

**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
Breast and Cervical Cancer Early Detection and
Control Advisory Committee
November 9, 2015**

Record of the Proceedings

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**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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**BREAST AND CERVICAL CANCER
EARLY DETECTION AND CONTROL ADVISORY COMMITTEE
November 9, 2015**

Minutes of the 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 Breast and Cervical Cancer Early Detection and Control Advisory Committee (BCCEDCAC). The proceedings were held on November 9, 2015.

BCCEDCAC is chartered to provide advice and guidance to the HHS Secretary and the CDC Director regarding the early detection and control of breast and cervical cancer. BCCEDCAC's recommendations focus on national program goals and objectives, implementation strategies, and program priorities (including surveillance, epidemiologic investigations, policy, education and training, information dissemination, and professional interactions and collaborations).

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

Opening Session

Jameka R. Blackmon, MBA, CMP

Public Health Advisor, Division of Cancer Prevention and Control
Centers for Disease Control and Prevention
BCCEDCAC Designated Federal Officer

Ms. Blackmon conducted a roll call to determine the BCCEDCAC voting members and *ex-officio* members who were in attendance. She announced that BCCEDCAC meetings are open to the

public and all comments made during the proceedings are a matter of public record. She reminded the BCCEDCAC voting members of their responsibility to disclose any potential individual and/or institutional conflicts of interest for the public record and recuse themselves from voting or participating in these matters.

| CONFLICT OF INTEREST DISCLOSURES | |
|---|---|
| ACET Voting Member (Institution/Organization) | Potential Conflict of Interest |
| Philip E. Castle, PhD (Albert Einstein College of Medicine) | No conflicts disclosed |
| Lisa C. Flowers, MD (Emory University School of Medicine) | No conflicts disclosed |
| Jean G. Ford, MD (Einstein Healthcare Network) | No conflicts disclosed |
| Sujata Ghate, MD (Duke University Medical Center) | No conflicts disclosed |
| Pamela A. (Wilcox) Hedin, RN, MBA (American College of Radiology) | No conflicts disclosed |
| Melissa D. Leypoldt, RN (Nebraska Department of Health and Human Services) | No conflicts disclosed |
| Jewel Mullen, MD, MPH, MPA (Connecticut Department of Public Health) | Grantee of CDC's Cancer Prevention and Control Program and National Breast and Cervical Cancer Early Detection Program (NBCCEDP) Cooperative Agreements (CoAgs); immediate past President of the Association of State and Territorial Health Officials, a CDC grantee |
| Marina B. Mosunjac, MD (Grady Memorial Hospital) | No conflicts disclosed |
| Marcus Plescia, MD, MPH (Mecklenburg County, North Carolina Health Department) | No conflicts disclosed |
| Richard C. Wender, MD (American Cancer Society) | No conflicts disclosed |

Ms. Blackmon announced that the 16 voting members and *ex-officio* members (or their proxies) in attendance constituted a quorum for BCCEDCAC to conduct its business (*Attachment 2: Roster of the BCCEDCAC Membership*). She called the proceedings to order at 1:09 p.m. EST and welcomed the participants to the virtual meeting. She confirmed that the BCCEDCAC members received the agenda for review in advance of the meeting (*Attachment 1: Published Meeting Agenda*).

Jewel M. Mullen, MD, MPH, MPA

Commissioner, Connecticut Department of Public Health
BCCEDCAC Chair

Dr. Mullen also welcomed the participants to the virtual BCCEDCAC meeting. She reminded the members of the implications of the Affordable Care Act (ACA) on NBCCEDP at the national level, patients across the country at state and local levels, and public health in general. At state and

local levels, ACA has provided new opportunities for public health and healthcare systems to build partnerships to improve population health; institutionalize a culture of health; strengthen clinical/community linkages; and assess, enhance and develop community health improvement plans. At the federal level, ACA has enabled new funding opportunities, such as State Innovation Model grants that focus on health system transformation and improved quality of care.

Dr. Mullen noted that the majority of the meeting would be devoted to BCCEDCAC's discussion on the future of NBCCEDP. She would solicit feedback in response to CDC's specific questions, but she asked the members to also consider other roles and responsibilities for Breast and Cervical Cancer (BCC) Programs: (1) improve health outcomes; (2) build an equitable health system to address clinical care and social determinants of health (SDOH); (3) further minimize BCC morbidity, mortality and disparities; and (4) support ongoing health system transformation initiatives.

DCPC Director's Report

Lisa Richardson, MD, MPH

Director, Division of Cancer Prevention and Control
Centers for Disease Control and Prevention

Dr. Richardson covered the following topics in her Director's report to BCCEDCAC. CDC published the "Cervical Cancer is Preventable" *Vitalsigns*TM report in November 2014, but emphasis was placed on the persistent number of cases and limited improvement in the mortality rate. Based on these data, CDC awarded a three-year contract to Battelle to conduct a case investigation of cervical cancers from September 2015-September 2018. The purpose of the study will be to better understand and identify specific factors that are causing women to continue to acquire and die from a preventable disease.

The retrospective study design will include 600 women in Louisiana and New Jersey who were diagnosed with invasive cervical cancer in 2013-2014. Screening and follow-up will be examined from pre-diagnosis to up to five years post-diagnosis based on medical chart reviews. During the two-year study period, cancer registries in both states will identify all women with cervical cancer and also will contact all cancer survivors to complete a mailed survey to determine barriers to screening and follow-up. Analyses of medical charts and one-on-one discussions with the study participants will be used to determine failures along the entire continuum of care, including initial screening, diagnostic work-up, follow-up and access to therapy.

