information about promising practices and interventions; answers inquiries and requests for information; operates a listserv forum for professionals; and advises on program and policy development. NCEA also facilitates the exchange of strategies for uncovering and prosecuting fraud and scams targeted at elders, a preponderance of whom are women.

#### *National Adult Protective Services Resource Center*

ACL maintains the National Adult Protective Services Resource Center (NAPSRC). The NAPSRC represents the largest dedication of technical assistance directly supporting the improvements in the quality, consistency, and effectiveness of APS programs across the country. The NAPSRC works to enable state APS programs to enhance their critical role in responding to elders and adults with disabilities, disproportionately women, who are facing abuse, neglect, and exploitation.

#### *National Adult Maltreatment Reporting System (NAMRS)*

Recognizing the lack of consistent national data on adult mistreatment, ACL has launched the design and pilot of a national reporting system based on data from state APS agency information systems, called the National Adult Maltreatment Reporting System (NAMRS). NAMRS is the first comprehensive, national reporting system for APS programs, collecting quantitative and qualitative data on the practices and policies of adult protective services (APS) agencies and the outcomes of investigations into the maltreatment of older adults and adults with disabilities. ACL received the first data set from all but two eligible reporting jurisdictions in 2017 and released the first report on the data submitted by states on August 29, 2017. Future reports are forthcoming and the data show that women are most often subject to elder abuse, neglect and financial exploitation.

#### *State Grants to Enhance Adult Protective Services*

ACL provides funding to states to enhance APS systems statewide, to include innovations and improvements in practice, services, and data collection and reporting. The goal of the program is to improve the experiences, health, well-being, and outcomes of the individuals served by APS, and to accurately document the improvements in outcomes in a manner that is consistent with national data collection efforts, including the National Adult Maltreatment Reporting System (NAMRS). 24 grantees in 23 states have received Enhancement grants and have enhanced their APS systems statewide, with innovations and improvements in practice, services, and data collection and reporting.

### *Voluntary Consensus Guidelines for State APS Systems*

In 2016 ACL released field-driven, consensus-informed, national guidelines for state APS systems in order to provide a core set of principles and common expectations for APS programs, and to encourage consistency in the policies and practices of APS across the country. Through the guidelines, ACL has opened dialogue and encouraged improvements and innovations in APS practice to help ensure that adults are afforded similar protections and service delivery, regardless of which state or jurisdiction they are in.

### *World Elder Abuse Awareness Day*

Every year, ACL joins with leaders from other federal departments and others throughout the United States and the world to recognize World Elder Abuse Awareness Day commemorated on June 15<sup>th</sup>.

### *Additional Activities*

For many years, AoA/ACL has been a member of the DHHS Violence against Women (VAW) Steering Committee. The VAW Steering Committee has the responsibility for coordinating the DHHS response to issues related to violence against women and their children, and also coordinates DHHS violence-related activities with those of other federal agencies. AoA/ACL's participation ensures that the interests of older women victims are represented in the Committee's work. In addition to participating on the DHHS VAW Steering Committee, AoA/ACL has partnered with a number of federal and non-governmental organizations to promote the inclusion of older women in responses to domestic violence.

In addition, ACL has joined the international community to advance policies for the rights of, and improved public health initiatives for, older women on a global scale. ACL plays a leading role in a number of multilateral collaborations, including:

- In March 2015, raising the issue of violence against older women as a global public health crisis at the 59<sup>th</sup> UN Commission on the Status of Women; In April 2015, participating in the listening roundtable, "Promoting Equal Futures Across the Lifespan," which brought together expert stakeholders in the fields of aging, health, domestic violence and elder abuse, and economic security; In May 2015, participating in a panel presentation at the 68<sup>th</sup> World Health Assembly regarding the development and implementation of appropriate prevention, treatment, and care strategies and programs, especially for older women victims. In June 2015, hosting a roundtable with the Office of the Vice President, "Supporting Survivors across the Lifespan," which convened advocates from leading sexual assault and domestic violence organizations across the country to identify gaps in services for older survivors and ways to improve the accessibility of programs; and.
- In June 2016, the United Nations Development Programme, International Center for Research on Women, and the World Bank, with ACL as co-author, all emphasized the importance of including older women in the discussion on global gender-based violence.

### *National Education and Resource Center on Women and Retirement Planning*



The Administration on Aging partners with the Women's Institute for a Secure Retirement (WISER) on a cooperative agreement to maintain the National Education and Resource Center on Women and Retirement Planning (the Center). The Center targets user-friendly financial education and retirement planning tools to low-income women, women of color, and women with limited English-speaking proficiency. Through the Center's one-stop gateway, women have access to comprehensive, easily understood information that promotes opportunities to plan for income during retirement and for long-term care. The Center conducts workshops nationwide on strategies for accessing financial and retirement planning information targeted to women and disseminates online newsletters, fact sheets, booklets, and special reports tailored to the specific needs of hard-to-reach women. It maintains an interactive website that contains important information for women on a range of financial issues, including information on saving, investments, pensions, Social Security, health and long-term care, divorce and widowhood, and financial fraud and abuse.

### ***Pension Counseling and Information Program***

ACL's Pension Counseling and Information Program ensures that older Americans have access to the help they need to secure the employer-sponsored retirement benefits they have earned. Often, these benefits are critical to older Americans' ability to live independently and with dignity. ACL funds six regional counseling projects across the nation, serving 30 states, and a technical assistance resource center to assist older Americans in accessing information about their retirement benefits and to help them negotiate with former employers or pension plans for due compensation. Clients are disproportionately women: three out of five women over the age of 65 have incomes that do not cover their basic daily needs. Further, older American women are twice as likely as older men to be living near or below the federal poverty line. Moreover, when women do have pensions, they tend to have smaller pension benefits than do men.

### ***Legal Assistance for Elders***

Legal assistance and elder rights programs under Title III-B of the Older Americans Act (OAA) are funded in every state and clients are disproportionately older women. Legal assistance interventions address priority legal issues experienced by elders with economic or social need, including civil legal redress for harm caused by elder abuse including financial damage caused by exploitation and fraud.

For example, a study by the Institute for Policy Integrity found that civil legal aid is effective in increasing a woman's chances for obtaining a protective order. Survivors of domestic violence rate the filing of a protective order as one of their most effective tools for stopping domestic violence, second only to leaving the abuser, *Supporting Survivors, The Economic Benefits of Providing Civil Legal Assistance to Survivors of Domestic Violence*, Institute for Policy Integrity, July 2015. According to one study, 83 percent of women experiencing domestic violence who were represented by an attorney successfully obtained a protective order, compared to only 32 percent of victims without an attorney, Judy Hails Kaci, *Aftermath of Seeking*

*Domestic Violence Protective Orders: The Victim's Perspective*, 10 J. of Contemp. Crim. Just. 204 (1994). Also see, Andrew R. Klein, Re-Abuse in a Population of Court-Restrained Male Batterers: Why Restraining Orders Don't Work, in *Do Arrests and Restraining Orders Work?* 192 (Eve S. Buzawa & Carl G. Buzawa, eds., 1996) (describing the results of a study Supporting Survivors: The Economic Benefits of Providing Civil Legal Assistance to Survivors of Domestic Violence).

There are over 800 OAA-funded legal services providers nationwide, which provide nearly one million hours of legal assistance per year.<sup>74</sup> Legal assistance provided under the Older Americans Act enables older women to preserve their autonomy and their independence.

### ***Oral Health***

The realization that oral health is strongly connected to overall health is growing. Beyond the health of teeth and gums, a visit to a dental professional can detect signs of poor nutrition, disease, infection, immune disorders, and some cancers, leading health experts to regard the mouth as “a mirror of health and disease.” Because oral health is integral to overall health, ACL is committed to improving the oral health of older adults. In October 2014, with funding from the HHS Office on Women's Health (OWH), ACL entered into a three-year agreement with the Lewin Group to identify and promote vetted, low-cost, community-based oral health services for older adults. This project aimed to develop an online, searchable database of community-based oral health programs across the nation and comprehensive Community Guide to Adult Oral Health Program Implementation (Oral Health Guide) that offers guidance to communities (e.g., state and local governments, coalitions, advocacy groups, senior centers) interested in starting or enhancing an adult oral health program. One can peruse the website's database of nearly 200 vetted adult oral health programs among 11 categories, including specific populations, service delivery setting, program funding, and more. The Guide is located in an interactive format on the ACL Oral Health website created during this project, and is also available to be downloaded in its entirety.

It is intended for entities with a stake in promoting oral health among older adults, including coalitions, state and local governments, advocacy groups, health centers, foundations, dental and medical associations, universities, hospitals, area agencies on aging, senior centers, and other health and social service organizations. Key tips, case studies, external resources, and other sources of support are included throughout the Guide for additional guidance in creating cost-effective and sustainable programs.

### ***Chronic Disease Self-Management Education***

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<sup>74</sup> ACL/Administration on Aging, FFY 2016 State Program Report.

In the United States, over 76 percent of Medicare beneficiaries have multiple (2 or more) chronic conditions,<sup>75</sup> placing them at greater risk for premature death, poor functional status, unnecessary hospitalizations, adverse drug events, and nursing home placement.<sup>76</sup> Additionally, adults with disabilities experience health disparities when compared with the general population (e.g., are more likely to have high blood pressure, be overweight or obese, not engage in fitness activities, and receive less social-emotional support than adults without disabilities). Chronic diseases also are quite costly, with 95 percent of health care costs for older Americans attributed to chronic diseases. The cost of providing health care for an individual aged 65 or older is three to five times higher than younger counterparts.

Evidence-based Chronic Disease Self-Management Education (CDSME) programs can help mitigate the chronic disease burden by empowering participants to better manage their chronic conditions. These impactful interventions are designed to enhance self-management of chronic illnesses, focus on building multiple health behaviors and generalizable skills such as goal setting, decision making, problem solving, and self-monitoring, and are proven to maintain or improve health outcomes of individuals with chronic conditions.

ACL has been supporting CDSME programs for many years through its discretionary and formula grants as well as collaborations on various federal initiatives. In FY2015 and FY2016, ACL invested more than \$12 million to support 20 grantees (state agencies, area agencies on aging, non-profit organizations, universities, and tribes). These grantees are charged with two primary goals: (1) significantly increasing participation in evidence-based CDSME programs by older adults and people with disabilities and (2) implementing innovative funding arrangements to support these programs. Between March 2015 and March 2017, more than 71,000 individuals participated in a CDSME program. Women represent the majority of CDSME participants, with nearly 47,000 (or 75 percent of those participants reporting relevant data) enrolled during this timeframe.

### ***Falls Prevention Programs***

In the United States, more than one out of four older people fall each year. One out of five falls causes a serious injury such as broken bones or a head injury, and each year 2.8 million older people are treated in emergency departments for fall injuries. Falls can be

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<sup>75</sup> Centers for Medicare & Medicaid Services, The characteristics and perceptions of the Medicare population. Data from the 2013 Medicare Current Beneficiary Survey. [data tables 2.5a]. <http://www.cms.gov/Research-Statistics-Data-and-Systems/Research/MCBS/Data-Tables-Items/2013CNP.html>. Accessed January 2018.

<sup>76</sup> Vogeli C, Shields AE, Lee TA, Gibson TB, Marder WD, Weiss KB, Blumenthal D. Multiple chronic conditions: prevalence, health consequences, and implications for quality, care management, and costs. *J Gen Intern Med* 2007; 22 (Suppl 3):391–395. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2150598>. Also, Parekh, A.K., et al. 2011. Managing Multiple Chronic Conditions: a Strategic Framework for Improving Health Outcomes and Quality of Life, *Public Health Rep.* 126(4):460–71.

not only injurious, but they can also be costly. Adjusted for inflation, the direct medical costs for fall injuries are \$31 billion annually.

Fortunately, research has shown that falls and falls risks can be reduced through systematic risk identification and targeted intervention, including a combination of clinical and community-based interventions. Evidence-based falls prevention programs exist that have been shown to reduce falls and/or falls risk factors, as well as providing a positive return on investment.

ACL has been supporting evidence-based falls prevention programs for many years through its discretionary and formula grants, as well as through collaborations on various federal initiatives. Since FY 2014, ACL has invested over \$16.7 million to support 39 grants (to state agencies, area agencies on aging, non-profit organizations, universities, and tribes) for implementing falls prevention programs. These grantees are charged with two primary aims: (1) to significantly increase participation in evidence-based falls prevention programs by older adults and older adults with disabilities; and (2) to implement innovative funding arrangements to support these programs. Since 2014, 53,767 individuals have participated in an ACL-funded evidence-based falls prevention program. Women represent the majority of falls prevention program participants, with 38,197 (or 81 percent) of the total participants enrolled in programs during this timeframe.

### ***State Health Insurance Assistance Program***

Through the State Health Insurance Assistance Program (SHIP), ACL provides funding to the states to strengthen their capability to support a national network of local SHIP offices to provide personalized, one-on-one counseling, education and outreach to Medicare beneficiaries within the community. The SHIP grantees empower, educate, and assist Medicare-eligible individuals, their families, and caregivers to help them make informed health insurance decisions related to Medicare. Of the more than 58 million Medicare beneficiaries, 55 percent are women<sup>77</sup>. Of the 9.9 million dual-eligible Medicare and Medicaid beneficiaries (63 percent of whom are women)<sup>78</sup>, roughly four in ten are under 65 years of age with permanent disabilities.<sup>79</sup>

### ***Senior Medicare Patrol Program***

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<sup>77</sup> CMS, Office of Enterprise Data & Analytics (OEDA). Medicare Enrollment Dashboard. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Dashboard/Medicare-Enrollment/Enrollment%20Dashboard.html>. Accessed 11 January 2018.

