U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
National Center for Chronic Disease Prevention and Health Promotion
Division of Cancer Prevention and Control

Virtual Meeting of the Advisory Committee on Breast Cancer in Young Women

August 11, 2014

Record of the Proceedings

TABLE OF CONTENTS

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ADVISORY COMMITTEE ON BREAST CANCER IN YOUNG WOMEN
August 11, 2014

Minutes of the Virtual Meeting

The U.S. Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC), National Center for Chronic Disease Prevention and Health Promotion, Division of Cancer Prevention and Control (DCPC), convened a virtual meeting of the Advisory Committee on Breast Cancer in Young Women (ACBCYW) on August 11, 2014.

ACBCYW is formally chartered to provide advice to the HHS Secretary and the CDC Director regarding the formative research, development, implementation, and evaluation of evidence-based activities designed to prevent breast cancer in young women (BCYW), particularly those at heightened risk.

Information for the public to attend the ACBCYW virtual meeting via webinar or teleconference was published in the *Federal Register* in accordance with Federal Advisory Committee Act regulations. All sessions of the meeting were open to the public (*Attachment 3: Participants' Directory*).

Opening Session

Temeika L. Fairley, PhD
Health Scientist, Division of Cancer Prevention and Control
Centers for Disease Control and Prevention
ACBCYW Designated Federal Officer

Dr. Fairley conducted a roll call to determine the ACBCYW voting members, *ex-officio* members and liaison representatives who were attending the virtual meeting. She announced that the voting members and *ex-officio* members constituted a quorum for ACBCYW to conduct its business on August 11, 2014 (*Attachment 2: Roster of the ACBCYW Membership*).

Dr. Fairley called the proceedings to order at 1:14 p.m. EST on August 11, 2014 and welcomed the participants to the ACBCYW virtual meeting. None of the voting members publicly declared conflicts of interest for any of the items on the published agenda (*Attachment 1: Published Meeting Agenda*).

Ann H. Partridge, MD, MPH
Clinical Director, Breast Oncology Center
Dana-Farber Cancer Institute
ACBCYW Chair

Dr. Partridge joined Dr. Fairley in welcoming the participants to the virtual meeting. She was pleased with ACBCYW's outstanding progress over the past year and its new activities to maintain momentum in the upcoming year. Dr. Partridge emphasized that ACBCYW's efforts are aligned with its charter to advise the HHS Secretary and CDC Director on the formative research, development, implementation, and evaluation of evidence-based activities designed to prevent BCYW, particularly young women at heightened risk, and also to provide support for young breast cancer survivors (YBCS).

Pamela Protzel Berman, PhD, MPH
Acting Director, Division of Cancer Prevention and Control
Centers for Disease Control and Prevention

Dr. Berman announced that efforts by CDC leadership to recruit and appoint a new DCPC Director over the next few months are ongoing. In the interim, she looked forward to continuing to work with ACBCYW in her new role as the Acting Director of DCPC.

Update on CDC's Breast Cancer in Young Women Activities

Temeika L. Fairley, PhD
Health Scientist, Division of Cancer Prevention and Control
Centers for Disease Control and Prevention
ACBCYW Designated Federal Officer

Dr. Fairley covered the following topics in her update to ACBCYW on CDC's BCYW activities. The Education and Awareness Requires Learning Young (EARLY) Act was enacted in 2010 and outlined three key provisions for CDC. CDC's completed, ongoing and future activities to respond to its legislative mandates are highlighted below.

Provision 1 of the EARLY Act authorizes CDC to provide support to young women with breast cancer. CDC funding will end in September 2014 for two three-year cooperative agreements (CoAgs): (1) three grantees of the DP11-1114 CoAg, “Enhancing Breast Cancer Genomics Practices Through Education, Surveillance and Policy” and (2) seven grantees of the DP11-1111 CoAg, “Developing Support and Educational Awareness for Young (<45) Breast Cancer Survivors in the United States.” Evaluation findings of the DP11-1111 CoAg will be available in May 2015.

CDC will award two new CoAgs for the 2014-2019 funding cycle. In response to the two Funding Opportunity Announcements, objective review panels for each completed reviews of ~30 applications that were submitted by state health departments, national organizations and academic institutions. CDC will notify ACBCYW of programs proposed by the new grantees after the awards are announced.

Provision 2 of the EARLY Act authorizes CDC to conduct research across diverse applied public health research areas. CDC’s new study, “Estimates of Young Breast Cancer Survivors at Risk for Infertility in the United States,” was published by Trivers KF et al in the August 2014 issue of *The Oncologist*. The National Institute of Environmental Health Sciences (NIEHS) funded and designed the “Sisters Study” and “Two-Sisters Study” as large, national population-based surveys to collect key data elements on YBCS and their sisters, including their risks, genetic predisposition, economic issues, insurance challenges and overall experiences. NIEHS completed the data collection phase of the studies so that CDC can shift to the data analysis and publication phases.

Provision 3 of the EARLY Act authorizes CDC to establish and target a national evidence-based education campaign to specific populations at risk and direct messages and educational resources to healthcare providers (HCPs). CDC redesigned and re-branded the BodyTalk Clinical Decision Support (CDS) Tool as Know:BRCA (Knowing Your BRCA Gene Mutation Risk Can Save Your Life). In April-June 2014, CDC piloted the Know:BRCA educational initiative through social media channels to provide the public with accurate information on BRCA and build awareness regarding the impact of BRCA gene mutations on the risk for breast and ovarian cancer.