CDC selected the study sites based on their annual incidence of cervical cancer: 200 cases/ year in Louisiana and 300 cases/year in New Jersey. With a 50%-60% accrual rate over the two-year study period, however, the number of cases is expected to increase to 250 in Louisiana and 350 in New Jersey. CDC currently is subcontracting with the two state cancer registries, obtaining Institutional Review Board approval for each site, and preparing the study package for submission to the Office of Management and Budget. CDC hopes to begin data collection in the field by March 2016. The key outcome of the study will be to develop interventions to improve the experience of women in systems of care.

CDC awarded new grants and the National Cancer Institute will award supplemental funding of up to \$2.7 million to 18 Cancer Centers to improve human papillomavirus (HPV) vaccination

uptake in communities. During a recent meeting, however, the grantees emphasized the need to normalize HPV vaccine along with all other childhood and adolescent vaccines. The grantees also noted that previous efforts to place HPV vaccine in a special category have caused public concern. The HPV Roundtable represents \approx 30-40 partners and is playing a critical role in this effort.

CDC launched the “Bring Your Brave: It’s Time to Talk About Breast Cancer Risk Campaign” during Breast Cancer Awareness Month in October 2015. The key features of the campaign included a website and infographic, personal story videos by 18 young women on Facebook and Twitter, paid search engine marketing and Facebook promotions, display advertisements and sponsored blogger outreach, multiple social media platforms, and earned media in print and digital formats. The campaign was targeted to young women <44 years of age and resulted in 8.1 million impressions and >100,000 engagements on social media. Placement of the campaign in 11 news outlets reached >6.7 million persons. An expanded paid campaign accumulated >9.2 million impressions in two weeks.

CDC is continuing to address ACA-related challenges reported by its funded BCC Programs. Most notably, insurance coverage has increased in a health reform environment. Paying for BCC preventive services that are covered by insurance for women is prohibited. Because additional co-pays or other costs may be incurred for diagnostic work-up if abnormalities are detected during BCC screening, women might not receive the full range of necessary services. The 60/40 requirement has been eliminated from NBCCEDP. A stronger evidence base is needed for patient navigation to document its role as an effective public health strategy. The issue of Medicaid reimbursement for patient navigation services for insured women has not been resolved to date.

CDC is continuing to monitor the status of Medicaid expansion across the country. The most recent data show 31 Medicaid expansion states (including the District of Columbia), 19 non-Medicaid expansion states, and one state that is considering the adoption of Medicaid expansion at this time. Based on the current status of state Medicaid expansion decisions and elimination of the 60/40 requirement from NBCCEDP, CDC is placing more emphasis on patient navigation as a wraparound service for women.

CDC acknowledges that several professional associations have adopted the following definition of patient navigation: “Individualized assistance offered to patients, families and caregivers to help overcome system barriers and facilitate timely access to quality health and psychosocial care from pre-diagnosis to all phases of the cancer experience.” CDC’s stronger emphasis on health systems is due to the need to shift from the traditional approach of opportunistic cancer screening that focused on service provision and follow-up to a more organized, systematic approach to reach vulnerable and underserved communities. Patient navigation will be an important component of this strategy to further decrease cancer morbidity and mortality.

CDC has initiated several efforts to strengthen its focus on patient navigation. Patient navigation indicators and process measures have been developed. Grantees will use these indicators to achieve specific results by measuring the following outcomes.

- Are the “appropriate” clients being reached and navigated to reduce disparities?
- Are navigators successfully reaching clients to assess barriers and facilitate screening, diagnosis and, if needed, access to cancer treatment?

- Do navigated clients start and complete screening, diagnostic testing and treatment in a timely fashion?
- Is patient navigation delivered with adequate rigor and dose (e.g., intensity, reach and duration)?

CDC is monitoring implementation of the patient navigation process and ensuring that its grantees receive high-quality training in this area. Most notably, CDC issued new patient navigation policies in 2015 to its NBCCEDP and Colorectal Cancer Control Program (CRCCP) grantees. A set of patient navigation indicators will be finalized for measurement in NBCCEDP and CRCCP. Aggregate data will be collected for 2015-2016. Clinical datasets are being revised to capture patient navigation-specific variables on all clients navigated regardless of the payment source for clinical services.

CDC extracted language from the logic model of the NBCCEDP CoAg to provide grantees with more explicit guidance on the programmatic strategic direction, activities and outcomes. CDC emphasized the need for grantees to shift to implementing evidence-based interventions (EBIs) to provide optimum care to clients and serve as a model for other programs.

Dr. Richardson concluded her update by describing the timeline of CDC's ongoing planning efforts. In 2015, CDC is asking BCCEDCAC, internal partners and external stakeholders to provide feedback and conceptualize new funding opportunity announcements (FOAs) for its cancer programs, including NBCCEDP. In 2016, CDC will develop new FOAs for its cancer programs to better meet the current and future needs of clients in a health reform environment. In 2017, CDC will announce, compete and award new FOAs for its cancer programs.

Impact of the Affordable Care Act on NBCCEDP

Faye Wong, MPH

Chief, Program Services Branch
Division of Cancer Prevention and Control
Centers for Disease Control and Prevention

Ms. Wong described the impact of ACA on NBCCEDP. ACA has affected NBCCEDP in four key areas. First, NBCCEDP funding served a small percentage of program-eligible women prior to the implementation of ACA. Second, the number of women screened in NBCCEDP has declined overall with ACA implementation. Third, several factors have impacted the decline in cervical cancer screening. Fourth, an updated study estimated that the remaining number of uninsured women will exceed the current capacity of NBCCEDP. CDC has initiated planning efforts for the future of NBCCEDP and will solicit input from BCCEDCAC and other stakeholders on the new FOA in 2017.