<sup>78</sup> CMS Medicare- Medicaid Coordination Office. Data Analysis Brief: Medicare-Medicaid Dual Enrollment from 2006 through 2015. December 2016. [https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/DualEnrollment\\_2006-2015.pdf](https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/DualEnrollment_2006-2015.pdf) Accessed 11 January 2018

<sup>79</sup> The Henry J. Kaiser Family Foundation. State Health Facts. Aged and Disabled Dual Eligibles as a Percent of Total Medicaid Beneficiaries. <https://www.kff.org/medicaid/state-indicator/ageddisabled-medicaid-beneficiaries/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>, Accessed 11 January 2018

ACL's Senior Medicare Patrol (SMP) Program serves as a key partner in the Administration's ongoing, aggressive efforts to fight health care fraud. Through the SMP Program, ACL provides funds for grantees to recruit, train, and mobilize senior volunteers to educate those in their communities to prevent, detect, and report Medicare fraud, errors, and abuse. Of the more than 58 million Medicare beneficiaries, 55 percent are women<sup>80</sup>. Of the 9.9 million dual-eligible Medicare and Medicaid beneficiaries (63 percent of whom are women)<sup>81</sup>, roughly four in ten are under 65 years of age with permanent disabilities.<sup>82</sup>

### ***The Administration on Intellectual and Developmental Disabilities***

The Administration on Intellectual and Developmental Disabilities (AIDD), within ACL, advises the Secretary on matters relating to individuals with intellectual and developmental disabilities and serves as HHS' focal point to support and encourage the provision of quality services to individuals with developmental disabilities and their families. It supports state and community efforts to increase the independence, productivity, and community integration of individuals with developmental disabilities and ensures that their rights are protected.

AIDD provides funding for 68 University Centers for Excellence in Developmental Disabilities Education, Research & Service (UCEDDs). This nationwide network of independent and interlinked centers represents an expansive national resource for identifying issues, finding solutions, and advancing research related to the needs of individuals with developmental disabilities and their families.

Women with disabilities are a medically underserved population. For example, women with disabilities face an increased risk of breast cancer mortality and are significantly less likely than women without disabilities to receive a clinical breast exam and recommended mammogram screenings. Many UCEDDs are implementing projects that address the health-related needs of women with disabilities. *Transforming the Healthcare of Women with Disabilities* is a project of the Tarjan Center at the University of California, Los Angeles. This initiative is a multi-site project (e.g., Columbia University Medical Center, Boston Children's Hospital, University of California Los Angeles, and Rehabilitation Institute of Chicago) addressing health disparities faced by women with

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<sup>80</sup> CMS, Office of Enterprise Data & Analytics (OEDA). Medicare Enrollment Dashboard. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Dashboard/Medicare-Enrollment/Enrollment%20Dashboard.html>. Accessed 11 January 2018.

<sup>81</sup> CMS Medicare- Medicaid Coordination Office. Data Analysis Brief: Medicare-Medicaid Dual Enrollment form 2006 through 2015. December 2016. [https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/DualEnrollment\\_2006-2015.pdf](https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/DualEnrollment_2006-2015.pdf) Accessed 11 January 2018

<sup>82</sup> The Henry J. Kaiser Family Foundation. State Health Facts. Aged and Disabled Dual Eligibles as a Percent of Total Medicaid Beneficiaries. <https://www.kff.org/medicaid/state-indicator/ageddisabled-medicaid-beneficiaries/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>, Accessed 11 January 2018

cerebral palsy, while improving their quality of life. Each site is focusing on a specific component of women's health with regard to women with cerebral palsy. The overall project aims to establish not only a strong base of knowledge about the specific issues and challenges in providing healthcare to women with disabilities but also to provide information, communication materials, and examples needed to deliver exceptional care unique to the needs of women with cerebral palsy and similar disabilities.

### ***Independent Living Administration***

The Independent Living Administration (ILA) promotes the independent living philosophy of consumer control, self-help and self-advocacy, development of peer relationships and peer role models, and equal access for individuals with significant disabilities to all aspects of society. The ILA also manages programs that provide information and referral services to help people with paralysis and limb loss continue to live in their homes and participate in their communities.

During the 2016 program year, the Dayle McIntosh Center for Independent Living sponsored training for deaf female consumers regarding important health screenings specific to women. Staff of ILA's Centers for Independent Living (CIL) participates on an advisory committee for a research project concerning unplanned pregnancies among women with disabilities. CIL staff also coordinates woman-to-woman peer support groups that address emotional and mental health issues of participants.

The Paralysis Resource Center (PRC), located within the Christopher and Dana Reeve Foundation, provides comprehensive information for people living with spinal cord injury, paralysis and mobility-related disabilities and their families. The PRC maintains a repository of information for women living with paralysis that include fact sheets on female sexuality, pregnancy, bladder and bowel functions, caregiver tips and hundreds of other topics ranging from state resources to other secondary complications of paralysis. A new toolkit was developed in partnership with the National Council on Disability for parents with disabilities experiencing discrimination.

The Amputee Coalition operates the National Limb Loss Resource Center and provides a wide range of information and resources to individuals affected by limb loss, limb differences and their families. The Amputee Coalition is committed to providing up-to-date information and resources to help women who have lost a limb or live with limb differences in their everyday lives. This includes Fact Sheets about parenting as a person with limb loss or limb differences, articles on pregnancy and options for assistive technology devices for new mothers. In addition, the Coalition's educational conference presentations regularly feature sessions focusing on the issues specific to women with limb loss or limb differences.

### ***CCWH Membership***

ACL is a member of the HHS Coordinating Committee on Women's Health.

## **Indian Health Service (IHS)**

The Indian Health Service (IHS), an agency within the Department of Health and Human Services, is responsible for providing federal health services to American Indians and Alaska Natives (AI/ANs). The provision of health services to members of federally-recognized Tribes grew out of the special government-to-government relationship between the federal government and Indian tribes. This relationship, established in 1787, is based on Article I, Section 8 of the Constitution, and has been given form and substance by numerous treaties, laws, Supreme Court decisions, and Executive Orders. The IHS is the principal federal health care provider and health advocate for Native American people, and its goal is to raise their health status to the highest possible level. The IHS provides a comprehensive health service delivery system for American Indians and Alaska Natives.

**Our Mission:** To raise the physical, mental, social, and spiritual health of American Indians and Alaska Natives to the highest level.

**Our Goal:** To ensure that comprehensive, culturally acceptable personal and public health services are available and accessible to American Indian and Alaska Native people.

**Our Foundation:** To uphold the Federal Government's obligation to promote healthy American Indian and Alaska Native people, communities, and cultures and to honor and protect the inherent sovereign rights of Tribes.

### ***The Indian Health Care System***

#### ***Indian Health Service (IHS) Direct Health Care Services***

- IHS services are administered through a system of 12 Area offices and 168 IHS and tribally managed service units.

#### ***Tribally Operated Health Care Services***

- Titles I and V of the Indian Self-Determination and Education Assistance Act (Public Law 93-638, as amended), provide Tribes the option of exercising their right to self-determination by assuming control and management of programs previously administered by the federal government. Since 1992, the IHS has entered into agreements with tribes and tribal organizations to plan, conduct, and administer programs authorized under section 102 of the Act. Today, over 60 percent of the IHS appropriation is administered by Tribes, primarily through self-determination contracts or self-governance compacts.

#### ***Urban Indian Health Care Services and Resource Centers***

- 34 urban programs provide services ranging from community health to comprehensive primary health care.

### ***Population Served***

- Members of 567 federally recognized Tribes
- 2.2 million American Indians and Alaska Natives

### ***Annual Patient Services (Tribal and IHS facilities)***

- Inpatient Admissions: 39,305
- Outpatient visits: 13,742,078

### ***Human Resources***

- Total IHS employees: 15,369, including
  - 2,648 nurses
  - 725 physicians
  - 698 pharmacists
  - 272 dentists
  - 115 physician assistants
  - 110 sanitarians

### ***Women's Health Care***

The basic primary care and preventive services that IHS offers to women include all aspects of reproductive health across the lifespan; gynecologic, pregnancy related, and family planning/contraception provided within a system that is patient-focused and culturally sensitive:

- ***Primary Care for Women:*** Inclusive of physical and behavioral health needs. Routine screening of all patients for tobacco, alcohol, and substance use, depression, Intimate Partner Violence and immunizations for preventive health including influenza, shingles, pneumonia, and human papilloma virus.
- ***Gynecologic:*** Breast and cervical cancer screening, general gynecologic conditions, sexually transmitted infections (STI) and HIV screening and treatment and related follow-up care based on findings.
- ***Pregnancy-related Care:*** Includes prenatal, labor and birth, postpartum, and newborn care.
- ***Family Planning:*** Provide options to a fully informed patient in order to make decisions that best meets her needs.



- **Home Visits:** Referrals for public health nursing for continued care with a spectrum of services including postpartum and newborn, surgery, family education, and other health concerns.

### ***Obstetrical (OB) Care and Education***

In June of 2015, a guided preceptor OB rotation was developed at Chickasaw Nation Hospital in Oklahoma to provide OB orientation and refresher training to RN staff at low delivery volume sites to gain and maintain evidence-based OB skills for IHS staff.

Funding was provided for various IHS facilities to purchase OB simulators for onsite training and monthly OB code scenarios to maintain clinical competency.

### ***Centering Pregnancy Program***

Centering Pregnancy is an evidence-based group prenatal education program to improve maternal and fetal health outcomes. Centering Pregnancy educational materials cover the same ACOG education topics e.g.; nutrition, breastfeeding, stress management, infant care, etc. as traditional practice. Many facilities throughout IHS are using the group prenatal approach as their main prenatal education program. Centering Pregnancy facilitates group, patient-centered discussions as opposed to education provided in traditional care which is often instructional and provider driven. Other facilities are in the training phase for providing group prenatal education. Some IHS facilities are also continuing on with group parenting education classes through the first to second year of a child's life.

### ***Partnerships***

IHS has had and continues to have a partnership with the American College of Obstetricians and Gynecologists (ACOG). Each year, an ACOG team travels to an IHS Area to assess the obstetrics and gynecology program's strengths, challenges and successes and make recommendations. ACOG also provides training and education to staff during the site visit. Each Area has an ACOG visit on an approximate five year cycle.

### ***Contraceptive Options for Women and Girls***

Pursuant to the Affordable Care Act, all forms of contraceptives are available at IHS facilities including the long acting reversible contraception (LARC) and subdermal implants and intrauterine devices (IUDs).

According to recommendations by the American Academy of Pediatrics, LARCs are the first-line contraceptive choice for adolescents and are safer than pregnancy. Access to contraceptive care for adolescents improve health by assessment through a

developmentally targeted sexual history; risk for sexually transmitted infections and HIV, risk for unintended pregnancy; screen for depression, IPV (Intimate Partner Violence), and substance use issues; and provide appropriate education for health and safety.

Within the *Indian Health Manual* of 2015, IHS established the policy and procedures to ensure that all IHS facilities make easily available the Plan B One-Step®, (Levonorgestrel) emergency contraception (EC) pill as an over-the-counter product where a licensed provider is not required to distribute the EC.

### ***The Baby-Friendly® Hospital Initiative***

An evidence-based practice care model designed to protect and promote breastfeeding as the safest, healthiest way to nourish babies. This initiative began as part of the former First Lady Michelle Obama's "Let's Move! In Indian Country" campaign dedicated to solving childhood obesity within a generation. Currently, 10 of the 10 IHS birthing hospitals have active designation as Baby-Friendly. At present, IHS hospitals are preparing for their re-designation of Baby Friendly status. Training and education of IHS nurses as lactation educators and consultants has become a priority and training is ongoing for staff at both hospitals and health centers and clinics.

### ***IHS Immunization Program: HPV Vaccine***

Cervical cancer is a significant health issue for AI/AN women. AI/AN women experience higher rates of cervical cancer and cervical cancer-related incidence and mortality compared with white women, and in some geographic regions, higher rates of HPV infection compared with white women. The human papillomavirus (HPV) vaccine prevents HPV-associated genital warts and cancers of the cervix, anus, oropharynx, vagina, vulva, and penis, and is routinely recommended for male and female adolescents starting at 11 years of age. AI/AN children < 19 years of age are eligible for free vaccines through the Vaccines for Children program, and the IHS Resource and Patient Management System and Electronic Health Record include provider reminders for HPV vaccine in accordance with the recommended schedule.

In addition, the system provides vaccine coverage reports to monitor coverage and patient lists to support reminder recall efforts. In IHS in 2015, 1<sup>st</sup> dose HPV vaccine coverage among female adolescents 13-17 years of age was 84.4 percent for all IHS Areas combined, compared to 62.8 percent for the general U.S. population, and coverage with 3 doses was 60.4 percent vs. 41.9 percent for the general U.S. population. While adolescents seen in Indian Health Service, Tribal and Urban facilities have higher coverage with HPV vaccine compared to the general U.S. populations, there are facilities with comparatively lower coverage. From 2013-2015 the IHS Immunization program supported a performance improvement project to identify and implement best practices at nine IHS and tribal sites with comparatively low HPV vaccine coverage, and continues to work with sites to increase HPV vaccine coverage for all patients.

### ***Violence Against Women and Girls***

### ***Domestic Violence Prevention Program (DVPP)***

The DVPP is a congressionally mandated, nationally-coordinated grant and federal award program for Tribes, Tribal organizations, federally operated programs, and Urban Indian organizations to provide violence prevention and treatment services. The DVPP promotes the development of evidence-based and practice-based models that represent culturally appropriate prevention and treatment approaches to domestic and sexual violence from a community-driven context. IHS funds a total of 83 projects totaling \$11,175,838.