CDC also released the online Know:BRCA CDS Tool for young women to assess their risk for having a BRCA gene mutation based on their personal and family cancer history. Young women in all 50 states used the online tool during the first week of its launch on May 8, 2014. The Know:BRCA CDS Tool includes several resources for patients and medical providers to learn more about BRCA gene mutations and assess individual risk.

These resources include a smartphone application, web-based tool, general breast cancer information, and specialized information on risks for hereditary breast and ovarian cancer. Target audiences for the Know:BRCA CDS Tool include young women 18-44 years of age at high risk for having a BRCA 1/2 gene mutation and health care providers.

CDC widely promoted Know:BRCA through a variety of platforms, including e-mail messages to ~100,000 listserve subscribers, a Tier 1 feature on the CDC.gov website, infographics on CDC's Instagram and Pinterest accounts, optimized search engine rankings, and visibility at the 6th Annual Congressional Women's softball game. In May-July 2014, the estimated Twitter activity for Know:BRCA ranged from 2-4 million impressions.

CDC was pleased that several external sources also used their social media platforms to promote and support Know:BRCA, including the *New England Journal Medicine*, Robert Wood Johnson Foundation, Yahoo! Health, HHS Office of Women's Health, Nurse's Links to Resources blog, American Association for Clinical Chemistry, Healthy Delaware, and other stakeholder organizations. CDC currently is engaging additional partners to expand promotion of Know:BRCA.

CDC launched a new Breast Cancer Website in April 2014 and is continuing to monitor Web metrics on unique visitors to the BCYW webpage. Of 3,420 unique users from May 1-July 31, 2014, >1,600 accessed the ehealth care provider section of the webpage. The 4,720 Know:BRCA sessions accounted for 22,082 page views. Of 593 users who accessed Know:BRCA, 194 completed the CDS tool and received results messages. Users have accessed Know:BRCA via desktop computers (~62%), mobile devices (~26%) and tablets (12%).

The major channels that are directing users to the Know:BRCA CDS tool on the BCYW webpage include links from other websites (50%), the Know:BRCA URL (25%), social media links (~25%), and keyword searches via Google, Bing or other search engines (<3%). Of 989 Know:BRCA sessions on social media, Facebook accounted for 86% and Twitter accounted for 14%. Of all 4,207 Know:BRCA sessions on the BCYW webpage, 24% were initiated directly by Facebook or Twitter users.

CDC currently is testing Know:BRCA digital advertisements with a small number (< 9) young women who have a family history of breast or ovarian cancer and young Ashkenazi Jewish women. After testing is completed, CDC plans to feature the digital advertisements on its new Breast Cancer Facebook page in time for Breast Cancer Awareness Month in October 2014. At this time, CDC is conducting several activities and soliciting input from stakeholders to increase the number of Facebook likes from 128 to an additional 250-300 likes.

CDC's new Breast Cancer Facebook page is targeted to women who are Facebook users with an interest in this topic, HCPs and CDC/DCPC grantees and partners. CDC established the Facebook page to achieve four key objectives:

- Create a forum for women who are engaged in the fight against breast cancer to discuss issues, share their experiences, gain support and increase knowledge
- Drive traffic to the Breast Cancer section of the CDC.gov website

- Increase CDC/DCPC's visibility in the breast cancer social media sphere;
- Provide science-based information about breast cancer for users to both learn and interact by reading, linking, sharing and clicking

CDC contracted a marketing firm to conduct the next phase of activities for the National BCYW Social Media Education and Awareness Campaign. The campaign will be targeted to four key audiences: young women 15-44 years of age, including those at elevated risk for and/or living with breast cancer (e.g., Ashkenazi Jewish and African American women); YBCS; young women of all racial, ethnic and cultural backgrounds; and health care providers.

Several topics have been proposed as potential focus areas of the campaign: breast health, breast cancer genetics, family history, the BRCA gene mutation and other breast cancer risk factors, cancer survivorship, and risk reduction among young women. However, the selection of specific topics for the campaign will be based on formative research and input by ACBCYW. CDC expects to formally launch the overall social media campaign in the spring of 2015.

In response to ACBCYW's suggestion to give more thought and attention to effective dissemination of Know:BRCA to HCPs, Dr. Fairley confirmed that CDC has considered several options in this regard. These strategies include collaboration with and outreach to professional organizations and clinical societies to release media alerts to their provider networks; e-mail messages to providers on the CDC Office of Public Health Genomics listserve; and paid digital media advertisements targeted to providers.

PANEL PRESENTATION: UPDATES ON THE CDC DP11-1111 COOPERATIVE AGREEMENT

A panel of two grantees presented updates on their DP11-1111 programs and activities. The updates are outlined below.

Update by the Young Women's Breast Cancer Program

Jennifer Ivanovich, MS
Assistant Professor, Genetic Counselor & Director
Young Women's Breast Cancer Program
Washington University School of Medicine

Ms. Ivanovich presented an update on Washington University School of Medicine's (WUSM) DP11-1111 Program, "Young Women's Breast Cancer Program" (YWBCP). WUSM identified several factors that distinguish young women with breast cancer from older women at all five stages of the cancer continuum: pre-diagnosis, diagnosis, treatment, survivorship and death. In young women, for example, the rate of stage IV cancer at diagnosis is increased. The likelihood of poorer quality of life is greater due to limited decision-making skills, cognitive or memory changes, and an inability to complete treatment because of work, family or other personal demands.