The 2015 Howard, *et al.* study and the 2015 Tangka, *et al.* study reported the reach of NBCCEDP in calendar years (CY) 2010-2012. The studies showed that for the NBCCEDP, 9.8% of U.S. women (or 5.2 million of 52.8 million women) were eligible for breast cancer screening and 11.1% of U.S. women (or 10.9 million of 98 million women) were eligible for cervical cancer screening. Of the total NBCCEDP-eligible population, 10.6% (or 549,000 of 5.2 million women) received breast cancer screening and 6.5% (or 705,970 of 10.9 million women) received cervical cancer screening through the NBCCEDP.

CDC's minimum data elements (MDEs) as of April 2015 showed that the number of women screened has decreased from 530,999 women in CY2007 to 356,770 women in CY2014 with ACA implementation. CDC's MDEs also showed that the percent of NBCCEDP-eligible women screened in Medicaid expansion and non-Medicaid expansion states decreased by 30% overall in CY2014. However, the reduction in non-Medicaid expansion states (42%) was nearly three times higher than the decrease in Medicaid expansion states (15%). The percent change in NBCCEDP screening from CY2013 to CY2014 greatly varied among states and ranged from a decrease of >35% to an increase of >33%.

CDC's MDEs showed a marked decrease in the number of women who received a mammogram or pap test from CY2007 to CY2014. These reductions are likely due to the implementation of ACA in 2013 and changes in the recommended cervical cancer screening intervals by the U.S. Preventive Services Task Force (USPSTF). National Health Interview Survey data also showed a reduction in BCC screening trends from CY2000 to CY2013.

CDC partnered with George Washington University to publish the *Health Care Reform and Women's Insurance Coverage for Breast and Cervical Cancer Screening* modeling study in October 2012 in anticipation of ACA implementation. However, the study was based on the assumption that all states would adopt Medicaid expansion. CDC collaborated with the American Cancer Society (ACS) Cancer Action Network to update the study in April 2015 to accurately reflect both Medicaid and non-Medicaid expansion states.

The updated study reported 29 Medicaid expansion states and 22 non-Medicaid expansion states as of April 2015. Prior to ACA implementation in 2013, the percent of uninsured women 21-64 years of age was lower in Medicaid expansion states (28.7%) compared to non-Medicaid expansion states (36.9%). Disparities are expected to further widen in 2017 based on estimates that show the percent of uninsured women 21-64 years of age will be 8% in Medicaid expansion states and 23.3% in non-Medicaid expansion states.

The updated study projected that the number and percent of low-income, uninsured women 21-64 years of age in Medicaid expansion states will decrease by more than 50% from 2013 (12.4 million or 32.2% of women) to 2017 (5.7 million or 14.6% of women). Based on the number of Medicaid expansion states as of April 2015, CDC has estimated the remaining population of uninsured women that NBCCEDP can serve in 2017: pap tests for 11.6% of uninsured women 21-64 years of age; mammograms for 21.2% of uninsured women 40-64 years of age; and mammograms for 38.5% of uninsured women 50-64 years of age. However, the number of low-income, uninsured women who are program-eligible will greatly exceed NBCCEDP's current capacity.

In addition to these estimates and projections, the updated study also outlined a number of important perspectives. Most notably, more states might adopt Medicaid expansion and other states might continue to change their current Medicaid expansion policies. ACA likely will continue to evolve based on the outcomes of court cases, Congressional enactment or Presidential action. Scientific recommendations about cancer screening might change ACA coverage. For example, USPSTF's draft recommendations on mammography screening with no cost sharing are likely to have a direct impact on women 40-49 years of age.

Ms. Wong responded to BCCEDCAC's questions regarding the impact of eliminating the 60/40 requirement from NBCCEDP. CDC has advised its grantees to avoid making radical changes in

terms of diverting BCC funds from screening women to conducting other activities. Due to the elimination of the 60/40 requirement, grantees now have no budgetary restrictions on the proportion of BCC funds that are spent on screening services versus other program activities. CDC has encouraged grantees to take incremental steps in shifting to population-level approaches because thoughtful and organized planning will be needed.

Overview of the HHS Program Integrity Initiative

CAPT Jacqueline Miller, MD
 Medical Officer, Program Services Branch
 Division of Cancer Prevention and Control
 Centers for Disease Control and Prevention

Dr. Miller presented an overview of the HHS Program Integrity Initiative. HHS Secretary Sebelius issued a memorandum to all operating divisions in May 2010 to launch the initiative and define its overarching purpose to strengthen program integrity efforts across HHS. The initiative was designed to achieve three key goals: (1) reduce risks for HHS programs, (2) increase program integrity awareness throughout HHS headquarters and regional offices, and (3) ensure taxpayer dollars are spent based on their original intent.

Each program was required to perform three major tasks in the initiative: (1) complete all four steps in the program integrity risk identification process; (2) address at least one risk in all 20 categories defined by HHS; and (3) provide justification for any categories that did not apply to the program.

In step 1 of the program integrity risk identification process, CDC identified risks for NBCCEDP.

| Category/Subcategory | Program-Specific Risk Description |
|--|--|
| Conflict of Interest (Federal Employees) | If NBCCEDP cannot confirm that project officers, evaluators and management staff do not have personal and/or financial conflicts, their evaluations and recommendations regarding grantee performance might not be considered independent and impartial. |
| Eligibility (Grantees) | If potential or current grantees do not have the funds or in-kind contributions necessary for NBCCEDP’s match requirements (\$1 of state funding to every \$3 of federal funding received) due to reductions in state funding levels, grantees may not be eligible to apply for and/or receive NBCCEDP funding and would be unable to provide free or reduced cost services to eligible women. |
| External Factors/ Economic Trends | If the medical community adopts new technologies related to BCC screening, NBCCEDP will have to identify and approve reimbursement of appropriate new technologies and adjust program resources to pay for increased costs. |
| Policy Environment | If the current law requiring 60/40 (60% of federal funds to be spent on screening services/40% of federal funds to be spent on screening promotion activities) is retained, the ability of NBCCEDP grantees to transition to a more population-based approach to increase cancer screening using EBIs and organized screening |