### ***Government Reporting Results Act (GPRA) screening for Domestic Violence/Intimate Partner Violence (DV/IPV)***

As recommended by the U.S. Preventive Services Task Force, all female patients between the ages of 14–46 are screened for intimate partner violence, including those at risk for teen dating violence.

### ***Tribal Forensic Healthcare***

In responding to violence against women and girls, IHS has funded the International Association of Forensic Nurses to deliver training related to the identification, collection, and preservation of medical forensic evidence obtained during the treatment of victims of sexual and domestic violence. These trainings allow medical professionals to acquire and maintain the knowledge, skills, and competent clinical forensic practice to improve the response to domestic and sexual violence in hospitals, health clinics, and health stations within the Indian health system and across the lifespan. More than 500 health care providers have been trained to conduct medical forensic examinations.

### ***Suicide Prevention***

#### ***Substance Abuse and Suicide Prevention Program (SASPP)***

The SASPP is a nationally-coordinated program focusing on providing ~~much-needed~~ methamphetamine and suicide prevention and intervention resources for Indian Country. This initiative promotes the use and development of evidence-based and practice-based models that represent culturally-appropriate prevention and treatment approaches to methamphetamine abuse and suicide prevention from a community-driven context. Currently IHS funds 175 grant and federal program awards, totaling \$27,972,247.

#### ***Zero Suicide Initiative***

IHS funds eight projects for \$3.2 million to participate in the Zero Suicide Initiative, a comprehensive approach to suicide care in the health care system. Projects began in November 2017 and will operate from 2017 through 2020.

### ***Resources***

#### ***The IHS National HIV/AIDS Program***

The IHS National HIV/AIDS Program coordinates and promotes HIV/AIDS prevention and treatment activities specific to AI/ANs as part of a comprehensive public health approach. In addition, IHS provides medical care to eligible beneficiaries. The HIV/AIDS Program goal is to ensure access to quality health services for AI/ANs living with HIV/AIDS and those at risk of contracting HIV and commonly co-occurring infections. The IHS has shown recent improvements in screening for HIV as per national recommendations, and in FY 2015 the IHS prenatal screening rate was 86.6 percent of pregnant women. Hospitals that have deliveries should have access to rapid HIV screening for those presenting without prenatal care as well have maternal and pediatric antiviral medications on hand for planned and unplanned births for HIV positive prenatal patients to reduce the risk of vertical transmission of HIV.

To improve access to HIV care in remote areas, IHS is using innovative tools such as telehealth, home care visits, and other programs. These strategies are essential to reach our neediest patients. IHS is also actively training clinicians in the options presented by Pre-Exposure Prophylaxis (PrEP) for HIV. In 2016, IHS formed two new cooperative agreements for HIV and AIDS prevention and engagement in care activities by tribes, tribal organizations and urban Indian organizations. Two awardees will receive up to \$100,000/year for up to five years for community services, including PrEP, risk reduction for persons who inject drugs, and support for people living with HIV and AIDS to stay in treatment. This effort is part of an ongoing collaboration between IHS and CDC, which funded the agreement and is providing subject-matter expertise to support the effort.

### ***The IHS Division of Diabetes Treatment and Prevention (DDTP) Program***

The Division of Diabetes Treatment and Prevention Program is responsible for developing, documenting and sustaining clinical and public health efforts to treat and prevent diabetes in American Indians and Alaska Natives. DDTP administers the Special Diabetes Program for Indians (SDPI), a \$150 million per year grant program for diabetes prevention and treatment activities at Indian Health Service/Tribal/Urban sites across the country. DDTP also conducts the annual Diabetes Care and Outcomes Audit which assesses dozens of diabetes care process and outcomes measures to help sites identify areas to focus improvement efforts. In both sexes, diabetes increases the risk in of many complications, such as cardiovascular disease and diabetes related kidney failure. In women, it also increases the risk of pregnancy complications, including miscarriage, birth defects, and birth complications for both mother and fetus. As such, prevention and control of diabetes is an important component of reproductive health.

### ***The Women's Health Resource and Patient Management System (RPMS)***

This software package tracks women receiving Pap Smears, colonoscopies, and breast and cervical cancer screening. It allows providers to run patient management and epidemiological reports to track procedures, due dates, and patient correspondence. During 2016, a committee reviewed the software capability and updated the statistical tracking to be consistent with current evidence-based guidelines and allow for easy insertion into the electronic health record.

### ***The Patient and Family Education Protocols and Codes***

The committee meets annually to review and standardize RPMS patient education protocols and codes. Specific women's health education codes are integrated into quality measures and clinical reports to provide a mechanism for clinicians to document patient education on recommended screenings, health promotion and disease prevention, family planning, pregnancy, exercise, and physical activity. The work of this committee is continuous to maintain consistency with current evidence-based care guidelines.

### ***CCWH Membership***

IHS is a member of the HHS Coordinating Committee on Women's Health.

## **National Vaccine Program Office (NVPO)**

In 1987 Congress created the National Vaccine Program Office (NVPO) to provide leadership and coordination on vaccine-related activities among federal agencies and non-federal stakeholders. The National Vaccine Program is designed to achieve optimal prevention of human infectious diseases through vaccinations and to achieve optimal prevention of adverse reactions following vaccinations.

Per the Secretary's priority on disease prevention through public health promotion, NVPO works to minimize the effects of vaccine-preventable diseases through leadership, coordination, and optimization of the U.S. immunization system. Its activities align directly to the National Vaccine Plan, which dictates the framework—goals, objectives, and strategies—for pursuing the prevention of infectious diseases through vaccinations.

The five overarching goals of the National Vaccine Plan follow:

1. Develop new and improved vaccines
2. Enhance the vaccine safety system
3. Support communications to enhance informed vaccine decision-making
4. Ensure a stable supply of, access to, and better use of recommended vaccines in the United States
5. Increase global prevention of death and disease through safe and effective vaccination

### ***Women's Health Projects***

#### ***Improving Adult Immunization Efforts***

Reducing vaccine-preventable diseases in adults is a national health priority that supports women's health, as well as the health of the entire population. Despite the widespread availability of safe and effective vaccines, adult vaccination rates remain low in the United States, leaving adults vulnerable to the heavy toll vaccine-preventable diseases can take on of both individuals and the communities in which they live. With this in mind, NVPO, in its coordinating role, has worked with numerous partners to develop plans, standards and tools to address suboptimal vaccination rates, and improve the uptake of recommended vaccines for all adults.

#### ***Expanding Maternal Immunization***

Maternal immunization provides important health benefits for pregnant women and their infants, and obstetricians as well as obstetrical care providers are now recommended to vaccinate all pregnant women against influenza and pertussis during each pregnancy. However, immunization coverage among pregnant women for influenza and pertussis-containing vaccines is suboptimal, leaving numerous pregnant women and their infants at risk for complications from vaccine-preventable diseases.

Recognizing the importance and impact of maternal immunizations on public health, the ASH charged the National Vaccine Advisory Committee (NVAC) with reviewing the state of maternal immunizations and existing best practices to identify programmatic gaps and/or barriers to the implementation of current recommendations regarding maternal immunization. As a result of this charge, the NVAC published two reports on maternal immunization highlighting important areas of opportunity to strengthen maternal immunization programs and increase uptake of recommended vaccines among pregnant women (influenza and Tdap vaccines).

One of the reports highlighted the need to enhance communication to address the safety and effectiveness of all currently recommended vaccines during pregnancy and to maximize provider recommendation and administration for these vaccines, as health care providers play a critical role in increasing uptake of vaccines for pregnant women. Therefore, NVPO collaborated with CDC in November 2016 to provide an educational webinar on the safety and efficacy of maternal immunization for health care providers who have direct contact with pregnant women. The event also covered strategies to address patient concerns around maternal immunization and provided related resources to all participants.

There is also a need to assure vaccine safety systems are adequate to detect adverse events due to vaccinations in either the newborn or the pregnant women and that public health officials can monitor the impact of maternal immunization on the prevention of morbidity and mortality of both the mother and the baby. To further these efforts, NVPO engaged in a number of research efforts aimed to support the acceptance of maternal immunizations among pregnant women and their physicians and the development of new vaccines for use in pregnant women.

One such collaborative study looks at the potential risks of birth defects and birth outcomes after the administration of vaccines during pregnancy. NVPO collaborated with the FDA, the Biomedical Advanced Research and Development Authority (BARDA), and Boston University's Slone Birth Defect Study (SBDS) in this study to establish a baseline of cases of microcephaly in the United States to better understand the possible risks of microcephaly during pregnancy prior to evaluating and testing a Zika virus vaccine. This study also aims to analyze the risk of birth defects and exposure of an anti-influenza antiviral (oseltamivir) during pregnancy in the 2009 H1N1 pandemic and to analyze the risk of birth defects after administration of Tdap alone or in combination with the influenza vaccine during pregnancy.

NVPO also funded two separate cooperative agreements to further vaccine safety research related to pregnant women and newborns. Other projects include work to expand the number of pregnant women in vaccine clinical trials and to clarify the liability environment around developing vaccines for pregnant women, which can be a barrier for vaccine development. In addition, the lack of liability protection of health care providers may lead them to be reluctant to administer vaccines to a pregnant woman.

### ***Increasing HPV Vaccination Rates***

On average, there are 25,900 yearly cases of Human Papillomavirus-associated (HPV) cancer in the United States. HPV is a ~~very~~ common virus; nearly 80 million people—about one in four—are currently infected in the United States. About 14 million people, including teens, become infected with HPV each year. In addition to genital warts, HPV infection can cause cervical, vaginal, and vulvar cancers in women as well as penile cancer in men; and oropharyngeal and anal cancer in the general population. Each year, about 39,800 new cases of cancer are found in parts of the body where human papillomavirus (HPV) is often found. HPV causes about 31,500 of these cancers (<https://www.cdc.gov/cancer/hpv/statistics/cases.htm>).

To prevent cancer associated with HPV infections, the Advisory Committee on Immunization Practices (ACIP) and the CDC, currently recommend HPV immunization for all children aged 11 or 12 with two doses of an FDA-approved vaccine (<https://www.cdc.gov/mmwr/volumes/65/wr/mm6549a5.htm>). Young women are recommended to be vaccinated for HPV vaccine through age 26 years, and young men through age 21 years.

Despite the ability of this vaccine to protect against HPV-associated cancers, coverage rates for completion of the HPV vaccine series remain below 50 percent for girls with disparities by race and socioeconomic status. Low immunization coverage levels have been attributed to many factors including cost, missed opportunities, strength of provider recommendation, and parental knowledge and attitudes.

- The National Vaccine Advisory Committee (NVAC), which is supported by NVPO, was charged by the ASH with reviewing the current state of HPV immunization, to understand the root cause(s) for the relatively low vaccine uptake (both initiation and series completion), and to identify existing best practices. The resulting NVAC report, *Overcoming Barriers to Low HPV Vaccine Uptake in the United States: Recommendations from the National Vaccine Advisory Committee*, was approved June 9, 2015.
- NVPO also serves on the Steering Committee of the American Cancer Society's HPV Roundtable, which convened a national coalition of public, private, and voluntary organizations with the goal of increasing HPV vaccination coverage in the United States. Key activities of the Roundtable include increasing awareness, provider and public education, and health and policy efforts. Building on its past efforts, NVPO is working with Roundtable members and the pharmacy sector to improve HPV vaccine uptake.

### ***Maintaining Vaccine Safety***

Ensuring the safety of vaccines is paramount to the health of the country. Since vaccines are recommended for use among healthy populations, they undergo rigorous safety assessment and monitoring throughout their lifecycle: during preclinical and clinical development, as part of the evaluation undertaken by FDA, and after they are granted licensure and in use by the public. NVPO and the Immunization Safety Task Force (ISTF) engage in numerous innovative initiatives to support and address gaps in the U.S. vaccine safety system including overseeing



several clinical studies, developing and evaluating novel methods of identifying increased risk of fetal loss following vaccination in pregnancy, and establishing a vaccine safety pregnancy database.

### ***Exploring Vaccine Confidence***

The success of any vaccine in protecting a population requires high coverage rates. In the U.S., coverage remains low for several of the vaccines recommended for adolescents and adults. Even in children, where coverage rates are high (above 90 percent for most), evidence suggests that nearly 12 percent of parents refuse at least one recommended vaccine for their child(ren), and 30 percent delay one or more vaccines, and exemptions obtained for personal reasons from school immunization requirements have been increasing. Together this data suggests a decline in vaccine confidence in the United States.;

Vaccination confidence is one of a number of factors that affect individual and population-level willingness to accept a vaccine. It means having confidence in the vaccine's safety and efficacy, confidence in the competency of the health professionals who administer the vaccine, and having trust in the motivations of the policy makers who decide which vaccines are needed and when.

Recognizing that immunizations are given across the lifespan and there are often differences in vaccination acceptance at different stages of life and in different settings, in June 2015 the NVAC issued a report – *Assessing the State of Vaccine Confidence in the United States*. This report highlights needs and priorities in four domains, and provides recommendations for fostering vaccine-related confidence. The World Health Organization's Strategic Advisory Group of Experts' (SAGE) on Immunizations also issued a report on vaccine hesitancy which illustrates that building and fostering vaccine confidence and acceptance is a worldwide need. In light of these reports, NVPO developed a comprehensive strategy to advance understanding of the role vaccine confidence plays in vaccine uptake, measure the state of vaccine confidence in this country, and improve efforts to support informed vaccine decision-making. The strategy highlights a variety of needs, some of which NVPO will lead efforts in the following:

- Literature reviews to provide summaries of vaccine confidence measures and potential approaches for strengthening confidence or addressing hesitancy;
- Curation of a repository of materials for health researchers and practitioners that address vaccine confidence;
- Focus group and survey research with mothers with low vaccine confidence in childhood immunizations; and
- Cooperative agreement awards to support research related to vaccine confidence.