Available treatment data are lacking and fertility issues have not been adequately addressed in young women with breast cancer. Moreover, the time period to live with treatment side effects is longer in this population. The survival rate is lower due to a much higher risk for a second malignancy or recurrence of cancer. The likelihood of health insurance coverage is lower as well.

Due to these distinguishing factors, WUSM established the vision, mission and operation of YWBCP based on three guiding principles. First, the status quo should be challenged to create positive change for young adults with cancer. Second, positive change should be created by a persistent pursuit of research, targeted education, support, advocacy and engagement of YBCS as the most essential partners. Third, diverse approaches should be built to reach young adults and lead clinical research that is focused on their aggressive disease.

WUSM launched several efforts after receiving its DP11-1111 award from CDC. In September 2011, WUSM created a logic model for YWBCP with inputs; immediate, intermediate and long-term outcomes; and activities in four programmatic areas: coach, support, educate and transition. In March 2012, WUSM conducted a regional needs assessment that showed the following results.

- The majority of YWBCP clients had completed their primary cancer treatment.
- Minority YBCS and women with limited financial resources were not adequately represented.
- Young women expressed an interest in connecting with other YBCS for peer support and information.
- Targeted support programming for women with metastatic breast cancer does not exist in the St. Louis region at this time.
- Young women expressed an interest in obtaining targeted information that is easy to manage.
- YBCS emphasized the difficulty in locating targeted programs.
- Support and educational programming for young adults with cancer are lacking in the St. Louis region.

In 2001-2013, WUSM implemented three initiatives to further engage young women: a support and educational program, genetics research program, and genome communications research. WUSM also made efforts to ensure that YWBCP would serve as a regional program with national outreach. Most notably, the St. Louis region accounts for 1,500 YBCS, while 4,125 YBCS and their family members throughout the United States have participated in WUSM's two genetics research programs.

WUSM designed YWBCP with activities in four programmatic areas. In the "Coach Program," a program coordinator meets with young women who have received a new breast cancer diagnosis in medical and surgical oncology clinics. Patients are given program materials and their information is added to the YWBCP print and electronic distribution lists.

Significant impacts on outreach to date include WUSM's meetings with >310 newly diagnosed young women, connections with women early in the treatment process, and an increase in the diversity of women reached. The Peer Network is designed to capitalize on the goodwill and knowledge of other YBCS and train YBCS to serve as peer mentors to others. Confidentiality and active listening are the cornerstones of training for the Peer Network.

In the "Support Program," monthly support meetings are held with presentations by keynote speakers and networking opportunities for the attendees. The meeting topics are selected by YBCS and have included fertility, sexuality, genetics, mindfulness, acupuncture, YBCS 20-39 years of age, restorative yoga and healthy nutrition.

Targeted support programming for young women with metastatic breast cancer has included biweekly structured psychosocial support meetings in the fall of 2012 and a symposium in March 2014. Targeted support programming has provided an opportunity for WUSM to address heterogeneity. WUSM also partners with Siteman Cancer Center Counseling Services to provide YBSC with free psychological counseling if needed.

The *Cancer Survivors' Resource Guide* is available to newly diagnosed young women and their families in both print and electronic formats. The Resource Guide provides information on a variety of practical matters, including general cancer support, employment and insurance, family support, financial issues, general health, grief support, hospice transportation and lodging, environmental issues and creative arts.

In the "Education Program," an Annual Education Symposium has been convened since 2012. The next symposium on September 13, 2014 is expected to attract ~100 YBCS. *Together Magazine* is targeted to YBCS and has been published since 2012. The 2014 edition was mailed to ~4,000 YBCS throughout the United States. The *Family History Guide* has been directly marketed to ~4,000 YBCS to date to assist young women in documenting their family history and better understanding their cancer risk. A process is underway to record genetic testing videos. The *Woman is Stronger Than the Disease Journal* was written by YBCS and is targeted to newly diagnosed young women. The journal is distributed both locally and nationally.

In the "Transition Program," the Young Adult Cancer Survivor Exercise Program was launched in September 2012 with a weekly strength and cardiovascular exercise program. YBCS have formed additional exercise groups since that time, including running and tennis groups. The Creative Expression Program featured monthly programming in 2012-2013, including "Inside Out: Celebrating Cancer Survivorship."

In addition to activities in four programmatic areas, WUSM also created a solid communications component for YWBCP with multiple platforms, including a website, monthly e-newsletter, social media, the Cancer Center Information Center, digital messaging boards, clinical engagement efforts, professional and community presentations, and local media.

WUSM has taken steps to ensure the sustainability of YWBCP beyond the CDC funding cycle. These efforts include strong support by the WUSM Division Chief, local grant funding, local fundraising events, and local and national philanthropic initiatives. However, WUSM recognizes that national grants are necessary to expand staff and enhance services. Most notably, survivorship programming is limited and a young adult cancer clinic has not been established at the WUSM Cancer Center.

WUSM has learned a number of valuable lessons in developing and implementing YWBCP. A sustainable infrastructure requires flexibility, creativity, persistence and solid grant management skills. A program must be flexible in order to meet the needs of young women on their individual terms, including those with limited financial resources and metastatic disease. A young adult cancer program must include innovative strategies, such as creative arts programming and exercise programs.

A YBCS program must build strong and diverse relationships with both passive and active partners and other adult and young adolescent cancer programs to achieve the greater good and effect positive change. To achieve this goal, WUSM redesigned the initial logic model for YWBCP with a long-term vision and future outcomes, including improved physical health, enhanced quality of life, life-long engagement and decreased mortality for young women.