| Category/Subcategory | Program-Specific Risk Description |
|---|--|
| | (e.g., patient navigation, surveillance and client reminders) may be more difficult. Update: 60/40 requirement eliminated. |
| Grants Management/ Financial | If NBCCEDP grantees are not successful in redirecting program funds to the areas of most need, grantees potentially may have unobligated funds and/or NBCCEDP may not be able to reach populations in greatest need for cancer services. |
| Contractors/Sub-Recipients | If grantees fail to manage performance of their subcontractors (providers) to meet NBCCEDP quality benchmarks for clinical service delivery (including timely and complete follow-up for women with abnormal screening tests), cancer diagnosis or treatment potentially could be delayed and result in increased cancer mortality. |
| Compliance | If NBCCEDP does not provide training opportunities to grantees regarding screening guidelines and program requirements, NBCCEDP providers (subcontractors) may not receive proper guidance to implement screening guidelines correctly. |
| Public Relations & Communications | If various advisory bodies, such as USPSTF and ACS, have contradictory screening guidelines that are promoted to the public, grantees, sub-grantees and women may receive communications from multiple sources with conflicting information on appropriate populations to screen. This approach may lead to confusion about the services provided per NBCCEDP policies. |
| Financial | If NBCCEDP does not monitor grantee expenditures of funds and accuracy of budgeting, NBCCEDP may not identify improper use of resources by grantees. |
| Human Resources (Hiring) | If a vacant project officer position in NBCCEDP has not been filled due to an inability and/or delay, NBCCEDP may not be able to provide adequate technical assistance and guidance on program requirements, resulting in declining program quality. |
| Information & Technology (Privacy and/or Security) | If NBCCEDP does not work with its grantees to adequately secure personal identifiable information collected by subcontractors, a breach of confidentiality could occur. |
| Payment System | If a grantee contracts with a third-party service provider to process invoices without adequate oversight, invoices may not be paid by the third party on time. This process could lead to a delay in reporting of accurate federal funding expenditures. |
| Conflict of Interest (Grantees) | If a grantee uses appropriated funds for lobbying activities, a violation of the anti-lobbying law will occur and could jeopardize potential funding for NBCCEDP. |
| Conflict of Interest (External Advisory Bodies) | If CDC cannot confirm the Federal Advisory Committee member requirements pertaining to Special Government Employees (e.g., the personal and financial independence of BCCEDCAC members who are responsible for making recommendations regarding implementation of NBCCEDP and securities of their familial relationships with industry corporate governance), committee recommendations might not be considered independent and impartial. |
| Contracting/Acquisition Management | If CDC's Procurements and Grants Office (PGO) does not award NBCCEDP funding prior to the end of the budget year due to |

| Category/Subcategory | Program-Specific Risk Description |
|----------------------|---|
| | Congressional budget delays, grantees may have to lay-off employees and/or disrupt services due to the absence of funding to continue CDC's NBCCEDP services. |

In steps 2 and 3 of the program integrity risk identification process, CDC developed a program-specific risk response strategy for NBCCEDP, including the identification of quarters that key activities and metrics are expected to be implemented.

| Risk | Key Implementation Activities and Metrics |
|--------------------------------------|---|
| External Factors/ Economic Trends | <ul style="list-style-type: none"> • Develop criteria for each review tool/framework (2015 Q1) • Determine tool/framework format and management (2015 Q2) • Identify potential resources for reimbursement comparison criteria (2015 Q3) • Build draft tool/framework (2015 Q3) • Solicit feedback on tool/framework (2015 Q3) • Pilot the tool/framework and integrate lessons learned (2015 Q4) • Perform at least three 3 technology reviews using the new tool/framework (2017 Q4) |
| Grants Management/ Financial | <ul style="list-style-type: none"> • Review current NBCCEDP policy definitions regarding screening and promotion activities (2015 Q1) • Receive guidance from PGO regarding Prevention and Public Health Fund guidelines and requirements (2015 Q1) • Track spend rates for grantees (2015 Q4) • Increase the percentage/number of women who receive services and are new to NBCCEDP, particularly among those in non-Medicaid expansion states (2015 Q4) |
| Contractors/Sub- Recipients | <p><i>Provider Reports</i></p> <ul style="list-style-type: none"> • Develop plan for grantees to communicate provider performance (2015 Q4) • Increase the percentage of grantees producing and distributing provider/practice-level performance feedback reports to subcontractors at least one time per year that include some or all of CDC's benchmarks from 70% to 100% by June 2018 <p><i>Best Practices</i></p> <ul style="list-style-type: none"> • Increase the percentage of grantees meeting CDC's benchmarks on completeness of follow-up and timeliness of diagnosis and treatment for both breast and cervical cancers by the April 2017 MDE submission • Develop and implement plan for grantees to share best practices for subcontractor management (2015 Q3) <p><i>Training</i></p> <ul style="list-style-type: none"> • Update grantee training schedule to include training on contract management (2015 Q2) |

| Risk | Key Implementation Activities and Metrics |
|-----------------------------------|--|
| | <ul style="list-style-type: none"> Identify and/or develop training materials (2015 Q4) Schedule, facilitate and execute training (2016 Q3) |
| Public Relations & Communications | <ul style="list-style-type: none"> Update communications materials (2015 Q1) Draft, approve and disseminate standard language for project officers regarding screening guidelines (2015 Q2) Develop fact sheets for providers and the general public regarding reimbursement policies (2015 Q3) Routinely review provider adherence to screening recommendations (2015 Q3) Add screening guidance and reimbursement policies to grantee training (2016 Q3) Improve grantee adherence to age-related policies (2016 Q3) |

In step 4 of the program integrity risk identification process, CDC addressed the Improper Payments Elimination and Recovery Improvement Act (IPERIA) and developed a process to routinely monitor risks over time. IPERIA was passed to improve the determination of improper payments by agencies, enhance recovery of improper payments, and reinforce and accelerate “Do Not Pay” efforts. The overall focus of the legislation is to eliminate waste, fraud and abuse of federal funds. CDC identified three risks in NBCCEDP that apply to IPERIA.