### ***CCWH Membership***

NVPO is a member of the HHS Coordinating Committee on Women's Health.

## **Office of Adolescent Health (OAH)**

The Office of the Adolescent Health (OAH) was established in 2010 within the Office of the Assistant Secretary for Health to coordinate adolescent health programs and initiatives across HHS. OAH supports multidisciplinary projects focused on improving adolescent health, including that of adolescent girls. It works in partnership with other HHS agencies to support evidence-based approaches to promoting adolescent health and preventing disease.

### ***Report on Current Level of Activities***

#### ***Teen Pregnancy Prevention Program***

The OAH Teen Pregnancy Prevention (TPP) Program is a national, evidence-based program that funds diverse organizations working to prevent teen pregnancy across the United States. OAH invests in the implementation of programs identified as evidence-based by the HHS Teen Pregnancy Prevention Evidence Review and the development and evaluation of new and innovative approaches to prevent teen pregnancy.

The OAH TPP Program was established in 2010 with a Congressional mandate to fund medically accurate and age appropriate programs to reduce teen pregnancy. At approximately \$101 million annually, the OAH TPP Program funds 84 grants to communities and five additional grants to provide capacity building assistance for funded organizations. The OAH TPP Program focuses on reaching populations with the greatest need with a goal of reducing disparities in teen pregnancy and birth rates.

#### ***Implementation of Evidence-based TPP Programs***

Approximately three quarters of OAH TPP grant funding is invested in implementing evidence-based teen pregnancy prevention programs – those proven through rigorous evaluation to reduce teen pregnancy, behavioral risk factors underlying teen pregnancy, or other associated risk behaviors. Grantees use a community-wide approach to implement evidence-based programs to scale to reach a large number of youth and communities in need. The approach includes the following:

- implementing evidence-based programs in multiple settings so youth receive critical information and skills at multiple times over the course of their adolescence;
- creating environments that are safe, supportive, and inclusive of LGBTQ and other vulnerable youth, and provide trauma-informed services;
- mobilizing community support and engaging youth and families to ensure program relevance; and

- providing linkages and referrals to a broad range of youth-friendly health care services.

Recognizing that not all organizations are ready to implement a holistic approach, OAH also funds grants to help build the capacity of youth-serving organizations to implement, evaluate, and sustain evidence-based teen pregnancy prevention programs.

### ***Developing New and Innovative Approaches***

To continue to expand the evidence base and address the changing needs of youth and communities, 25 percent of OAH TPP grant funding is dedicated to developing and testing new and innovative approaches to preventing teen pregnancy, including

- supporting technology- and program-based innovations that are promising approaches to preventing teen pregnancy, but need further development before being ready for evaluation; and
- rigorous evaluation of new and innovative approaches to preventing teen pregnancy. These approaches are designed to fill gaps in the current evidence base and include interventions for males, Latino, American Indian, and LGBTQ youth, and youth in the foster care and juvenile justices systems, as well as interventions that are technology-based and/or in clinics, schools, and communities.

During the first five years of the OAH TPP Program (Fiscal Years 2010-2014), grantees reached nearly half a million youth. They also trained more than 6,800 professionals and established partnerships with over 3,800 community-based organizations across the U.S. During FY15-16, the second cohort of TPP grantees reached 279,208 youth in 39 states and the Marshall Islands, trained over 7,000 professionals, and established partnerships with 3,665 organizations.

### ***Release of Evaluation Results from the First Five Years of the Teen Pregnancy Prevention Program***

From FY2010–2014, the OAH TPP Program funded 41 rigorous, independent evaluation studies that significantly contributed to the field’s knowledge of where, when, and with whom programs are most effective.

The results from these 41 rigorous evaluations were released on the OAH website ([http://www.hhs.gov/ash/oah/oah-initiatives/tpp\\_program/cohorts-fy-2010-2014.html](http://www.hhs.gov/ash/oah/oah-initiatives/tpp_program/cohorts-fy-2010-2014.html)) and in a supplement of *American Journal of Public Health*. The journal supplement highlighted findings from a subset of grantees of the OAH TPP’s 41 studies. The research articles were categorized into two groups according to their funding purpose. They present:

- findings from replications of program models that previously showed evidence of effectiveness and
- findings from new and innovative programs that were rigorously evaluated for the first time.

A number of editorials discussed the TPP Program, lessons learned, and expert commentary. Several editorials described the TPP Program, its evaluation portfolio, and the intensive evaluation technical assistance activities that supported the evaluation studies. Three editorials provided additional discussion and context for understanding lessons learned from the studies and how to interpret mixed findings. Four editorials expanded on the evaluation studies.

The *American Journal of Public Health* Supplement on Building the Evidence to Prevent Teen Pregnancy can be viewed at <http://ajph.aphapublications.org/toc/ajph/106/S1>

### ***Cross-Agency Teen Pregnancy Prevention Collaboration***

OAH (part of OASH) partners with the Assistant Secretary for Planning and Evaluation (ASPE) and the Administration for Children and Families (ACF) to support and oversee the HHS Teen Pregnancy Prevention Evidence Review. OAH works closely with colleagues in ASPE, CDC, and ACF to coordinate and collaborate on all evaluation activities. In addition, through a partnership between the OAH and CDC, funding was awarded for a five-year grant period to support three projects to develop and evaluate new TPP interventions for young males. OAH also works collaboratively with contractors to provide technical assistance to grantees and ensure that evaluation designs are rigorous and feasible.

### ***Pregnancy Assistance Fund***

OAH leads the Pregnancy Assistance Fund (PAF) Program, which was established in 2010 to provide a network of seamless services to help expectant and parenting youth and young families get the support they need. Funded through the Affordable Care Act, the OAH PAF Program aims to improve the educational, health, and social outcomes of expectant and parenting teens, women, fathers, and their families. The PAF Program funds competitive grants totaling \$25 million each year to 17 states and three tribal entities.

Grantees of the OAH PAF Program conduct activities in high schools, community colleges, community centers, and other settings to reach and support vulnerable young people who are expecting a baby or already have a child to help improve their futures. PAF Program funds are used to raise awareness and help expectant and parenting young people complete high school or postsecondary degrees and gain access to health care, childcare, family housing, and other critical supports. The funds are also used to improve services for pregnant women who are victims of domestic violence, sexual violence, sexual assault, and stalking.

Grantees serve the whole family unit, including the mother, father, child, and their families. Activities vary slightly across states and tribes depending on the needs and resources of the communities. Services frequently provided include case management, education support services, parenting skills information, health care services and concrete social supports, such as transportation and referral to housing or childcare.

To provide expectant and parenting young families with a seamless network of supportive services, grantees identify and work with partners in different sectors including health, education, labor and other social services. This cross-agency coordination helps fill in service gaps for expectant and parenting young families by specifically targeting and addressing through collaboration the most prevalent issues that prevent them from reaching their full potential as individuals and parents.

Recognizing the unique needs of young men and the potential multi-generational benefits of a young father's continuing engagement with their child, the OAH PAF Program increased its focus on serving young fathers. Grantees funded in 2015 have expanded their programs to recruit, retain, and engage young fathers as well as young mothers so that these young men can be more actively involved in their children's lives. To date, the PAF Program has reached over 60,000 expectant and parenting teens and their families. Of this total number reached, 55% of program participants were expectant or parenting mothers, 8% were expectant or parenting fathers, and 37% were children.

Since 2010, the OAH PAF Program has awarded 37 grants to states and tribes across the United States. By helping expectant and parenting youth, the OAH PAF Program is working to improve the educational, health, and social outcomes of expectant and parenting teens, women, fathers, and their families. In FY 2017, a new cohort of 1 States and 1 Tribal entity were awarded funds for a one-year project period.

### ***OAH Teen Pregnancy Prevention and Pregnancy Assistance Fund Resource Center***

The OAH Teen Pregnancy Prevention and Pregnancy Assistance Fund Resource Center provides training materials and resources for grantees and other organizations working to reduce teen pregnancy and STDs and support expectant and parenting teens and their families. All materials are free and downloadable. The Resource Center provides training resources on topics such as building collaboration; engaging diverse populations; performance management; serving and engaging males and young fathers; strategic communication; and sustainability. It offers e-learning modules, informative podcasts, webinars and training materials, current teen pregnancy information, and other resources. <https://www.hhs.gov/ash/oah/resources-and-training/tpp-and-paf-resources/index.html>

### ***National Evaluations***

OAH supports several national evaluations to continue to build the evidence base for effective strategies to prevent teenage pregnancy and provide support for expectant and parenting teens. Each grantee is required to conduct an evaluation of its program.

The Teen Pregnancy Prevention Replication Study examines multiple replications of three evidence-based program models. The Pregnancy Assistance Fund evaluation is

evaluating the implementation of three programs aimed at supporting expectant and parenting teens. The third evaluation study is in the form of a contract to identify and develop evaluation studies to test understudied evidence-based teen pregnancy prevention programs, adaptations to existing evidence-based approaches, and core components, key activities, and implementation strategies of common programs. Another study has a focus on implementation and impact evaluation of a commonly implemented, but understudied teen pregnancy prevention program.

The fifth study examines the feasibility and impact of scaling up evidence-based programs and the mechanisms through which 50 OAH grantees aim to reach the highest risk populations. This study will also include a rigorous, cross-grantee study to assess the effectiveness of the larger holistic approach. A meta-analysis evaluation is also being conducted to synthesize the evidence from across previously funded federal and grantee-led evaluations and will examine program or contextual elements that affect youth outcomes. Finally, a secondary data analysis grant aims to identify risk typologies and outcome markers to improve early teen pregnancy prevention.

Recently completed studies include an evaluation of seven new and innovative models for preventing teen pregnancy and a cost-analysis that assessed the costs of implementing several popular evidence-based teen pregnancy prevention programs.

### ***Additional Women's Health Projects***

#### ***Think, Act, Grow (TAG)***

Adolescent Health: Think, Act, Grow® (TAG) is HHS' call to action to promote adolescent health. OAH is proud to be taking the lead on this effort to tip the U.S. towards promoting and investing in adolescent health. TAG is a comprehensive, strengths-based, positive youth development approach to improving adolescent health. TAG's goals are to raise awareness about the importance of adolescent health; engage stakeholders, including youth-serving organizations and caring adults; get adolescent health on the national agenda; and spur action to improve adolescent health.

To develop TAG, OAH engaged more than 80 individuals representing organizations from six youth-serving sectors who all agreed that in order for adolescents to be healthy and develop well, they need the following *Five Essentials*: 1) positive connections with supportive people, including parents, coaches, neighbors, family members, teachers, etc.; 2) safe and secure places to live, learn, and play; 3) access to high quality, teen-friendly health care; 4) opportunities to engage as learners, leaders, team members, and workers; and 5) coordinated adolescent and family-centered services.

TAG includes a resource, "Parents, Families, and Guardians: Making a Difference" that provides information for Parents, grandparents, family members, and guardians about the role they play in promoting the health of the adolescents in their care.

<https://www.hhs.gov/ash/oah/tag/for-families/index.html>

TAG has a broader emphasis than just the home, but also includes safe and supportive places such as schools, neighborhoods, communities, and healthy environments foster and support healthy adolescent development across the spectrum, including physical and mental health, social interactions, and cognitive growth. It includes a set of resources for parent and families on health services, adolescent development and what to expect in talking with teens about visits with a health care provider. Health care that is adolescent-centered and involves parents, but allows for increased autonomy as adolescents reach their late teens, is desired and a focus of TAG.

<https://www.hhs.gov/ash/oah/tag/for-families/index.html>

Free TAG resources available on the OAH website include the TAG Playbook (which outlines the *Five Essentials*, concrete action steps for each youth-serving sector, and resources); a TAG toolkit with sample social media posts; webinars that highlight local programs; successful strategies from innovative programs across the U.S.; and public service announcements. Coming soon to the website are three videos and discussion guides featuring adolescent health experts.

Since TAG was launched in 2014, more than 40 national organizations have committed to promoting this call to action to improve adolescent health. OAH has made more than 25 presentations on TAG at conferences, meetings and webinars and TAG was the subject of a feature story in the American Public Health Association's publication *The Nation's Health*. In addition, OAH has distributed 19,257 *TAG Playbooks* to 89 individuals and national, state and local organizations since Sept 2015. Plans for 2017 include systematically assessing TAG-related activities in HHS regions, and in states and some cities.

### ***Consultation with Women's Health Professionals***

OAH is a member of the Interagency Working Group on Youth Programs. In addition, OAH leads the HHS Adolescent Health Working Group.

### ***CCWH Membership***

OAH serves as a member of the HHS Coordinating Committee on Women's Health.



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

The Assistant Secretary for Planning and Evaluation (ASPE) advises the Secretary of the Department of Health and Human Services on policy development in health, disability, human services, data, and science, and provides advice and analysis on economic policy. ASPE leads special initiatives, coordinates the Department's evaluation, research and demonstration activities, and manages cross-Department planning activities such as strategic planning, legislative planning, and review of regulations. Integral to this role, it conducts research and evaluation studies, develops policy analyses, and estimates the cost and benefits of policy alternatives under consideration by the Department or Congress.

ASPE's work spans women's health issues across age, biological, and sociocultural contexts. The ASPE Office of Human Services Policy focuses on poverty, human service delivery, and policies affecting adolescent girls, mothers, and low-income women across ages and cultures. For example, the Office of Human Services Policy works on teen pregnancy prevention, Temporary Assistance for Needy Families (TANF), homelessness, justice-involved women, and teen dating violence. The ASPE Office of Disability, Aging and Long-Term Care Policy is charged with developing, analyzing, evaluating, and coordinating HHS policies and programs that support the independence, productivity, health, and long-term care needs of women with disabilities, as well as aging women. The ASPE Office of Health Policy is responsible for health care financing and delivery-related policy development, including services delivered to women.