Update by the Arizona Young Breast Cancer Survivor Support Initiative

Carrie Cantrell, LMSW, MPH
Program Coordinator
Arizona Young Breast Cancer Survivor Support Initiative
John C. Lincoln Health Network

Ms. Cantrell presented an update on John C. Lincoln Health Network's (JCLHN) DP11-1111 Program, "Arizona Young Breast Cancer Survivor Support Initiative" (AYBCSSI). JCLHN conducted a needs assessment in 2012 that showed YBCS in Arizona requested assistance in five major areas: identifying support for family and friends, addressing body image issues, connecting with other YBCS, leveraging financial assistance, and helping to understand the breast cancer diagnosis.

JCLHN designed AYBCSSI with activities in four programmatic areas based on results of the needs assessment. “Education and outreach” activities for AYBCSSI have reached ~64,000 individuals to date. These initiatives have included provider office visits (>320), community education presentations (19), psychosocial education support groups (>31), large-scale survivor and provider education events (7), outreach events (85), newsletters (18), and community collaborations and partnerships (62).

The AYBCSSI Facebook page has reached 26,494 persons since its initiation, while 20% of AYBCSSI’s 242 tweets have been retweeted through Twitter. AYBCSSI’s educational videos collectively have received 315 views. The videos have covered diverse topics, including breast cancer discussions with children, an understanding of breast cancer, surgical options, radiation therapy, lymphedema and reconstruction surgery. JCLHN currently is developing Spanish versions of the videos. Coping Kits are available to YBCS, caregivers, children and other target audiences, while Provider Kits are available for clinicians. To date, 110 kits have been provided through the AYBCSSI website and Navigation Program.

“Support” activities for AYBCSSI have reached >100 individuals to date. Support groups have included “THRIVE” for young women, “Supporting the Women They Love” for caregivers, and the Sonoran Breast Cancer Learn and Support Group. A partnership has been established with the Young Survival Coalition to make linkages between YBCS and moderate online support groups.

“Navigation” activities for AYBCSSI have resulted in the successful navigation of ~70 newly diagnosed young women to date. Navigators are designated for young women through the JCL Breast Health and Research Center, referrals from community partners and website contacts.

“Resource provision” activities for AYBCSSI include the web-based *Arizona Breast Cancer Resource Guide* to provide high-quality and confidential resources to empower, encourage and educate YBCS. The Resource Guide includes 48 sections and subsections on survivorship issues and 5 sections on education and risk reduction. JCLHN recently updated the Resource Guide with educational videos, resources for YBCS in rural areas of Arizona, and resources for Spanish speaking YBCS.

Usage of the Resource Guide has grown over the past year with a 13% increase in the number of unique visitors, a 31% increase in the number of monthly visits, and an increase in the number of page views. The duration spent on the Resource Guide website per visit has decreased by one hour. These outcomes demonstrate that more unique visitors are accessing and using the website more efficiently.

JCLHN currently is focusing on efforts to ensure long-term sustainability of AYBCSSI beyond the CDC funding cycle. A lay navigator will continue to conduct education and outreach activities for professionals, patients and communities; maintain the social media component for YBCS; and convene support groups on an as-needed basis.

The JCL Breast Health and Research Center will regularly update the Resource Guide and will continue to disseminate Coping Kits and Provider Kits as requested. The Resource Guide will continue to be available to YBCS statewide, but some education and outreach activities will be limited to the metropolitan Phoenix area. Navigation activities for newly diagnosed young women and activities to connect YBCS will be continued as well. JCLHN also will explore strategies to broaden the reach of AYBCSSI through technology.

ACBCYW noted a great deal of overlap between some activities conducted by DP11-1111 grantees and their partners, but limited collaboration and communication across organizations. Several members emphasized the need for grantees to foster stronger partnerships, particularly to compile their successes and lessons learned in engaging more minority young women and those with limited financial resources. For example, JCLHN's efforts in reaching Hispanic YBCS and Native American YBCS in rural areas would be valuable to other DP11-1111 grantees.

Dr. Fairley confirmed that CDC has taken steps to increase synergy and collaboration across YBCS grantees. In the 2014-2019 funding cycle, for example, grantees will be required to establish partnerships with other organizations that target services and activities to YBCS. CDC recognizes that broad dissemination and sharing of information and knowledge will be critical for grantees to sustain their programs beyond the CDC funding cycle.

Update by the ACBCYW Ad Hoc High Risk Workgroup

Rochelle L. Shoretz, JD
Executive Director and Founder, Sharsheret
ACBCYW Member & High Risk Workgroup Chair

Ms. Shoretz covered the following topics in her workgroup report to ACBCYW. The workgroup has completed several major tasks over the past four years. In 2010-2012, the workgroup initiated research on breast cancer risk in young women in accordance with ACBCYW's charge. In 2012, the workgroup presented its report to ACBCYW that outlined relevant research findings, key topics for ACBCYW to consider, and draft recommendations for ACBCYW's formal action. In 2013, the workgroup finalized its draft recommendations for incorporation into ACBCYW's letter to the HHS Secretary. The workgroup reconvened in February and June 2014 to discuss three major topics.