- If the Contracting Officer’s Representative does not appropriately manage the contract, improper payments could be made to the contractor.
- If CDC does not accurately complete NBCCEDP’s funding documentation for processing by PGO, grantees may receive an improper payment amount.
- If CDC does not monitor expenditures of funds and accuracy of budgeting among NBCCEDP grantees, CDC may not identify improper use of resources by grantees.

CDC’s risk monitoring phase for NBCCEDP is underway. Ongoing monitoring will be conducted and data on the identified risks will be collected on a quarterly basis. Key activities and metrics will be reported to CDC and HHS every six months. This process will be used to remove old metrics and add new indicators as needed. An annual status report will be presented to the CDC Integrity Governance Board. Because CDC established significant controls for NBCCEDP to address IPERIA requirements, HHS has not requested additional active monitoring.

BCCEDCAC Open Discussion: The Future of NBCCEDP

Jewel M. Mullen, MD, MPH, MPA
 Commissioner, Connecticut Department of Public Health
 BCCEDCAC Chair

Dr. Mullen explained that the purpose of the open discussion would be for BCCEDCAC to provide input on the future direction of NBCCEDP, particularly since CDC’s development of the 2017 FOA is underway. On the one hand, she asked the members to be mindful of several important limitations, such as a lack of resources to meet the current need and demand, uninsured women who have no knowledge of their program eligibility, and providers with no background or

experience in referring patients to NBCCEDP. On the other hand, she encouraged the members to consider new opportunities, such as CDC's national public health leadership to transform health systems and improve population health.

Dr. Mullen noted that CDC developed three specific questions for BCCEDCAC to address during the discussion.

1. What approaches should grantees implement to expand their roles to increase BCC screening?
2. What are NBCCEDP's largest external challenges and what steps should grantees take to overcome these issues?
3. What is the reality of grantees partnering with health systems to implement population-level EBIs (e.g., leveraging funds for implementation, obtaining endorsement of partners or communicating the expertise of grantees)?

Questions 1-2: Expanded role, external challenges and resolutions for grantees

- CDC should compile experiences and lessons learned from BCC Programs that have successfully reached and served hard-to-reach women. These programs could be used as models for other grantees with less success in this area. Moreover, metrics should be created for BCC Programs to achieve specific goals in reaching and serving hard-to-reach women in their individual patient populations (e.g., African American, Hispanic or Native American women).
- CDC should ensure that a rigorous process is implemented to monitor the quality of screening services provided by BCC Programs. National efforts have been underway for quite some time to increase access to care, but studies in the published literature have documented that access to poor quality facilities is detrimental.
- CDC should include language in the 2017 FOA to meaningfully track and monitor the quality of BCC Programs, generate efficiencies, and ensure that providers meet all domains of the NBCCEDP quality measures. CDC also should ensure that its existing MDEs play an important role in the increasing number of quality initiatives states are implementing to achieve healthcare transformation. For example, the Health Resources and Services Administration (HRSA) recently awarded funds to establish state-based quality collaboratives.
- CDC's outreach, care delivery and data collection should be targeted to SDOH to better understand system-level and structural barriers to accessing BCC Programs. The 2017 FOA should include a stronger focus on SDOH; more explicit emphasis on overall disparities rather than client-level issues to better reach and serve hard-to-reach women; and specific language and guidance to assist BCC Programs in better addressing health disparities. Most notably, the 2017 FOA should highlight the continued significance of BCC mortality by race/ethnicity and geographic location as well as the persistence of these disparities over time. The 2017 FOA also should inform BCC Programs of new opportunities that are available to conduct quality of care activities in monitoring Medicaid patients, particularly in Medicaid expansion states and Federally Qualified Health Centers (FQHCs). CDC's non-cancer programs (e.g., heart disease/stroke, reproductive health and HIV) that already have incorporated an SDOH component into their activities should be reviewed as models in this effort. Overall, CDC should use disparities as an opportunity to shift the focus from screening to ensuring that all newly-diagnosed women receive high-

quality cancer care. Dr. Thomas Frieden, Director of CDC, published an article in the October 29, 2015 edition of the *New England Journal of Medicine* that illustrated a health impact pyramid with public health, clinical systems and SDOH at the same level. CDC should distribute Dr. Frieden's article to BCC Programs to emphasize that SDOH is a cross-cutting issue in the delivery of all services and care rather than a separate initiative.