### ***Women's Health-Related Goals and Objectives***

ASPE's goals are the Department's goals as demonstrated through the Department's strategic plan and related research, evaluation, and policy coordination. For example, ASPE's research activities include an analysis of the National Center for Health Statistics (NCHS) data sets to examine trends in the use of clinical preventive services, including service utilization trends among women. This analysis of trends helps ASPE monitor the impact of the Affordable Care Act.

ASPE staff serve on a number of inter- and intra-agency working groups coordinating policy and program development related to improving women's health. Working groups include the *Interagency Working Group on Healthcare Quality and Healthcare Disparities*, led by AHRQ, which prepares annual *National Healthcare Quality and Disparities Reports*. These reports include measures on women's health and disparities by age, gender, and socioeconomic status. ASPE also participates in the *HHS Violence against Women Steering Committee* and the *Federal Teen Dating Violence Workgroup*. These committees build linkages across HHS to improve the Department's response for victims of interpersonal and domestic violence.

### ***Women's Health Projects***

Under the *Teen Pregnancy Prevention Initiative*, ASPE manages several projects addressing rates of teen pregnancies, births, and sexually transmitted infections. The latest estimates indicate that approximately 550,000 teen girls in the United States learn they are pregnant each year. HHS is committed to supporting evidence-based programs and innovative approaches to reducing teen pregnancy.

Over the past six years, ASPE has managed the *Teen Pregnancy Prevention Evidence Review*, which identifies program models with demonstrated positive impacts on teen pregnancies or births, sexually transmitted infections, or associated sexual risk behaviors. This project is overseen by ASPE in collaboration with ACF and OAH.

In addition, ASPE manages the *Federal Teen Pregnancy Prevention Replication Study*, a rigorous experimental evaluation of nine replications of evidence-based programs funded by OAH's *Teen Pregnancy Prevention Program*. ASPE has also published and disseminated policy briefs concerning women and the Affordable Care Act.

In September 2015 ASPE launched a project, Building Evidence for Domestic Violence (DV) Services, to bring together researchers, practitioners, and policy makers in a roundtable to explore ways to safely build a robust evidence base for core DV services. The work conducted through this project will serve as a first step in developing a research plan to support domestic violence programs and services. The project aims to 1) catalog existing rigorous evaluations of domestic violence services, 2) identify and explore potential barriers to conducting research, 3) identify creative methodologies to safely evaluate interventions for victims, and 4) develop a set of recommendations for strengthening future research.

In 2016, ASPE also launched the *Domestic Violence Housing First Demonstration Evaluation*. This study will rigorously evaluate the Domestic Violence Housing First (DVHF) demonstration program coordinated by the Washington State Coalition against Domestic Violence (WSCADV). This evaluation will build on research conducted during the pilot phase of DVHF, contributing to the evidence base on the impacts of housing services for domestic violence survivors by examining housing stability, survivor safety, and children's wellbeing over time<sup>83, 84, 85</sup>.

In June 2016, ASPE's Office of Health Policy published *The Affordable Care Act: Promoting Better Health for Women*, an analysis of the impact of the Affordable Care Act on health care access, affordability, and quality of care for women. Many of ASPE's Affordable Care Act publications, which are available online at

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<sup>83</sup> 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, 103-132.

<sup>84</sup> Sullivan, C.M., Bybee, D.I., & Allen, N.E. (2002). Findings from a community-based program for battered women and their children. *Journal of Interpersonal Violence*, 17, 915-936.

<sup>85</sup> Mbilinyi, L. (2015). The Washington State Domestic Violence Housing First program: Cohort 2 final evaluation report. Seattle, WA: Washington State Coalition Against Domestic Violence. Retrieved May 20, 2016 from [http://wscadv.org/wp-content/uploads/2015/05/DVHF\\_FinalEvaluation.pdf](http://wscadv.org/wp-content/uploads/2015/05/DVHF_FinalEvaluation.pdf)

*<https://aspe.hhs.gov/affordable-care-act-research>*, include data reported by gender. For example, all of the Marketplace enrollment reports include enrollment counts by gender.

### ***CCWH Membership***

ASPE is a member of the HHS Coordinating Committee on Women's Health. ASPE has appointed two representatives to serve on the CCWH.

## **Office of HIV/AIDS and Infectious Disease Policy (OHAIDP)**

The Office of HIV/AIDS and Infectious Disease Policy (OHAIDP) is located within the Office of the Assistant Secretary for Health (OASH). OHAIDP advises the Assistant Secretary for Health (ASH) and other senior HHS officials on the appropriate and timely implementation and development of policies, programs, and activities related to HIV/AIDS, viral hepatitis, and tick-borne diseases, as well as blood and tissue safety and availability.

The lives of women and girls are affected by all of the infectious diseases that OHAIDP addresses. They are among the persons who are at-risk for these infections and those who have been exposed to the pathogen and now have the infection. Some of these infections, such as hepatitis C, can be cured in almost all cases. Others (such as Lyme disease) can be cured easily in some patients if the patient is diagnosed in a timely manner. But other infection like HIV and hepatitis B cannot be cured and require medical care and treatment for an entire lifetime. These conditions are a special concern to public health because they can be transmitted to others, including unborn infants.

The largest activity of OHAIDP is the work it does to manage the Secretary's Minority AIDS Initiative Fund (SMAIF). These resources are appropriated by Congress to improve the efficiency and effectiveness of HIV prevention and care programs for racial and ethnic minorities. SMAIF supports cross-agency demonstration projects that test innovative strategies and solutions that focus on creating lasting systems change and forming strategic partnerships and collaborations that breaks down silos and develops ways for states, local, and federal agencies to work together. Those projects provide outreach, education, and technical assistance to implement best practices to improve HIV prevention, care, and health outcomes for minority communities and support collaborative efforts to solve complex problems that limit the efficiency, effectiveness, and impact of the federal response. These projects work to build the capacity of providers to deliver high-quality services to communities of color that have been hit the hardest by HIV, including women, girls, and transgender women.

In 2016, SMAIF supported 31 projects in 40 states, DC, Puerto Rico, and Guam that were conducted by more than 200 community organizations. Many SMAIF programs benefit the health of women and girls living with HIV part of larger efforts to improve HIV diagnosis, engagement in HIV medical care, and to reduce levels of HIV in the body. Successful efforts include the CAPUS Links program in Louisiana, which linked 90% of people who were newly diagnosed with HIV to medical care in 30 days or less. It includes efforts to integrate HIV testing and deliver high quality HIV care in 12 health centers in 4 states. This project tested more than 77,000 patients who had never been tested for HIV in the first two years and it enabled providers to deliver high quality HIV medical care to more than 7,500 patients.

Increasing the capacity of people living with HIV, especially women, to participate in community prevention and care planning efforts is also supported with SMAIF funding. These funds support a new training program to support leadership development and to build capacity among people living with HIV from disproportionately affected groups of

people of color, including transgender women. This project was awarded to the Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau (HAB) and OHAIDP will provide additional resources to support expansion of the program to specifically increase the participation of transgender women of color as part of this three-year effort.

A continuation SMAIF project impacting women and girls, awarded to the Substance Abuse and Mental Health Services Administration (SAMHSA), is to support efforts to reduce both Intimate Partner Violence (IPV) and HIV through screening and referrals offered in behavioral health care settings by SAMHSA grantees. The Updated National HIV/AIDS Strategy (NHAS) incorporates the objectives and recommendations of the Federal Interagency Working Group on the Intersection of HIV/AIDS, Violence against Women and Girls, and Gender-Related Health Disparities; one of the recommendations is to support and strengthen integrated and patient-centered HIV and related screenings for STIs, substance use, mental health, IPV, and viral hepatitis infections and linkage to care.

Additionally, SMAIF is the primary source of funding for the federal government's activities to improve the health of women and girls by providing current HIV-related information (and other relevant topics) through the internet and social media channels. AIDS.gov supports activities and events specifically designed to meet their needs, promoting the work of HIV-related and other relevant content, events, and activities for women and girls that have been developed by OWH, the Centers for Disease Control and Prevention (CDC), and other federal and community partners, and offering technical assistance on using digital media for effective outreach to women and girls.

In June 2017, AIDS.gov was rebranded to HIV.gov to reflect the advances in medical science and treatment of HIV, and to further improve the user experience through easier navigation to related content, enhanced search functionality, and ability to share specific pieces of content.

### ***Expert Advice and Consultation***

The Presidential Advisory Council on HIV/AIDS (PACHA) is a federal advisory committee that is managed within OHAIDP. According to the PACHA charter, the Council shall have no more than 25 members. Council members include prominent community leaders with particular expertise in, or knowledge of, matters concerning HIV and AIDS, public health, global health, philanthropy, marketing or business, as well as other national leaders.

The PACHA provides advice, information, and recommendations to the Secretary of HHS regarding programs, policies, and research to promote effective treatment, prevention and cure of HIV disease and AIDS, including considering common co-morbidities of those infected with HIV as needed to promote effective HIV prevention and treatment and quality services to persons living with HIV disease and AIDS. Additionally, the White House asks PACHA to provide, on an ongoing basis, recommendations on how to effectively implement the Updated National HIV/AIDS

Strategy, as well as monitor the Strategy's implementation. PACHA's recommendations include priorities intended to promote effective prevention, access to care, and treatment of HIV, including programs and policies impacting women and girls.

OHAIDP continues to oversee the implementation of the National HIV/AIDS Strategy for HHS, which calls for reducing HIV transmission, increasing access to HIV care and improving health outcomes, reducing HIV-related disparities and health inequities, including gender disparities. The NHAS also calls for the federal government to achieve a more coordinated national response to the HIV epidemic, which OHAIDP supports through improved HIV data standardization, reduced HIV reporting obligations for grantees, and attempts to improve HIV data system interoperability. As part of this activity, OHAIDP has participated in two White House Office of National AIDS Policy (ONAP)-sponsored consultations with transgender women to identify unmet needs and opportunities to reduce HIV infections and improve treatment outcomes in this disproportionately affected population. These discussions have led to ongoing opportunities for input and dialogue with HHS, including a planned virtual listening session that will be held in December 2016 on potential strategies to better address the needs of transgender women through SMAIF. OHAIDP participated in the development of the first NHAS indicator focused on transgender women that will be released by ONAP in December 2016. The NHAS indicator to increase the percentage of transgender women in HIV medical care who are virally suppressed to at least 90% by 2020 was included as one of three developmental indicators that were released in the December 2016 NHAS Indicator Supplement. In November 2017, the first data for this indicator were published in the HRSA Ryan White HIV/AIDS Program Services Report (RSR). The report showed that 79% of transgender women who received HIV medical care in the Ryan White HIV/AIDS Program in 2016 had a suppressed viral load. This result exceeded the target for that year, which was 74.7%.

### ***Blood and Tissue Safety and Availability***

The health of millions of people depends on the safety and availability of blood and tissue products whenever they are needed. Threats to the stability of the blood and tissue supply systems as well as protection against new blood-borne infections is a major part of OHAIDP's work.

For example, Zika is a new and significant public health threat that poses risks to pregnant women and their unborn infants. Because Zika is a blood-borne infection, it is necessary to ensure the safety of the blood supply to prevent transfusion-associated cases of Zika. OHAIDP monitors the Zika virus blood donor testing results for the U.S. and the U.S. Territories blood collecting centers. As of December 1, 2017, OHAIDP has reported that there are 54 confirmed positive testing results in samples of donated blood (13.5 million) collected in the continental U.S. (CONUS) and 356 confirmed cases of Zika-positive blood donor testing results for Puerto Rico from 111,808 blood units tested. Because of restrictions on blood donation, new screening requirements, and the added cost of Zika screening, there is a risk that supplies of some blood products could be exhausted in some communities or that local blood collection centers would become insolvent and cease operation. OHAIDP monitors the blood availability of blood and blood products for the United States. OHAIDP, with active support from OASH leadership, was instrumental in identifying and coordinating efforts to ensure the

availability of safe blood for Puerto Rico. This avoided a shortage of safe blood when the island was considered endemic for the Zika virus and they could not accept blood donations from the island inhabitants. OHAIDP continued supporting the blood requirements from the CONUS until the U.S. Food and Drug Administration (FDA) approved a ZIKA Investigation New Drug (IND) Nucleic Acid Testing (NAT) on August 26, 2016.

OHAIDP conducted the *Tissue and Donor Epidemiology Study (TODES)* to improve transplant safety as well as the *National Blood Collection and Utilization Survey (NBCUS)*. The Advisory Committee on Blood and Tissue Safety and Availability, which is managed within OHAIDP, addresses the availability of an adequate and safe tissue and blood supply. Many of these activities have implications for reducing administrative burdens and improving prevention, treatment, and care services that benefit all Americans, including women and girls.

Additionally, OHAIDP conducted the National Tissue and Utilization Survey to collect information on tissue recovered from U.S. deceased and living donors. The overarching objective of this survey is to generate national estimates for tissue recovery through utilization activities that occurred during calendar year 2014. The collection and reporting of relevant data from U.S. tissue banks will provide useful data to inform, strategic and regulatory agendas.

### ***Collaboration with HHS and Other Federal Agencies and Offices***

Federal agencies have continued to accelerate their efforts to achieve an AIDS-free generation. During the timeframe of March 23, 2015-March 23, 2017, HIV.gov (formerly AIDS.gov) continued to support the White House Office of National AIDS Policy (ONAP) in its work affecting women and girls. Specifically, HIV.gov staff worked with ONAP to develop communications and infographics on the National HIV/AIDS Strategy, and its related reports and documents, and with its work around intimate partner violence as a risk factor for HIV among women and girls. Additionally, HIV.gov provided ongoing advice to OWH on digital planning, methods to improve the reach of messaging to women and girls, and evaluation.