For topic 1, the workgroup discussed directions for ACBCYW's future work and further research in the area of risk. The workgroup suggested three directions in this regard: (1) develop an understanding of "average risk" and "higher risk" as compared to "high risk;" (2) develop messaging to translate "average risk" and "higher risk" for young women; and (3) develop messaging to young women regarding risk reduction based on cancer prevention data. The workgroup is now requesting ACBCYW's feedback on the three suggested directions as well as input to avoid overlap with activities by the Ad Hoc General Population Workgroup.

For topic 2, the workgroup discussed a potential modification of its charge in which the sole focus on high-risk young women would be expanded to include messaging for average-risk young women. The workgroup's original charge was to gather initial background information and advise ACBCYW on (1) developing an understanding of the meaning of "high risk" in the context of BCYW and (2) identifying potential evidence-based messages to disseminate to this population. The workgroup drafted a modified charge for ACBCYW's consideration and input.

> Gather initial background information and advise ACBCYW regarding:
>
> 1. Developing an understanding of the meaning of "average risk" and "above average risk" in the context of breast cancer in young women
> 2. Identifying potential evidence-informed messages regarding breast cancer risk to disseminate to this population
> 3. Identifying potential evidence-based actions young women can take to reduce their risk of breast cancer

For topic 3, the workgroup discussed the new Know:BRCA Campaign. The workgroup agreed that the entire ACBCYW membership should engage in a comprehensive discussion to make further progress on the campaign. For example, ACBCYW could propose strategies to CDC to leverage media attention for the campaign in light of Breast Cancer Awareness Month and Ovarian Cancer Awareness Month. ACBCYW also could develop talking points for individual members to use when contacted by the media about the campaign in the upcoming months.

Ms. Shoretz concluded her update with a request for ACBCYW's decision on the workgroup's next steps. On the one hand, the workgroup could be maintained with a modified charge (e.g., serving as a research arm for the General Population Risk Workgroup and proposing strategies to raise awareness and visibility of the Know:BRCA Campaign). On the other hand, the workgroup could be disbanded due to the completion of its original charge that ACBCYW issued in 2010.

ACBCYW agreed that the workgroup is still needed and should not be disbanded. The members proposed two new activities for the workgroup's modified charge: (1) address ovarian cancer in the context of young women at high risk for breast cancer, particularly those with BRCA 1/2 gene mutations and (2) focus on non-BRCA genetic mutations and other high-risk factors for young women. ACBCYW noted that developing messaging for these populations of high-risk young women would be important from both public health and clinical perspectives.

Dr. Fairley confirmed that time would be set aside during the next meeting for ACBCYW to further discuss and reach consensus on the workgroup's modified charge. In the interim, the workgroup would be maintained with its current charge to identify evolving science, review new data, and address other pressing issues in the area of young women at high risk for breast cancer.

Update by the ACBCYW Ad Hoc General Population Risk Workgroup

Lisa A. Newman, MD, MPH, FACS
Professor of Surgery and Director
University of Michigan Health Systems
ACBCYW Member & General Population Risk Workgroup Chair

Dr. Newman covered the following topics in her first workgroup report to ACBCYW. The workgroup convened a teleconference meeting in July 2014 to clarify its charge; review data to better define and characterize the target population; and draft messaging for breast cancer risk in the general population of young women. The workgroup developed and focused on several key questions to fulfill its charge.

<u>Question 1</u>*: What is the target audience for general population risk messaging?* The workgroup reviewed U.S. Census data that showed the population of women 20-45 years of age in the United States has substantially grown from ~42 million in 1980 to ~52 million in 2010 (or an increase of ~10 million women over the past 30 years).

<u>Question 2</u>*: What is the breast cancer burden of the target audience? Has the burden been increasing over time?* The workgroup reviewed the 2009 Anders, *et al.* study that used Surveillance, Epidemiology and End Results (SEER) data to document population-based breast cancer incidence rates by age and timeline. By age, younger women accounted for much lower incidence rates than older post-menopausal women.

By timeline, incidence rates for women <45 years of age have been relatively stable over the past 30 years. Although changes were observed in women >50 years of age, incidence rates in this population began to rapidly decline after 2002. This decrease is a result of published data from the Women's Health Initiative that documented a link between post-menopausal hormonal replacement therapy and an elevated breast cancer risk.

<u>Question 3</u>*: What are the race/ethnicity-associated variations in the breast cancer burden of young women?* The workgroup reviewed SEER data that showed higher population-based breast cancer incidence rates in all age categories for white and African American women compared to women in other racial/ethnic groups. White women account for the highest breast cancer incidence rates overall, but population-based incidence rates are slightly higher in African American women <45 years of age. Of all breast cancer patients <50 years of age, white women account for ~20% and African American women account for ~33%. Breast cancer incidence increases with age for all women. The average age at breast cancer diagnosis is 61 years for white women and 57 years for African American women.

<u>Question 4</u>: *Has the number of young women with breast cancer increased?* The workgroup reviewed the 2008 Brinton, *et al.* study that was based on 1992-2004 SEER data for all breast cancers combined, *in situ* cancers only and invasive cancers only. Despite relatively stable incidence rates, the study reported a steady increase in breast cancer in young white and African American women over time due to the growth of the young female population in the United States.

<u>Question 5</u>: *Are breast cancers in young women associated with worse survival? What are the race/ethnicity-associated variations in survival among young breast cancer patients?* The workgroup reviewed five-year relative survival rates by year and age of diagnosis and death. The data showed steady improvements in breast cancer survival rates among all women in the 20-49, 60-64 and 65-74 age groups in 1975-2006.