- CDC should provide BCC Programs with clear measures of system-level changes and demonstrate their effectiveness. The BCC system-level measures should include follow-up on abnormal screening test results, time to diagnostic resolution and community outreach. The BCC system-level measures also should be performance-based, lead to public health accreditation, and play a role in other health system transformation initiatives and health reform efforts funded by the Centers for Medicare & Medicaid Services and the Center for Medicare & Medicaid Innovation. CDC should use the 2017 FOA as a new opportunity to provide public health leadership in a health reform environment and raise the profile of NBCCEDP in a public health/healthcare delivery system collaboration.
- CDC should use population-level data to assist BCC Programs in identifying hard-to-reach women at the local level. Local health departments and their partner coalitions are valuable resources as well due to their knowledge and expertise in local population health needs. Most notably, several local health departments gather data on specific neighborhoods by periodically administering community health surveys and developing epidemiologic profiles. CDC encourages its grantees to serve on Comprehensive Cancer Control Program (CCCP) coalitions, but the 2017 FOA should include stronger language on the need to build local partnerships. BCC Programs typically are poorly represented on these state coalitions. Membership on CCCP's cross-sector and diverse statewide cancer coalitions would provide BCC Programs with more access to insurers, hospitals/health systems, quality improvement initiatives and FQHCs/ primary care.
- CDC should conduct a feasibility assessment to determine whether NBCCEDP actually has the capacity to reach and serve more hard-to-reach women in the future in light of existing budget constraints. At this time, for example, NBCCEDP is only reaching $\approx 11\%$ of women who are eligible for breast cancer screening and $\approx 7\%$ of women who are eligible for cervical cancer screening.
- CDC should collect MDEs from BCC Programs to demonstrate that the 30% reduction in screening NBCCEDP-eligible women is directly related to ACA. In the Nebraska BCC Program, for example, the number of women who presented for screening decreased by $>30\%$ after ACA implementation. Of these former clients, 20% obtained new insurance under ACA and 10% obtained coverage from the Health Marketplace.
- CDC should use the 2017 FOA as an opportunity to initiate innovation in underserved populations. For example, CDC should conduct a study on HPV vaccination in mother/daughter pairs.

Question 3: Health system partnerships

- CDC has informed BCC Programs of the expectation to build partnerships with health systems at local and community levels. However, CDC should provide BCC Programs with innovative strategies to share data, incentives to jointly conduct other activities, and creative payment structures to ensure the success of health system/public health partnerships.

- CDC's funded public health programs for hypertension prevention, asthma control and improved birth outcomes partnered with their state and local health departments to conduct outreach, research and educational activities with health systems, providers and payers. CDC should include language and guidance in the 2017 FOA to encourage BCC Programs to replicate this model. For example, BCC Programs and health systems could collaborate in using electronic medical records to identify patients who are not meeting cancer screening goals.
- CDC now requires grantees in programs throughout the agency to target their efforts to six high-burden conditions to achieve more efficient and effective synergies between public health and healthcare: hypertension, tobacco, healthcare-associated infections, teen pregnancy, diabetes and asthma. CDC leadership selected these six conditions due to the large body of evidence on system-level interventions that are available to reduce the burden. CDC should consider adapting and including language from this initiative in the 2017 FOA to assist BCC Programs in developing and implementing population-level interventions in a public health/healthcare collaborative. Based on a recommendation by external stakeholders, these grantees will develop a dashboard to monitor health system adoption.
- CDC should compile and review data from states that were granted a 60/40 waiver. The data should be used to strengthen the ongoing focus on health system changes in BCC Programs and identify factors that contributed to the decrease in utilization of BCC screening services in 2014.

At the conclusion of the discussion on CDC's three specific questions, Dr. Mullen opened the floor for BCCEDCAC to provide comments and input on additional issues for CDC to consider in its ongoing efforts to develop the 2017 FOA for NBCCEDP.

Question 1: What components of NBCCEDP should CDC retain in the 2017 FOA?

- CDC proposes to maintain a two-prong approach in which BCC Programs will continue to screen and serve uninsured women, while incorporating a system-level approach to reach more women. The BCCEDCAC members expressed strong support for CDC's proposed approach.

Question 2: What population-level disparities should CDC explicitly address in the 2017 FOA?

- Recent data show that mortality rates between whites and African Americans have narrowed for virtually all adult cancers except breast cancer. Breast cancer disparities are continuing to widen between these two populations. CDC should include language in the 2017 FOA for BCC Programs to design campaigns and other outreach activities in close collaboration with health systems, communities and other local partners. Extensive engagement of partners in addressing disparities at the local level beyond screening will help to narrow the gap at the national level.

Dr. Miller, Dr. Richardson and Ms. Wong thanked BCCEDCAC for providing CDC with valuable input and thoughtful insights regarding the future of NBCCEDP. They confirmed that CDC would extensively consider and discuss the feedback during its ongoing efforts to develop the 2017 FOA. In the interim, they made several preliminary remarks in response to the suggestions raised during the discussion.

- Hard-to-reach women:* CDC introduced a new initiative in July 2015 for BCC Programs to use their individual state-level data to identify hard-to-reach women who are eligible for NBCCEDP, but are not receiving screening services. CDC recently awarded a new research contract that will support the creation of a template/guidance to assist BCC Programs in using their state-level data to develop and target interventions to hard-to-reach women. CDC also included a new indicator in its risk assessment for BCC Programs to enroll a larger proportion of eligible women in NBCCEDP who have never received screening services. CDC is aware that this population is higher in non-Medicaid expansion states. However, CDC's MDEs showed that in program year 2014, NBCCEDP was responsible for first-time cervical cancer screening of ≈65% of eligible women and first-time mammography screening of ≈45% of eligible women. Moreover, the Congressional Appropriations Committee recently directed CDC to prioritize BCC funding based on burden. CDC will review population-level data on mortality and screening rates, poverty rates and geographic distribution to award BCC funding based on burden.
- Quality of care:* CDC is more focused on the quality of care provided through the BCC Program not the quality of the actual test performed. Providers that do not meet the guidelines of the Mammography Quality Standards Act (MQSA) or are not MQSA-certified/ accredited should not be a BCC Program provider or subcontractor. CDC requires cytology laboratories to meet standard qualifications to ensure that women are provided with high-quality service for their screening test results. CDC also compares clinical and screening data of clients to program quality standards to monitor specific indicators, such as the timeliness of diagnostic testing of women with abnormal screening results and referral to treatment of women with a new cancer diagnosis. In the future, CDC hopes to develop a mechanism to monitor quality measures of women who receive BCC screening outside of the BCC Programs.
- Program efficiencies:* CDC's current efforts to modify its clinical data will decrease the need to collect individual client-level data. This shift will enable CDC to gather more population-based data. Moreover, CDC will be better positioned to coordinate with HRSA's Uniform Data System that FQHCs currently are reporting. Interagency efficiency will be strengthened when BCC Program providers no longer are required to report multiple measures to different funding agencies.
- SDOH/disparities:* CDC's national efforts to regularly collect SDOH data directly from clinical data systems of BCC Programs or private facilities likely would be unsuccessful due to the vast amount of information that currently is gathered. Instead, SDOH data should be collected from local studies or surveys. For example, BCC Programs could collaborate with community-based organizations, clinics and facilities to collect SDOH data on their individual target populations. The results of an SDOH study or survey could help BCC Programs to better target screening interventions to hard-to-reach women. Based on BCCEDCAC's input, however, CDC will consider the possibility of conducting a full-scale evaluation of NBCCEDP to focus on SDOH. The new study would be similar to the evaluation CDC conducted in the 1990s on access to BCC care in a sample of seven states. Because insurance status is one of the most significant SDOH issues, the new study could be designed to determine the quality of BCC services and care provided to uninsured women and Medicaid patients.