OHAIDP is partnering with OWH on two new projects that impact women and girls' health. First, HIV.gov and OWH are developing a video series, Positive Spin Women, which promotes digital storytelling and shares the true stories of women living with HIV who have successfully navigated the HIV care continuum to reach viral suppression. The series is designed to educate and motivate women living with HIV to get into care and adhere to treatment to guard and improve their long-term health and lower their risks for transmitting HIV. Positive Spin Women is in production and is scheduled to launch in the spring of 2018.

Another project OHAIDP is committed to is the development of content on viral hepatitis and messages specific to women and girls. Due to OHAIDP's development and implementation of the viral hepatitis website, which was launched on May 19, 2016,

there is an exciting opportunity for HHS to share resources and tools that specifically address the needs of women with regard to the prevention, care and treatment of Hepatitis B virus (HBV) and Hepatitis C virus (HCV). OHAIDP is eager to bring on a fellow to help with this ongoing activity.

### ***Stakeholder Events***

Since the release of the *2015 Report on HHS Activities to Improve Women's Health*, HIV.gov's regular promotion, technical assistance, and other support for women and girl's health included activities for the 2016 observance of National Women and Girls HIV/AIDS Awareness Day (NWGHAAD). Each year, HIV.gov has a key set of activities for the NWGHAAD observance. These include inviting OWH to share resources and updates for the observance with over 20 agencies represented on the Federal HIV/AIDS Web Council (FHAWC); featuring NWGHAAD on the HIV.gov homepage callout box and updating the NWGHAAD resource page to include OWH events and graphics; featuring multiple posts on the HIV.gov blog, including cross-posting blogs from other federal programs; promoting NWGHAAD and other OWH activities on HIV.gov's Twitter, Facebook, and Pinterest channels multiple times before and on the day; promoting OWH's NWGHAAD walk in Washington, D.C.; and sending emails to FHAWC members promoting OWH activities and resources. Many of these activities were repeated in 2017.

In addition to these standard activities for the 2016 observance of NWGHAAD, HIV.gov also promoted OWH's "Ambassador" and "Voices" videos, which featured women talking about their experiences of living with HIV, and OWH's *Know the Facts First* campaign to educate girls about STDs (promotion that continues); participated in CDC's NWGHAAD "blog hop"; and joined a Thunderclap for OWH. Activities for 2017 will be developed in consultation with OWH, CDC, and other federal and community partners.

Because of disproportionate rates of Hepatitis C virus infection, African Americans are among the populations prioritized by the Action Plan for the Prevention, Care and Treatment of Viral Hepatitis (Action Plan), which outlines steps to educate communities about the benefits of viral hepatitis prevention, care, and treatment, as well as actions to enhance healthcare provider knowledge about the populations most heavily impacted. The national Action Plan underscores the importance of the participation and engagement of partners from many sectors beyond the federal government in order to achieve the plan's life-saving goals, especially those related to addressing health disparities like improving outcomes for African Americans living with Hepatitis C.

In recognition of both National Women's Health Week and Hepatitis Awareness Month, OHAIDP, OWH, and OMH co-sponsored a webinar, Hepatitis C and African American Women, on Thursday, May 7, 2015. More than 400 people participated in the webinar.

Webinar presenters discussed how women may be affected by Hepatitis C, challenges and strategies to improve testing and access to care, and what steps individuals and health



care providers can take to address Hepatitis C among women in the African American community.

On September 29, 2015, OHAIDP hosted an expert meeting, the *Technical Consultation on the Elimination of Perinatal Hepatitis B in the U.S.* to review a) perinatal HBV prevention gaps, opportunities, best practices, and resources; and b) identify next steps at the provider, hospital, and health systems levels to eliminate perinatal HBV transmission in the United States.

One of the four overarching goals of the Action Plan is the elimination of mother-to-child transmission of HBV. To advance efforts toward that goal, in September 2015, HHS convened a one-day technical consultation, bringing together over 40 diverse experts and stakeholders. The consultation yielded a number of practical recommendations and identified model programs and policies that would, if widely implemented, reduce mother-to-child transmission of Hepatitis B. The full meeting report on the *Technical Consultation on the Elimination of Perinatal Hepatitis B* in the United States can be found here: <https://www.hhs.gov/hepatitis/blog/2015/12/22/approaches-to-eliminating-perinatal-hbv-transmission-report-from-an-hhs-technical-consultation.html>

### ***CCWH Membership***

OHAIDP is a member of the HHS Coordinating Committee on Women's Health.

## Office of Minority Health (OMH)

The Office of Minority Health (OMH) is dedicated to improving the health of racial and ethnic minority populations through the development of health policies and programs that will help eliminate health disparities.

OMH programs address disease prevention, health promotion, risk reduction, healthier lifestyle choices, use of health care services, and barriers to health care for racial and ethnic minority populations in the United States. During the reporting period, OMH administered the following programs and activities that address women's health.

- The *HIV/AIDS Health Improvement for Reentrants Program (HIRE)*, supported by the Secretary's Minority AIDS Initiative Fund, resulted in improved HIV/AIDS and Hepatitis C virus (HCV) health outcomes of individuals who are formerly incarcerated and are re-entering into their community, by supporting community-based efforts to ensure their successful transition from state or federal prison back to their communities. Seven grantees were funded to implement the program in three of the five states with the highest incidence of HIV or confirmed AIDS in populations who were incarcerated in state and federal prisons the end of 2008: New York, Florida, and Georgia. Using a systems navigation approach, HIRE grantees provided access to prevention and treatment services to the re-entry population that included transition assistance, prescription drug assistance, substance use disorder treatment, behavioral health services, housing, education, employment assistance, family, and community involvement. Grantees reached more than 6,000 justice-involved re-entrants, including women, their partners and community members. The HIRE program was funded for a four year project period from September 2012 to August 2016.
- As part of the *Mobilization for Health: National Prevention Partnership Awards (NPPA) Program*, OMH funded the *South Side Coalition on Urban Girls (SSUG) Girl...KnoW More! Project*. The project aimed to improve the health and wellness of girls ages 14-18 living in urban communities by reducing the incidence of human papilloma virus (HPV) and sexually transmitted infections (STIs) through a year-long comprehensive community saturation model. The model consisted of four components: 1) Adolescent Prevention and Education; 2) Parent/Community Awareness and Education; 3) Capacity Building Training; and 3) Digital and Social Media. During FY 2015, the *Girl...KnoW More!* project reached over 10,000 girls in targeted Chicago, Illinois neighborhoods through workshop facilitation and social media. Findings suggested an increase in knowledge regarding HPV and STIs among participants, as well as intentions suggesting a positive impact on reduction of HPV and STIs, and an increase in participants' self-esteem and critical thinking skills.
- Through the *NPPA Program*, OMH funds the *Healthy Homes for Healthy Kids and Families Project*. The project is designed to promote health equity and reduce health disparities in the City of Manchester, New Hampshire through strategies that improve clinical and community preventive services, provide disadvantaged residents with

resources and skills to live healthier lives, and improve outreach efforts to minority and limited English proficiency populations. This systematic approach is strategically aligned and connected with health care delivery systems and public health resources within the community to increase access to preventive health services and ensure a healthy start for all children and their families. As of the end of FY 2016, the project had begun efforts to conduct home visits to expectant mothers, assisted more than 14,500 individuals in obtaining healthcare coverage and helped more than 252 families receive assistance with navigating community/social services (including interpretation services).

- OMH funded the *National Health Education Lupus Program (NHELP)* in FY 2016 to reduce lupus-related health disparities among racial and ethnic minority and/or disadvantaged populations disproportionately affected by this disease under two priority initiatives:

- Priority A: to conduct a national health education program on lupus to increase and improve awareness, diagnosis, and treatment outcomes for individuals living with lupus;
- Priority B: to develop and begin implementing an education program on clinical trials that educates and recruits minorities and/or disadvantaged populations, particularly groups underrepresented in clinical research.

The NHELP supports three grantee projects under Priority A that will increase: (1) the number of health professionals and student trainees who are knowledgeable and skilled in the diagnosis and treatment of lupus; (2) the number of health professionals with enhanced knowledge and expertise in the signs and symptoms of lupus, treatment adherence, and screening; (3) the number of people who are aware of the disease and knowledgeable about its symptoms and warning signs; and (4) the number of providers that use culturally and linguistically appropriate lupus materials to disseminate information to patients and families, including educational and multi-media materials.

NHELP supports an additional grantee program under Priority B to develop and begin implementing an education program on clinical trials that educates and recruits minorities and/or disadvantaged populations underrepresented in clinical research.

- The *Youth Empowerment Program (YEP)* addresses unhealthy behaviors in at-risk minority youth, provides them with opportunities to learn skills, gain experiences that contribute to more positive lifestyles, and enhance their capacity to make healthier life choices in areas such as sexual risk behavior and teen pregnancy. YEP employs a highly innovative and multi-partnership collaborative approach involving institutions of higher education, primary and secondary schools, sports organizations, youth clubs, other related community organizations and institutions, and the community at-large on reducing risky behaviors among targeted minority youth 10 to 18 years of age. A total of seven grantees are funded under the YEP program for a five year project period. During FY 2015 and FY 2016, YEP participants engaged in cultural activities; summer programming; college preparation; community service; mentoring; financial literacy sessions; and internships, and reached over 12,000 at-risk minority youth and their families and community stakeholders. Approximately 51 percent of YEP participants are female.

- Beginning in March 2016, OMH has helped educate the public on the impact of and prevention of the Zika virus infection. OMH created Zika Resources webpages, which contain information and links to resources across the federal government and in every U.S. state and territory. The webpages, available in English and Spanish, have a section dedicated to pregnant women. OMH has also collaborated with HHS partners, including the Centers for Disease Control and Prevention (CDC), the OASH's Office of Population Affairs (OPA), and the Assistant Secretary for Preparedness and Response (ASPR), on translation of fact sheets, development of blog posts, and organizing and participating in social media events related to Zika and women's health.
- OMH partnered with tOASH's Office on Women's Health who led the development and launch of the *Breast Reconstruction Awareness Campaign* in October 2016 and was also supported by the National Cancer Institute (NCI), the Centers for Medicare & Medicaid Services (CMS), the Centers for Disease Control and Prevention (CDC), and HRSA's Office of Rural Health Policy (ORHP). The goals of the campaign are to increase awareness of the benefits afforded women through the Women's Health and Cancer Rights Act of 1998 regarding breast reconstruction after a mastectomy and to provide resources for health care providers and patients to support conversations about breast reconstruction. OMH ensured that the information and materials considered the existing breast reconstruction disparities among African American and Hispanic women, were culturally and linguistically appropriate, and were written in plain language. OMH developed resource pages on its website, in English and Spanish, dedicated to provide resources and information about the cancer disparities among African American and Hispanic women. OMH also posted blogs in English and Spanish to create awareness about breast cancer, the importance of early detection, and resources available for patients.
- In FY 2015 and FY 2016, the Deputy Assistant Secretary for Minority Health and Director of the Office of Minority Health continued to be actively engaged in outreach efforts to women across the nation on the Affordable Care Act and the many provisions of the law that impact women's health. These activities included national media appearances and interviews, speaking engagements, stakeholder meetings and calls, webinars, and conferences.
- In FY 2015 and FY 2016, OMH supported national observances related to women's health, including National Women's Health Week, Women's History Month, and National Women and Girls HIV/AIDS Awareness Day. OMH also promoted campaigns and initiatives led by other federal agencies and shared information related to women's health through social media and newsletters to stakeholders.
- OMH created the *Preconception Peer Educators (PPE) Program* in 2008, to reach college-age African American students with targeted health messages, emphasizing preconception health and health care. The OMH Resource Center introduces the PPE Program to college campuses and communities, and the program is implemented by faculty and/or state or non-profit health workers. Trained college students become peer

educators with materials and activities to train their college peers and surrounding community members. Currently there are fifty schools nationwide acting as PPE sites and nearly 500 students at those schools participating in PPE activities. Approximately 2,200 women and men have been trained since the start of the PPE program, and they in turn have educated an estimated 12,000 individuals.

- In FY 2015 and FY 2016, the Region X Minority Health and Women's Health teams led the coordination of the *Improving the Health and Well-being of Latinas: Tools and Resources for Public Health and Social Service Providers* event, with support from other HHS Region X federal partners and community health organizations. At the events, tools and information were provided to participants for their use when working with Hispanic/Latina women around health issues. Session topics included updates on the Affordable Care Act and From Coverage to Care, mental health issues in Latina communities, domestic violence awareness, the Adverse Childhood Experiences Study, diabetes, the Zika virus, and other subjects requested by attendees via evaluations. Each session explored the impact of health disparities on Latinas and the health status of Latinas, and provided community resources. The audience included public health and social service providers who work with Hispanic/Latina women including community health workers, promotores de salud (Spanish-speaking community health workers), community health educators and case managers.

### ***CCWH Membership***

OMH is a member of the HHS Coordinating Committee on Women's Health.

## Office of Population Affairs (OPA)

The Office of Population Affairs (OPA) oversees the Title X Family Planning Program, first authorized by the Public Health Service in 1970. The *Title X Family Planning Program* provides access to family planning and related preventive health services with priority given to low-income persons. Services are provided voluntarily and available on a confidential basis.

OPA is overseen by the Deputy Assistant Secretary for Population Affairs within the Office of the Assistant Secretary for Health.