By age, younger women had worse relative survival rates than older women in the past. However, differences in age-related survival rates have been decreasing due to advancements in systemic therapy for breast cancer subtypes that are more prevalent in young women. By race/ethnicity, relative survival rates have been persistently worse in African American women than in white women in both the <50 and ≥50 year age groups.

In addition to answering the five key questions, the workgroup also reviewed data to identify other relevant patterns related to breast cancer in the general population of young women in the United States. The 2013 Johnson, *et al.* study reported an increasing incidence of young breast cancer patients 25-39 years of age diagnosed with stage IV disease. The study documented a tremendous increase in the incidence of metastatic breast cancer in this population from 1.53/100,000 in 1976 to 2.90/100,000 in 2009.

The 2011 Amirikia, *et al.* study used population-based California Cancer Registry data to document incidence rates of triple-negative breast cancer by age and race/ethnicity. The study showed that the triple-negative breast cancer incidence rate was nearly two-fold higher in African American women compared to white women and those in other racial/ethnic groups in all age categories. Based on the results of the data review, the workgroup drafted several breast cancer risk messages for CDC to promote to the general population of young women.

Message 1: Breast cancer is the most common malignancy diagnosed among women in the United States. Therefore, breast health awareness is important for women of ALL ages. Know:BRCA is a useful website for assessing individual breast cancer risk.

Message 2: Breast cancer is relatively uncommon among the general population of women younger than 45 years of age in the United States. However, breast cancer is slightly less uncommon among young African American women compared to young white, Hispanic and Asian American women.

The workgroup agreed that CDC should disseminate message 2 with solid data and graphics to enhance its effectiveness and clearly distinguish between "relatively uncommon" versus "slightly less uncommon." In terms of data, the following points should be emphasized in message 2.

- For every 100,000 women in the United States 20-44 years of age, ~50 are diagnosed with breast cancer each year and ~5 will die from the disease.
- In most cases, age is a woman's greatest risk for developing breast cancer. For example, ~6 out of every 100,000 women 20-29 years of age develop breast cancer each year compared to 46 out of every 100,000 women 30-39 years of age who develop the disease.
- African American race is a risk factor for developing breast cancer at young ages. For every 100,000 women 20-44 years of age in the United States, ~4 additional African American women develop breast compared to white women. The risk of developing breast cancer increases with age for both African American and white women.

In terms of graphics, existing charts can be used to compare breast cancer risk by age for women in the general population versus those with hereditary susceptibility. A chart created by the American Cancer Society also can be used to demonstrate age-specific probabilities of developing invasive breast cancer. For example, the chart shows that the probability of a woman 20 years of age developing breast cancer in the next 10 years is 0.06% (or 1 in 1,760). The probability increases by age from 0.44% in women 30 years of age (or 1 in 229) to 3.73% in women 70 years of age (or 1 in 27).

Message 3: Young women should be aware of their individual risk profile and whether the profile suggests a breast cancer risk that is higher than in the general population of young women. An elevated risk will depend on family history; prior biopsy results with the potential for increased risk (e.g., atypia or lobular carcinoma *in situ*); and prior chest wall radiation exposure with the potential for increased risk (e.g., intensified breast cancer screening).

Message 4: Young women should know that breast cancer is uncommon in the general population of American women younger than 45 years of age, but the disease CAN occur with subtle signs. Young women should be aware of clinically significant danger signs of breast cancer (e.g., bloody nipple discharge, new lumps, patches of nipple-areolar skin that appears scaly or eczematoid, a new or persistent rash, or inflamed breast skin). Young women undergoing mammography screening should be aware that mammograms have an increased false-negative rate for women younger than 50 years of age. Regardless of their most recent mammogram result, these women should seek medical attention if a clinically significant danger sign appears.

Message 5: Young women should be aware of specific actions to take to reduce their risk of developing breast cancer in the future. Any amount of breastfeeding is beneficial. Breastfeeding 12 months or more across one or more pregnancies offers the best level of protection. Alcohol intake should be reduced. Alcohol consumption increases the risk of breast cancer. The risk grows as the amount of alcohol consumed increases. Regular exercise for 4 or more hours per week may lower the risk of breast cancer, particularly for women of normal or low body weight.

Message 6: Additional research is necessary to determine the impact of key factors on breast cancer risk, including poverty, socioeconomic factors and sexual lifestyle (e.g., lesbian, bisexual and transgender women).

Message 7: Young women should be aware that routine mammography screening is associated with a wide range or spectrum of benefits. Although these benefits vary by age, mammography becomes increasingly valuable with older age. ACBCYW recognizes that multiple factors might impact a woman's decision to initiate mammography screening at 40 rather than 50 years of age. Clinicians and other healthcare providers have issued different guidance regarding the age to initiate routine mammography screening. ACBCYW recommends that American women should initiate routine mammography screening at 40 years of age.

The workgroup was divided on whether ACBCYW should endorse a specific age for initiating mammography screening in the United States. The workgroup agreed that the full ACBCYW membership should discuss two options in the context of message 7.

Option 1 would be for ACBCYW to continue to endorse U.S. Preventive Services Task Force (USPSTF) current (2009) recommendation on breast cancer screening. "Women 50-74 years of age should undergo mammography screening every two years. Women are encouraged to discuss with their physicians whether to opt-in for screening prior to 50 years of age." The workgroup noted that several organizations have adopted the current USPSTF recommendation, including the American Academy of Family Physicians, and American College of Physicians.