- *System-level measures:* CDC recently awarded funds to 31 CRCCP grantees to implement EBIs to increase colorectal cancer screening through health system changes. To measure these changes, CDC encouraged the CRCCP grantees to identify and collaborate with health system partners through formal memoranda of agreement. The CRCCP grantees will conduct an assessment of their partner clinics to identify barriers to screening, collect baseline and annual screening rates, and determine EBIs that were implemented and contributed to specific health system changes. CDC will use these data to measure health system changes over time. Due to the recent elimination of the 60/40 requirement from NBCCEDP, CDC will be better positioned to apply health system-level measures to BCC Programs.
- *Local efforts:* CDC acknowledges that NBCCEDP grantees are not as high a priority for CCCP coalitions as CRCCP grantees. Colorectal cancer also has high mortality rates and low screening rates among both insured and uninsured populations, but less funding and resources are allocated to colorectal cancer than to breast cancer. Based on BCCEDCAC's input, however, CDC will explore strategies to inform CCCP coalitions across the country about the implications of ACA on BCC Programs. This approach might encourage CCCP coalitions to engage and increase outreach to BCC Programs.
- *Impact of ACA:* CDC will conduct a study over the next three years that will follow-up on former NBCCEDP clients who obtained BCC screening and services from other sources through ACA implementation. The study will aim to determine the impact of ACA on this subpopulation of women from a quantitative perspective (e.g., obtaining screening services and maintaining insurance coverage).
- *Innovation:* CDC will consider developing and implementing a prevention and education program to address BCCEDCAC's suggestion on innovation. For example, CDC could provide BCC Programs with information and materials on HPV vaccination to distribute to enrolled mothers. However, BCC Programs would need to partner with state agencies that have oversight of the Vaccine for Children's Program to actually administer HPV vaccine to daughters.
- *Health system partnerships:* CDC has been providing BCC Programs with strong leadership and guidance on building partnerships with health systems, shifting to a population approach and incorporating system-level changes. Although this effort was initiated with the release of the NBCCEDP FOA in 2012, CDC expects the BCC Programs to make much more progress in these areas since the 60/40 requirement has now been eliminated.
- *60/40 waiver data:* CDC granted 60/40 waivers to three states, but these BCC Programs did not implement interventions that addressed system-level changes. For example, Utah launched a mass media campaign to increase awareness of the availability of the BCC Program in frontier parts of the state. Utah used Behavioral Risk Factor Surveillance System data to measure outcomes and reported an increase in screening rates. CDC also funded a pilot project for states to provide patient navigation/care coordination services to women who received BCC screening outside of NBCCEDP. Several states that participated in the pilot documented success in providing care coordination/patient navigation to women whose BCC screening services were paid by sources other than NBCCEDP.

- *Impact of conflicting guidelines:* CDC is working to provide BCC Programs with educational materials for dissemination to their partner providers and clients to eliminate confusion regarding inconsistencies between screening guidelines: screen women 40-44 years of age (ACS) and screen women 49-49 years of age (USPSTF).
- *Population-level disparities:* CDC is aware of multiple studies that show African American women receive poorer quality therapy along the entire continuum of care than women in other racial/ethnic groups. The literature also has documented that the most aggressive cancers are more common in African American women. Based on BCCEDCAC's input, CDC will develop the 2017 FOA with language for BCC Programs to strengthen their focus on disparities.

Dr. Miller explained that CDC's next steps will be to review the meeting minutes and develop a list of key suggestions based on BCCEDCAC's open discussion on the future of NBCCEDP. The list will be distributed to the members for review and comment and will serve as BCCEDCAC's recommendations to CDC in developing the 2017 FOA.

Public Comment Session

Ms. Blackmon opened the floor for public comments; no participants responded.

Closing Session

Ms. Blackmon announced that the terms of eight BCCEDCAC members would expire on March 31, 2016:

- Dr. Philip Castle
- Dr. Lisa Flowers
- Dr. Jean Ford
- Ms. Pamela (Wilcox) Hedin
- Ms. Melissa Leypoldt
- Dr. Marina Mosunjac
- Dr. Jewel Mullen
- Dr. Richard Wender

The participants joined Ms. Blackmon in applauding the outgoing members for their valuable contributions to the field of BCC early detection and control during their tenures on BCCEDCAC. She confirmed that certificates of appreciation and letters of recognition would be mailed to the outgoing members.

Dr. Mullen thanked CDC for allowing her the privilege of serving as the BCCEDCAC Chair. Although her term would end in the near future, she confirmed that she would continue to serve as a strong supporter and advocate for NBCCEDP in the field. Ms. Wong thanked all of the BCCEDCAC members for continuing to contribute their time and expertise to help CDC improve NBCCEDP.