In 2016, OPA provided grant funding to 91 public or private non-profit entities that operated nearly 3,900 centers across the country that provide quality family planning services. Each year, Title X-funded service grantees submit data to OPA through the *Family Planning Annual Report* (FPAR), and OMB-approved data collection system. OPA is in the process of revising the FPAR system to collect encounter-level family planning-related data using Electronic Health Records (EHR) systems (coined ‘FPAR 2.0’). OPA is working with the American College of Obstetricians and Gynecologists (ACOG) to transition FPAR 2.0 into final testing and implementation phases. ACOG will complete the following tasks:

- finalize the Integrating the Healthcare Enterprise (IHE) Family Planning profile;
- identify and develop the best interoperability standard that will be used to capture FPAR 2.0 data elements from service sites;
- determine how and where to store collected data securely;
- pilot the interoperability standard with Title X service sites;
- develop a web-based cloud application to accommodate sites that do not have an interoperable EHR system in place; and
- align FPAR 2.0 efforts with complementary women’s health data collection projects, such as ACOG’s Maternal Quality Improvement Project (MQIP) and the Women’s Health Registry Alliance.

This advancement will better measure performance and allow comparability at the national, regional, and local levels as well as establish a format for collecting performance measures, and tracking progress toward measuring contraceptive access.

- In 2016, OPA led initiatives and projects to address public health challenges of controlling the impact of the Zika Virus.
- In August 2016, *Providing Family Planning Care in the Context of Zika: A Toolkit for Providers from the U.S. Office of Population Affairs*, was published in the online Journal, *Contraception*. This article details the need for providing Zika-related care for non-pregnant clients of reproductive age and highlights OPA’s Zika toolkit, <https://www.hhs.gov/opa/zika/toolkit/index.html> *Providing Family Planning Care for Non-Pregnant Women and Men of Reproductive Age in the Context of Zika: A*

Toolkit for Healthcare Providers. This article further delineates the need for using a client-centered approach when counseling clients about safely achieving and preventing pregnancy in the context of Zika. This article was designed to help providers meet these needs.

- In the summer of 2016, OPA awarded supplemental funding to enhance Title X-funded family planning projects in Arizona, California, Mississippi, Puerto Rico, Texas, and the Virgin Islands. These supplemental funds were given to support increased availability of family planning services and access to contraception for women and men during the Zika outbreak. In April, 2016 OPA also awarded supplemental funding to the two Puerto Rico grantees for similar purposes regarding expanding Title family planning services in the context of the Zika outbreak. Other federal agencies (CDC and HRSA) also concentrated efforts to increase access to contraceptive services across Puerto Rico, and those efforts make it difficult to isolate the outcomes of the Title X supplemental funding alone.
- In June & August 2016, OPA met with representatives of eight states (AZ, CA, FL, GA, LA, MS, SC, TX), HHS representatives (e.g., CDC, HRSA/BPHC, CMCS), and selected national organizations (e.g., ACOG, ASTHO) to discuss increasing access to contraception in the context of Zika, with the expectation that there would be more local transmission of Zika in those states, and the needs would be greater. Fortunately, the local transmission was not as great as was anticipated.
- In September 2016, OPA's acting director, Susan Moskosky, authored a commentary in *Public Health Reports*, entitled "*Pregnancy Intention—More Important Than Ever.*" This commentary notes, "Providers should educate their reproductive-age clients about the potential risk of Zika infection before the client decides to get pregnant and help pregnant women avoid infection through mosquito bites or unprotected sex with an infected or exposed partner."
- In September 2016, Twitter D.C. hosted HHS at their new headquarters for an all-day event to cover various aspects of the Zika Virus. Through the use of video Q/A, OPA's acting director along with OWH's director educated key audiences about aspects of Zika, especially providing Zika-related care to non-pregnant clients of reproductive age.

In collaboration with the CDC's Division of Reproductive Health, OPA published "*Providing Quality Family Planning Services Recommendations (QFP)*" in April 2014. These recommendations establish national guidelines for providing family planning and related preventive services.

To support grantees in providing quality services and implementing the QFP recommendations, OPA funds a Family Planning National Training Center (FPNTC) to ensure that personnel working in Title X family planning service projects have the knowledge, skills, and attitudes necessary to effectively deliver high-quality family planning services. A new 4-year cooperative agreement for the Family Planning **National**

**Training Center was awarded in September 2016 to JSI, Inc.** It continues the work of previous National Training Centers with a focus on improving the capacity of Title X providers to deliver high-quality family planning services. The FPNTC works closely with the OPA-funded National Clinical Training Center, at the University of Missouri-Kansas City, which provides clinical training for all types of clinical providers within the Title X network, including nurse practitioners, certified nurse midwives, physicians, and physician assistants.

### ***Affordable Care Act Activities***

To increase the ability of Title X providers to remain sustainable after implementation of the Affordable Care Act, OPA focused its efforts in two main areas:

1. preparing the Title X service delivery network—grantees and Title X centers—for changes in the health care system; and
2. understanding the impact of Affordable Care Act and health systems changes on the Title X program and its providers.

The training centers funded by OPA have produced a number of resources for family planning providers related to the Affordable Care Act and the provision of quality family planning. These resources are available at [www.fpntc.org](http://www.fpntc.org).

In August 2014, OPA funded four competitive cooperative agreements to create the *Affordable Care Act Collaborative*. These organizations assessed the impact of health system changes on Title X centers as a result of the Affordable Care Act. The Affordable Care Act Collaborative studied if and why service sites continue to see a disproportionate number of uninsured patients and assessed the long-term factors affecting the sustainability of Title X centers. These factors included cost, billing, reimbursements, and network inclusion as well as confidentiality. Final reports from these projects were received in fall of 2017.

### ***Women's Health Goals and Objectives***

To increase the number of unintended pregnancies averted by providing Title X family planning services, particularly to low-income individuals, OPA seeks to

- Maintain the proportion of clients served who have family incomes at or below 200 percent of the federal poverty level, at 90 percent of total unduplicated family planning users.
- Increase the proportion of female clients at risk of unintended pregnancy who indicate using a highly or moderately effective method of contraception as their primary method of contraception.



Recently, to further support the advancement of quality family planning services, OPA submitted three contraceptive care measures to the National Quality Forum (NQF) for endorsement, and at the end of October, 2016, the NQF board had endorsed these contraceptive measures. NQF-endorsed measures are considered the gold standard for healthcare measurement in the United States. These measures will allow all levels of the health care system to monitor quality of care, compare performance across systems, and save money through the reduced costs of unintended pregnancy and childbearing.

### ***Collaborations with HHS Agencies and Offices***

- With HRSA's Maternal and Child Health Bureau (MCHB), and Bureau of Primary Health Care (BPHC) to coordinate training and other relevant activities related to family planning that enhances the delivery of quality family planning services.
- With the CMS Center for Medicaid and CHIP Services (CMCS), and CDC/DRH, OPA collaborates to fund the Association of State and Territorial Health Officials (ASTHO). ASTHO manages a learning community focused on increasing contraceptive access by identifying reimbursement and other strategies that enhance the prevention of unintended pregnancy. The Learning Community includes family planning, state Medicaid, Maternal Child Health, and Primary Care providers in 28 states,
- With CMS's Center for Consumer Information and Insurance Oversight (CCIIO) to help clients enroll in affordable health insurance programs.
- With the CDC Division of Reproductive Health (CDC/DRH) to strengthen the evidence base and continue developing national standards for the content and delivery of quality family planning services.
- With the *Eunice Kennedy Shriver* National Institute of Child Health Development and other federal and non-federal agencies to identify gaps in family planning research and develop strategies to address those gaps.
- With the CDC National Center for Health Statistics (NCHS) to support development and implementation of the National Survey of Family Growth.
- With the HHS Office of the National Coordinator (ONC), OPA participated in an initiative to build a coalition among federal offices in HHS, private-sector electronic health records (EHR) vendors, and IT consultants to pilot test and standardize the way in which data related to Chlamydia screening can be improved within EHR systems.
- With the National Association of Community Health Centers (NACHC) on a project to increase access to quality family planning services in federally qualified health centers by piloting the contraceptive care measures in primary care settings.

### ***Collaborations and Consultations***

OPA works with several national organizations to track issues relevant to family planning providers and on issues impacting women's health.

OPA participates on the following workgroups and committees:

- White House Working Group on the Intersection of HIV, Intimate Partner Violence and Gender-related Health Disparities
- The HHS Violence Against Women Working Group
- The Preconception Health and Health Care Steering Committee
- Preconception Care for HIV+ Women (HAB/HRSA and CDC)
- Adult Committee on Immunization Practice (CDC)
- The Adolescent Health Working Group (OAH)
- The Healthy People 2020 Family Planning Workgroup
- The U.S. PrEP and Women Working Group

### ***CCWH Membership***

OPA is a member of the HHS Coordinating Committee on Women's Health.

## **The Office of the Surgeon General (OSG)**

The Office of the Surgeon General (OSG) is part of the Office of the Assistant Secretary for Health. As the Nation's Doctor, the Surgeon General provides Americans with the most up-to-date and best scientific information available on how to improve their health and reduce the risk of illness and injury. The Surgeon General serves as the Nation's leading spokesperson on matters of public health.

In 2010, the Affordable Care Act designated the Surgeon General as the Chair of the National Prevention Council (NPC), which provides coordination and leadership among 20 executive departments with respect to prevention, wellness, and health promotion activities. OSG represents the HHS Secretary and the Assistant Secretary for Health on topics addressing public health practice.

### ***Health & Human Services Workforce***

The Office of the Surgeon General serves as command for the U.S. Public Health Service. The Surgeon General is the commanding officer of over 6,700 uniformed public health and medical professionals stationed in over 800 locations throughout the United States and globally to respond to public health emergencies. Officers are assigned throughout government agencies and other locations, including vulnerable communities.

The Commissioned Corps Women's Issues Advisory Board (CCWIA) focuses on improving women's health issues as well as advancing the role of women in leadership positions throughout the public health workforce. As of December 5th, 2016, Commissioned Corps officers are authorized 84 days of non-chargeable leave for postpartum recovery, beginning the day after the mother is discharged from the hospital. This is an increase from the number of days (42 days for normal delivery, 56 days for Caesarean section) that mothers were previously authorized.

### ***Advance the Health and Well-being of American Women***

#### ***National Girls & Women in Sports Day (February 2016)***

In partnership with the Office of Women's Health and the President's Council on Fitness, Sport & Nutrition, the Surgeon General met with national ambassadors from the council, former athletes and foundation leaders to discuss the importance of women participating in sport. The Surgeon General committed his office's voice on this issue and implemented the Call to Action on walking, with a special focus on women increasing their physical activity.

#### ***Women's Heart Health Month (February 2016)***

The Office of the Surgeon General focused their national efforts on raising the country's awareness of the role heart disease plays in millions of women's lives. The Surgeon General's social media account featured posts about women's heart health to our over 99,700 Twitter followers. In addition, the Surgeon General attended the *Go Red for Women* gala in New York, New York celebrating the continued fight to improve women's heart health.

### ***Flint Water Crisis (March 2016)***

The Office of the Surgeon General visited Flint, Michigan, during the height of the water crisis. As a representative of HHS, the Surgeon General held community roundtable meetings with health professionals, faith leaders, and community advocates to address the federal response to the crisis. The Surgeon General hosted a community town hall to hear the concerns of residents and leaders in the local community. During the Surgeon General's individual home visits, he had the opportunity to sit with mothers who spoke of the challenges of caring for their children in the midst of this crisis. He also met with pediatricians who work directly with mothers of children affected by the lead.

### ***Zika Prevention & Education (August/September 2016)***

The Surgeon General was identified as the principal spokesperson for addressing the spread of the Zika Virus in the United States. In response to the challenges identified, especially for mothers in the Hispanic community, the Surgeon General traveled to Puerto Rico and Miami, Florida, hosting media and stakeholder conference calls to address the most up-to-date guidance on the spread of Zika. The Surgeon General visited a women's health center and hosted a roundtable discussion with pregnant mothers.

To engage relevant stakeholders, the Surgeon General partnered with the American College of Obstetrics and Gynecology in August 2016. They hosted a national call for healthcare providers serving female patients to answer pressing questions about the signs and symptoms of Zika as well as most viable options for care. In addition, the Surgeon General hosted a Twitter chat with MomsRising on September 28, 2016, during their #WellnessWed series on Zika prevention.

### ***Turn the Tide Rx Opioid Addiction Campaign (September 2016)***

The Office of the Surgeon General initiated the *Turn the Tide* campaign focused on the exponential growth of the opioid addiction problem in the U.S. An important driver of the opioid epidemic is legally written prescriptions from doctors, dentists, nurse practitioners, and physician assistants. By improving prescribing practices, clinicians can reduce the supply of misused opioids while still treating pain safely and effectively. This national campaign was based on the concept of "prescribers talking to prescribers." The Surgeon General sent a letter to over 2 million prescribers, urging them to (1) improve prescribing practices; (2) inform their patients about the risks of opioid addiction; and (3) connect people with opioid use disorders to evidence-based treatment.

In response to this national crisis, the Surgeon General was featured on [www.womansday.com](http://www.womansday.com) on September 8, 2016, with an article on drug addiction. In addition, the HHS Office of Women's Health convened experts and stakeholders on

September 29, 2016, to examine issues associated with the opioid crisis through the lens of women's health. Benefiting from recent work underway by federal agencies and other organizations, this meeting provided an opportunity to foster a national conversation about best practices in opioid use disorder prevention and treatment for women. It also supported a vigorous collaboration among researchers, public health practitioners, clinicians, policy makers, women with lived experience, and others. The Surgeon General joined a panel during the summit to announce the *Turn the Tide* campaign and share his vision for ending the country's opioid epidemic. A summary of the event is available online: <https://www.womenshealth.gov/files/documents/final-report-opioid-508.pdf>.