Option 2 would be for ACBCYW to endorse an alternative position. "Mammography screening should be initiated at 40 years of age. Patients are encouraged to discuss with their physicians whether to opt-in for screening prior to 50 years of age." The workgroup noted that a number of professional societies currently recommend mammography screening beginning at 40 years of age. Moreover, international programs in six countries recommend mammography screening beginning at 40, 45 or 47 years of age. However, the workgroup acknowledged that the relevance of international guidelines and practices to the U.S. female population is questionable due to substantial differences in demographics with respect to age, racial/ethnic diversity and disparities issues.

The workgroup reviewed the Presidential Proclamation that the White House issued for National Breast Cancer Awareness Month in October 2010. The Affordable Care Act (ACA) ensures that persons diagnosed with breast cancer would not be excluded from coverage for a preexisting condition or charged higher premiums. Health insurance companies are now required to cover annual mammography screening for women >40 years of age with no additional cost, based on the 2002 USPSTF recommendation on breast cancer screening. Following passage of the ACA, USPSTF issued a Grade B recommendation for mammography screening every 1 to 2 years for women 50-74 years of age with or without clinical breast examination, but designates coverage according to the 2002 USPSTF recommendations.

Editorial Note from CDC:
The above segment reflects the view of the ACBCYW. However, CDC's position on this topic Is as follows.

> *In November 2009, USPSTF changed its breast cancer screening recommendations to biennial mammography for women aged 50–74 years and stated that women aged 40–49 years do not need to be screened routinely. However, the Patient Protection and Affordable Care Act of 2010 (as amended by the Healthcare and Education Reconciliation Act of 2010 and referred to collectively as the Affordable Care Act [ACA]) specifically designates coverage of the breast cancer screening according to the recommendations issued before November 2009 (ACA §2713) (14).*

The workgroup's extensive discussion on message 7 eventually resulted in a suggestion for ACBCYW to consider advising CDC to recommend mammography screening beginning at 40 rather than 50 years of age. *Editorial Note: The Committee did not hold a formal vote on this topic, thus a formal recommendation was not put forward at this time.* The workgroup cited three key issues to support its decision. First, disparities in breast cancer incidence and mortality are persistent in the United States. Compared to young white women, young African American women face a higher likelihood of being diagnosed with breast cancer and biologically-aggressive tumors. Effective efforts for the screening and early detection of biologically-aggressive tumors should continue to be targeted to and promoted in populations of young, racially/ethnically-diverse women.

Second, population-based breast cancer incidence continues to be lower in young women than in older women. Mammography screening of young women continues to have a lower yield. However, the absolute volume or number of young women in the United States has substantially increased over the past several decades. The growth of this population has resulted in a larger absolute number of young breast cancer patients who would benefit from mammography screening.

Third, population-based data show increased rates of young breast cancer patients diagnosed with metastatic disease. ACBCYW's strong support of mammography screening as a strategy to hopefully reverse the trend of more stage IV breast cancers in young women should be emphasized.

ACBCYW commended the workgroup on its comprehensive data review, but the members were divided on message 7. On the one hand, several members noted that some professional societies are reconsidering their current recommendations to initiate mammography screening at 40 years of age. Moreover, the Institute of Medicine (IOM) has published guidelines on the rigorous process that organizations should undertake to develop and disseminate credible and trustworthy health-related guidance.

Before message 7 is formally recommended to CDC for consideration and action, ACBCYW should advise CDC to commission an IOM study on mammography screening for women <50 years of age. Based on similar cancer-related studies by IOM panels, the new IOM study ideally could be completed within nine months at a cost of $300,000-$400,000. The ACBCYW recommended that the findings of the workgroup's data review should be included in the proposed new IOM study.

On the other hand, some ACBCYW members did not support CDC funding a new IOM study due to the availability of existing data. Most studies have documented the wide range of benefits offered by mammography screening that will increase as women age. Regardless of any new studies or existing data, however, the age at which to initiate mammography screening will continue to differ among patients, physicians, advocacy groups and professional societies. In addition to published recommendations, a woman's individual preferences and desired outcomes of mammography screening should be taken into consideration.

Dr. Partridge confirmed that during the next meeting, ACBCYW would engage in a more extensive discussion to formalize the workgroup's messages for submission to the CDC Director and HHS Secretary. In the interim, she and Dr. Fairley encouraged ACBCYW to consider whether formal guidance to CDC is warranted on funding an IOM study on mammography screening beginning at 40 years of age. ACBCYW also was advised to consider the six other messages proposed by the workgroup to more effectively publicize breast cancer risk to providers and young women in the general population.

Update by the ACBCYW Ad Hoc Provider Workgroup

Generosa Grana, MD, FACP
Director, Cooper Cancer Institute
ACBCYW Member & Provider Workgroup Chair

Dr. Grana covered the following topics in her workgroup report to ACBCYW. The workgroup's most recent teleconference meeting focused on refining the target audiences of "patients" and "providers" and assessing ongoing activities. These activities include potential adaptation of three CDC-funded programs in Georgia, Michigan and Oregon; CDC's research project, "Enhancing Breast Cancer Genomics Practices Through Education, Surveillance and Policy," led by Dr. Katrina Trivers; and CDC's Know:BRCA Campaign.

The workgroup is continuing to focus on provider messaging for young women 15-45 years of age, young women at high risk for breast cancer due to a strong family history or hereditary gene mutations, and YBCS. The workgroup agreed to maintain its focus on the following types of HCPs: primary care physicians with expertise in internal medicine, family medicine and obstetrics/gynecology, nurse practitioners, physician assistants and professional societies. However, the workgroup expanded its target audience of providers to include naturopaths and insurers.