Ms. Blackmon announced that she would poll the members in or around June 2016 to confirm the date, time and location of the next annual BCCEDCAC meeting. The next meeting would be held in person in Atlanta.

With no further discussion or business brought before BCCEDCAC, Ms. Blackmon adjourned the meeting at 11:56 a.m. on November 7, 2014.

I hereby certify that to the best of my knowledge, the foregoing Minutes of the proceedings are accurate and complete.

Date

Jewel Mullen, MD, MPH, MPA
Chair, Breast and Cervical Cancer Early
Detection and Control Advisory Committee

CENTERS FOR DISEASE CONTROL AND PREVENTION
BREAST AND CERVICAL CANCER EARLY DETECTION AND
CONTROL ADVISORY COMMITTEE

NOVEMBER 9, 2015

Virtual Meeting

Dial-in #: 1-800-369-1873

URL: <https://www.mymeetings.com/nc/join>

Conference Number: PW5275620



Attachment 1
Published Meeting Agenda

MEETING OBJECTIVES:

Committee members are charged with advising the Secretary, Department of Health and Human Services (DHHS), and the Director, Centers for Disease Control and Prevention (CDC), regarding the early detection and control of breast and cervical cancer. Committee members will discuss and make recommendations regarding national program goals and objectives; implementation strategies; and program priorities.

Day 1: Monday, November 9, 2015

1:00 P.M. – 1:10 P.M.

Opening: Welcome and Roll Call

Jameka Blackmon, MBA, CMP
Designated Federal Officer, DCPC, CDC

1:10 P.M. – 1:20P.M.

Welcome, Introductions of Members, and Overview of Agenda

Jewel M. Mullen, MD, MPH, MPA
Commissioner, Connecticut Department of Public Health
BCCEDCAC Committee Chair

1:20 P.M. – 1:30 P.M.

Division of Cancer Prevention and Control Update

Lisa Richardson, MD, MPH
Director, DCPC, CDC

1:30 P.M. – 1:45 P.M.

Impact of ACA on the National Breast and Cervical Cancer Early Detection Program (NBCCEDP)

Faye Wong, MPH

Chief, Program Services Branch, DCPC, CDC

1:45 P.M. – 2:00 P.M.

HHS Program Integrity Initiative

Jacqueline Miller, MD

Medical Officer, DCPC, CDC

2:00 P.M. – 3:45P.M.

Group Discussion: The Future of the NBCCEDP

Jewel M. Mullen, MD, MPH, MPA

Commissioner, Connecticut Department of Public Health
BCCEDCAC Committee Chair

3:45 P.M. – 4:00 P.M.

Public Comment, Wrap-Up, and Announcements

Jameka Blackmon, MBA, CMP

Designated Federal Officer, DCPC, CDC

Jewel M. Mullen, MD, MPH, MPA

Commissioner, Connecticut Department of Public Health
BCCEDCAC Committee Chair



Attachment 2 Roster of the BCCEDCAC Membership

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Attachment 3 **Participants' Directory**

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Melissa D. Leypoldt, RN
Nebraska Department of Health and Human Services

Marina B. Mosunjac, MD
Grady Memorial Hospital

Jewel Mullen, MD, MPH, MPA (Chair)
Connecticut Department of Public Health

Marcus Plescia, MD, MPH
Mecklenburg County (NC) Health Department

Richard C. Wender, MD
American Cancer Society

BCCEDCAC Members Absent

Wendy Rosamund Brewster, PhD, MPH
University of North Carolina School of Medicine

Bruce Nedrow Calonge, MD, MPH
The Colorado Trust

Carolyn Muller, MD
University of New Mexico Cancer Center

BCCEDCAC Ex-Officio Members Present

M. Carolyn Aoyama, CNM, MPH
Indian Health Service

Beth Collins Sharp, PhD, RN, FAAN
(Proxy for Nancy C. Lee, MD)
Office on Women's Health, U.S. Department of Health and Human Services

Yvonne T. Green, RN, CNM, MSN
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Nancy C. Lee, MD
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David L. Lerner, MD
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National Cancer Institute, National Institutes of Health

Richard E. Wild, MD, JD, MBA, FACEP
Centers for Medicare and Medicaid Services

BCCEDCAC Ex-Officio Members Absent

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Sabrina A. Matoff-Stepp, PhD
Health Resources and Services
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**BCCEDCAC Designated Federal
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Jameka R. Blackmon, MBA, CMP
DCPC Public Health Advisor

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Attachment 4 Glossary of Acronyms

| Acronyms | Description |
|----------|---|
| ACA | Affordable Care Act |
| ACS | American Cancer Society |
| BCC | Breast and Cervical Cancer |
| BCCEDCAC | Breast and Cervical Cancer Early Detection and Control Advisory Committee |
| CCCP | Comprehensive Cancer Control Program |
| CDC | Centers for Disease Control and Prevention |
| CoAgs | Cooperative Agreements |
| CRCCP | Colorectal Cancer Control Program |
| DCPC | Division of Cancer Prevention and Control |
| EBIs | Evidence-Based Interventions |
| FOAs | Funding Opportunity Announcements |
| FQHCs | Federally Qualified Health Centers |
| HHS | U.S. Department of Health and Human Services |
| HPV | Human Papillomavirus |
| HRSA | Health Resources and Services Administration |
| IPERIA | Improper Payments Elimination and Recovery Improvement Act |
| MDEs | Minimum Data Elements |
| MQSA | Mammography Quality Standards Act |
| NBCCEDP | National Breast and Cervical Cancer Early Detection Program |
| PGO | Procurements and Grants Office |
| SDOH | Social Determinants of Health |
| USPSTF | U.S. Preventive Services Task Force |