### ***Step it Up: The Surgeon General's Call to Action to Promote Walking & Walkability***

This *Call to Action (CTA)* has five goals, with related strategies, to support walking and walkability in the U.S. Implementation of these strategies will make it easier and safer for people to walk, use a wheelchair, ride a bike, and be physically active in other ways to advance the health and well-being of the American public.

1. Make Walking a National Priority
2. Design Communities that Make It Safe and Easy to Walk for People of All Ages and Abilities
3. Promote Programs and Policies to Support Walking Where People Live, Learn, Work, and Play
4. Provide Information to Encourage Walking and Improve Walkability
5. Fill Surveillance, Research, and Evaluation Gaps Related to Walking and Walkability

### ***Step it Up Challenge (October 2016)***

Heart disease continues to be the leading cause of death in women. Lack of physical activity is a contributing factor to this statistic. In October 2016, the Surgeon General's office in partnership with Fitbit developed the *Step it Up Walking Challenge*. Along with partners such as Let's Move (with a video from former First Lady Michelle Obama), Fitbit, Women's Heart Health (Barbra Streisand) and Jordin Sparks, the Surgeon General encouraged women and their families to increase their physical activity as a strategy for chronic disease prevention. Over 600,000 participants walked for over 60 billion steps.

### ***E-Cigarette Use Among Youth & Young Adults (December 2016)***

On December 8, 2016, the Surgeon General released the first report on electronic cigarette use among youth and young adults. This landmark report confirmed that e-cigarettes have the potential to cause lasting damage to the health of youth under the age of 25. To ensure mothers were aware of the findings, the Surgeon General participated in an interview with MomsRising on December 16.

### ***CCWH Membership***

OSG is a member on the HHS Coordinating Committee on Women's Health.

## V. CONCLUSION

Section 3509 of the Affordable Care Act directs HHS agencies and offices to establish goals and objectives and coordination for issues of particular concern to women, including through the CCWH. The law facilitates access to information regarding matters relating to health information, health promotion, preventive health services<sup>86</sup>, research advances, and education in the appropriate use of health care through the mandated NWHIC. Section 3509 outlines the steps and activities needed within various HHS federal agencies and offices to address the gaps and disparities in women's health and to support innovative and evidence-based programs.

In addition to the requirements under section 3509, the Affordable Care Act includes other provisions specific to women's health. They include the prohibition on gender rating in new health insurance plans starting in 2014 and access to recommended women's preventive services without cost-sharing in non-grandfathered health plans.

OWH, AHRQ, CDC, FDA, HRSA, NIH, and SAMHSA have completed or made significant progress on the requirements outlined in section 3509. In addition, various other HHS federal agencies and offices have contributed to and participated in such efforts, including through the CCWH.

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<sup>86</sup> *The Guide to Clinical Preventive Services*, U.S. Department of Health and Human Services, <http://www.uspreventiveservicestaskforce.org/Page/Name/tools-and-resources-for-better-preventive-care>.

## Appendix GLOSSARY

Acronym	Meaning
AACP	American Association of Colleges of Pharmacy
AARP	American Association of Retired Persons
AAWS	Associate Administrator for Women's Services
ACF	Administration for Children and Families
ACL	Administration for Community Living
ACNM	American College of Nurse Midwives
ACOG	American College of Obstetricians and Gynecologists
ACRWH	Advisory Committee on Research on Women's Health
ACSI	ForeSee American Customer Satisfaction Index
ACWS	Advisory Committee for Women's Services
ADRC	Aging and Disability Resource Centers Program
AHA	American Hospital Association
AHRQ	Agency for Healthcare Research and Quality
AI/AN	American Indian/Alaska Native
AIDD	Administration on Intellectual and Developmental Disabilities
AIM	Alliance for Innovation on Maternal Health
AMCHP	Association of Maternal and Child Health Programs
AoA	Administration on Aging
APHA	American Public Health Association
ASCQ-Me	Adult Sickle Cell Quality of Life Measurement Information System
ASH	Assistant Secretary for Health
ASPE	Assistant Secretary for Planning and Evaluation
AUCD	Association of University Centers on Disabilities
AWHONN	Association of Women's Health Obstetric and Neonatal Nurses
BD-STEPS	Birth Defects Study to Evaluate Pregnancy Exposures
BFB	Best Fed Beginnings
BIRCWH	Building Interdisciplinary Research Careers in Women's Health
BLAs	Biologic License Applications
BMI	Body Mass Index
BPHC	Bureau of Primary Health Care (HRSA)
BRAIN	Brain Research through Advancing Innovative Neurotechnologies Initiative
BRCA	<u>B</u> reast <u>C</u> ancer Susceptibility Gene
BSS	Brief Screening Survey
CAPUS	Care and Prevention of HIV in the U.S. Demonstration Project

CBER	Center for Biologics Evaluation and Research (FDA)
CBHSQ	Center for Behavioral Health Statistics and Quality
CBOs	Community-Based Organizations
CCIO	Center for Consumer Information and Insurance Oversight (CMS)
CCSQ	Center for Clinical Standards and Quality
CCRWH	Coordinating Committee on Research on Women's Health (NIH)
CCWH	Coordinating Committee on Women's Health
CDC	Centers for Disease Control and Prevention
CFSAC	Chronic Fatigue Syndrome Advisory Committee
CHAT	Curbing HIV/AIDS Transmission Among High Risk Minority Youth and Adolescents
CHC	Coalition for a Healthier Community (OWH)
CHIP	Children's Health Insurance Program
CHWs	Community Health Workers
CLAS	Culturally & Linguistically Appropriate Services
CMCS	Center for Medicaid and CHIP Services (CMS)
CME	Continuing Medical Education
CMS	Centers for Medicare & Medicaid Services
CNE	Continuing Nursing Education
CNPP	Center for Nutrition Policy and Promotion (USDA)
CoIIN	Collaborative Improvement & Innovation Network (HRSA)
COPD	Chronic Obstructive Pulmonary Disease
CPE	Continuing Pharmacy Education
CPS	Clinical preventive services
CRT	Cardiac Resynchronization Therapy
CUSP	Comprehensive Unit-based Safety Program
DASH	Deputy Assistant Secretary for Health
DASH-WH	Deputy Assistant Secretary for Health – Women's Health
DDTP	Division of Diabetes Treatment and Prevention
DOJ	U.S. Department of Justice
DOL	U.S. Department of Labor
DP	Dihydroartemisinin-piperaquine
DPCPSI	Division of Program Coordination, Planning, and Strategic Initiatives
DV/SA	Domestic Violence/Sexual Assault
DVRN	Domestic Violence Resource Network
EARLY	Education and Awareness Requires Learning Young
ECPs	Essential Community Providers
EEDs	Early Elective Deliveries
EHR	Electronic Health Record
EMTs	Emergency Medical Technicians



EPA	U.S. Environmental Protection Agency
FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration
FPAR	Family Planning Annual Report
FSO	For Sisters Only
FSW	Female Sex Workers
FVPSA	Family Violence Prevention and Services Act
FY	Fiscal Year
GDM	Gestational Diabetes Mellitus
GYT	Get Yourself Tested
H3	Healthy Babies, Healthy Moms, Healthy Communities
Hep A	Hepatitis A
Hep B	Hepatitis B
HHS	U.S. Department of Health and Human Services
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome
HP/DP	Health Promotion/Disease Prevention
HPV	Human Papillomavirus
HRCDV	National Health Resource Center on Domestic Violence
HRSA	Health Resources and Services Administration
HRSA MCHB	HRSA's Maternal and Child Health Bureau
HTN	Hypertension
IPTp	Intermittent Preventive Treatment for Pregnant Women
IPV	Intimate Partner Violence
iQUIT	Incentives to Quit Smoking for Connecticut Medicaid Program
IRS	Indoor Residual House Spraying
ITNs	Insecticide-Treated Nets
KEMRI	Kenya Medical Research Institute
L&D	Labor & delivery
L2L	Linkages to Life Program: Rebuilding Broken Bridges for Minority Families Impacted by HIV/AIDS
LARC	Long-Acting Reversible Contraception
LB	Lesbian and Bisexual
LGBT	Lesbian, Gay, Bisexual, and Transgender
LHIs	Leading Health Indicators
LHW	Lay Health Worker
MCHB	Maternal and Child Health Bureau (HRSA)
ME/CFS	Myalgic Encephalomyelitis/Chronic Fatigue Syndrome
MEPS	Medical Expenditure Panel Survey
MICH	Maternal, Infant, and Child Health
MIECHV	Maternal, Infant, and Early Childhood Home Visiting Program
MIPCD	Medicaid Incentives for Prevention of Chronic Diseases

MIYO	Make It Your Own
MMR	Measles, mumps, and rubella
MPINC	Maternity Practices in Infant Nutrition and Care
MRC	Medical Reserve Corps
MSM	Men who have sex with men
NACCHO	National Association of County and City Health Officials
NASADAD	National Association of State Alcohol and Drug Abuse Directors
NBCCEDP	National Breast and Cervical Cancer Early Detection Program
NBCUS	National Blood Collection and Utilization Survey
NBDPS	National Birth Defects Prevention Study
NCHS	National Center for Health Statistics (CDC)
NCI	National Cancer Institute (NIH)
NDAs	New Drug Applications
NFCSP	National Family Caregiver Support Program
NHAS	National HIV/AIDS Strategy
NHEPLHP	National Health Education Program on Lupus for Healthcare Providers
NHSC	National Health Service Corps
NICHD	<i>Eunice Kennedy Shriver</i> National Institute of Child Health and Human Development
NICHQ	National Initiative for Children's Healthcare Quality
NICU	Neonatal Intensive Care Unit
NIDCR	National Institute of Dental and Craniofacial Research (NIH)
NIH	National Institutes of Health
NIH IC	NIH's Institute & Center
NINDS	National Institute of Neurological Disorders and Stroke (NIH)
NPC	National Prevention Council
NSDUH	National Survey on Drug Use and Health
NSFG	National Survey of Family Growth
NVAC	National Vaccine Advisory Committee
NVPO	National Vaccine Program Office (HHS)
NWCD	National Women's Checkup Day (OWH)
NWGHAAD	National Women and Girls HIV/AIDS Awareness Day
NWHIC	National Women's Health Information Center (OWH)
NWHW	National Women's Health Week (OWH)
OAA	Older Americans Act
OAHA	Office of Adolescent Health
OASH	Office of the Assistant Secretary for Health
ODPHP	Office of Disease Prevention and Health Promotion
OER	Office of Extramural Research
OEREPP	Office of Extramural Research, Education, and Priority Populations

OHAIDP	Office of HIV/AIDS and Infectious Disease Prevention
OHCC	Oral Health Coordinating Committee
OMH	Office of Minority Health
ONAP	Office of National AIDS Policy
ONC	Office of the National Coordinator
OPA	Office of Population Affairs
OPCFSN	Office of the President's Council on Fitness, Sports, & Nutrition
OSSD	Organization for the Study of Sex Differences
OWH	Office on Women's Health
PACHA	The Presidential Advisory Council on HIV/AIDS
PAF	Pregnancy Assistance Fund
PALA+	President's Challenge Presidential Active Lifestyle Awards
PBHCI	Primary and Behavioral Health Care Integration
PBRK	Physiologically Based Pharmacokinetic
PCAR	National Person-Centered Assessment Resource
PCI	Percutaneous Coronary Intervention
PCORI	Patient-Centered Outcomes Research Institute
PCOS	Polycystic Ovary Syndrome
PEPFAR	President's Emergency Plan for AIDS Relief
PHS	Public Health Service
PHSA	Public Health Services Act
PMI	President's Malaria Initiative
PMTCT	Prevent Mother-To-Child Transmission
PPE	Preconception Peer Educators
PPW	Pregnant and Postpartum Women
PrEP	Pre-Exposure Prophylaxis
PROMIS	Patient Reported Outcomes Measurement Information System
QFP	Quality Family Planning Services Recommendations
R2Q	Rewards to Quit
RAPP	Real AIDS Prevention Project
RFA	Request for Application (formal statement soliciting grant or cooperative agreement applications)
RPMS	Resource and Patient Management System
RWHC	Regional Women's Health Coordinator
SAMHSA	Substance Abuse and Mental Health Services Administration
SBI	Screening and Brief Intervention
SCOR	Specialized Centers of Research
SG	Surgeon General
SMAIF	Secretary's Minority AIDS Initiative Fund
SMP	Senior Medicare Patrol
SP	Sulfadoxine-pyrimethamine

SPNS	Special Projects of National Significance
SPPC	Safety Program for Perinatal Care
SSA	Social Security Administration
STD	Sexually Transmitted Disease
STEM	Science, Technology, Engineering, and Math
STI	Sexually Transmitted Infections
SUDs	Substance Use Disorders
SWCC	SAMHSA's Women's Coordinating Committee
SYL	Show Your Love
TANF	Temporary Assistance for Needy Families
TCTT	Take Charge. Take the Test.
Tdap	Tetanus, Diphtheria, Pertussis Vaccine
TEDS	Treatment Episode Data Set
TEP	Technical Experts Panel
TODES	Tissue and Donor Epidemiology Study
TTACs	Training & Technical Assistance Centers
UCEDDs	University Centers for Excellence in Developmental Disabilities Education and Services
USDA	U.S. Department of Agriculture
USPHS	U.S. Public Health Service
USPSTF	U.S. Preventive Services Task Force
UV	Ultraviolet
VAW	Violence Against Women
VLP	Virus-like Particle
WASLI	Women's Addiction Services Leadership Institute
WHLI	Women's Health Leadership Institute
WHO	World Health Organization
WIC	Women, Infants, & Children
WISER	Women's Institute for a Secure Retirement
WSN	Women's Service Networks
YEP	Youth Empowerment Program
YMCA	Young Men's Christian Association
YRBSS	Youth Risk Behavior Surveillance System