The workgroup revisited its previous strategies to more effectively reach and disseminate information to HCPs, including organizational meetings, licensing boards and training programs. The workgroup also proposed options to reach the new target audience of insurers, such as medical directors of health plans, collaborations with national partners, newsletters, e-mail blast notices and provider conferences. The workgroup noted the success of the Michigan grantee in using medical directors of health plans and national insurers (e.g., Aetna, Cigna and United Health) to distribute information to their provider memberships and patient populations.

The workgroup emphasized the need to administer a national survey to improve provider education and identify gaps in practice. Topics for the national survey should include general breast health for young women, risk assessment and genetic testing, and the needs of YBCS. Mechanisms to administer the national survey should include Doc Styles, insurers, licensing groups, professional societies, and at least five CDC grantees in the new 2014-2019 funding cycle. The workgroup raised the possibility of collaborating with the new grantees at the outset of their awards.

The workgroup acknowledged the outstanding research and activities conducted by the Georgia, Michigan and Oregon grantees in the areas of surveillance, policy, and public and provider education regarding hereditary syndromes. However, the workgroup agreed that these activities should be expanded beyond hereditary syndromes to include young women 15-45 years of age, young women at high risk for breast cancer, and YBCS.

The workgroup agreed that an environmental scan should be conducted to identify, publicize, disseminate and evaluate available education and decision support tools other than Know: BRCA. The workgroup continued to emphasize the importance of increasing the use of electronic medical records (EMRs) to enhance outreach and improve the dissemination of breast cancer risk information to HCPs.

Dr. Fairley emphasized that tangible products and other resources are now available to reach providers. As a result, she asked the workgroup to engage in discussions with CDC on identifying key organizations that could serve as strong partners in provider outreach efforts at the federal level. She further noted that CDC is continuing to consider strategies to increase the use of EMRs, but a considerable amount of resources is necessary to operate and maintain these systems.

ACBCYW informed CDC that small EMR companies and contractors with expertise in developing outpatient EMR functionalities could be used to disseminate information to providers on addressing breast cancer risk in their patient populations. These companies have expressed a strong interest in designing new, relevant and clinically useful EMR systems. ACBCYW and CDC could identify specific milestones that should be included in an EMR system throughout a woman's continuum of care (e.g., first gynecologic visit, breast lump, mammogram abnormality or biopsy result).

Dr. Partridge summarized the workgroup's next steps based on the discussion. CDC would attend the workgroup's next teleconference meeting to begin identifying partner organizations with success in outreach to providers of young women and developers of decision support for EMR systems. The workgroup and CDC would explore strategies for Dr. Raquel Arias, an ACBCYW member, to strengthen her liaison role to the American Congress of Obstetricians and Gynecologists (ACOG).

Dr. Marisa Weiss, the liaison representative for Breastcancer.org, would determine ACOG subcommittees that would be relevant for ACBCYW members to join. The presence of individual ACBCYW members on ACOG subcommittees would increase synergy between the two groups and educate clinicians on the need to target more care to underserved and high-risk patients in their practices.

Public Comment Session

Dr. Fairley opened the floor for public comments; no participants responded.

Closing Session

Dr. Partridge thanked the ACBCYW workgroups, CDC grantees and staff for continuing to devote their time and expertise to conduct outstanding research and activities regarding BCYW. She emphasized that ACBCYW should engage in an extensive discussion during the next meeting on next steps for the current grantees to sustain and advance their programs over time. ACBCYW also would devote time during the next meeting to formalize recommendations by the workgroups for submission to the CDC Director and HHS Secretary.

Dr. Partridge noted that lessons learned and successes from the current grantees would greatly inform YBCS grantees in the upcoming 2014-2019 funding cycle. Most notably, sustainability beyond CDC funding, outreach to and engagement of underserved patient populations, and more efficient and effective collaboration across programs should be underlying themes in all projects proposed by the new grantees.

The participants joined Dr. Partridge in applauding Dr. Fairley, Ms. Carolyn Headley, the ACBCYW Committee Management Specialist, and other DCPC staff for planning, organizing and managing an extremely productive ACBCYW meeting.

With no further discussion or business brought before ACBCYW, Dr. Fairley adjourned the meeting at 4:40 p.m. on August 11, 2014.

Attachment 1: Participants' Directory

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Attachment 2: Glossary of Acronyms

ACA	Affordable Care Act
ACBCYW	Advisory Committee on Breast Cancer in Young Women
ACOG	American Congress of Obstetricians and Gynecologists
AYBCSSI	Arizona Young Breast Cancer Survivor Support Initiative
BCYW	Breast Cancer in Young Women
CDC	Centers for Disease Control and Prevention
CDS	Clinical Decision Support
CoAg	Cooperative Agreement
DCPC	Division of Cancer Prevention and Control
EARLY Act	Education and Awareness Requires Learning Young Act
EMRs	Electronic Medical Records
HCPs	Healthcare Providers
HHS	U.S. Department of Health and Human Services
IOM	Institute of Medicine
JCLHN	John C. Lincoln Health Network
SEER	Surveillance, Epidemiology and End Results
USPSTF	U.S. Preventive Services Task Force
WUSM	Washington University School of Medicine
YBCS	Young Breast Cancer Survivors
YWBCP	Young Women's Breast Cancer Program