

**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
Program Services Branch**



**Breast and Cervical Cancer Early Detection and Control
Advisory Committee
March 4-5, 2008
Atlanta, Georgia**

DRAFT Record of the Proceedings

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ATTACHMENT 1

List of Participants

BCCAC Members

Dr. Amelie Ramirez, Chair
Dr. George Birdsong
Dr. Otis Brawley
Dr. Victoria Lee Champion
Dr. Dee Ann DeRoin
Mr. Bradley Hutton
Dr. LaVerne Mensah
Dr. Kimberly Redding
Dr. Michael Ross
Ms. Karen Schmitt
Dr. Alan Waxman

Ex-Officio Members

Ms. Carolyn Aoyama
(Indian Health Service)
Ms. Yvonne Green
(CDC Office of Women's Health)
Dr. Wanda Jones (Department of Health
and Human Services)

Dr. Jon Kerner
(National Cancer Institute/NIH)
Dr. Irene Sandvold (Health Resources and
Services Administration)
Dr. Richard Wild (Centers for
(Medicare and Medicaid Services)

Designated Federal Official

Ms. Debra Younginer,
Executive Secretary

CDC Representatives

Dr. Barbara Bowman, DCPC Acting Director
Dr. Janet Collins, NCCDPHP Director
Dr. Donatus Ekwueme
Mr. James Gardner
Dr. Herschel Lawson
Dr. Lucy Peipins
Dr. Lisa Richardson
Dr. Florence Tangka
Ms. Chastity Walker
Ms. Faye Wong

ATTACHMENT 2

Acronyms Used In These Meeting Minutes

ACS	— American Cancer Society
AHRQ	— Agency for Healthcare Research and Quality
AI/AN	— American Indian/Alaska Native
API	— Asian/Pacific Islander
B&C	— Breast and Cervical Cancer
BCCAC	— Breast and Cervical Cancer Early Detection and Control Advisory Committee
BRFSS	— Behavioral Risk Factor Surveillance System
Cancer Control PLANET	— Plan, Link, Act, Network with Evidence-Based Tools
CAT	— Cost Assessment Tool
CCC	— Comprehensive Cancer Control
CDC	— Centers for Disease Control and Prevention
CSB	— Cancer Surveillance Branch
DCPC	— Division of Cancer Prevention and Control
DMIST	— Digital Mammographic Imaging Screening Trial
EARB	— Epidemiology and Applied Research Branch
FFDM	— Full-Field Digital Mammography
GIS	— Geographic Information System
HHS	— Department of Health and Human Services
HPV	— Human Papillomavirus
MDEs	— Minimum Data Elements
NBCCEDP	— National Breast and Cervical Cancer Early Detection Program
NCCDPHP	— National Center for Chronic Disease Prevention and Health Promotion
NCI	— National Cancer Institute
NPCR	— National Program of Cancer Registries
NHIS	— National Health Interview Survey
OMB	— Office of Management and Budget
PSB	— Program Services Branch
Wise Woman	— Well-Integrated Screening and Evaluation for Women Across the Nation

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**BREAST AND CERVICAL CANCER
EARLY DETECTION AND CONTROL ADVISORY COMMITTEE
March 4-5, 2008
Atlanta, Georgia**

Draft Minutes of the Meeting

The 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 (NCCDPHP), Division of Cancer Prevention and Control (DCPC), Program Services Branch (PSB), convened a meeting of the Breast and Cervical Cancer Early Detection and Control Advisory Committee (BCCAC). The proceedings were held on March 4-5, 2008 in Building 19 of CDC's Global Communications Center in Atlanta, Georgia.

Opening Session

Dr. Amelie Ramirez, Chair of BCCAC, called the meeting to order at 8:56 a.m. on March 4, 2008. She welcomed the attendees to the proceedings and opened the floor for introductions. None of the BCCAC members declared any new conflicts of interest for the record. The list of participants is appended to the minutes as Attachment 1.

Dr. Barbara Bowman, Acting Director of DCPC, pointed out that organizational charts for NCCDPHP, DCPC and PSB were distributed in the meeting packets for the BCCAC members to review.

Emerging Issues Impacting the National Breast and Cervical Cancer Early Detection Program (NBCCEDP)

Ms. Faye Wong, Chief of the PSB, provided a historical context of NBCCEDP and described several emerging issues that are impacting the program. The Breast and Cervical Mortality Prevention Act of 1990 covers a number of areas, including breast and cervical cancer (BCC) screening; referrals, follow-up and support services; public and professional information and education; quality assurance; the absence of treatment funds; and evaluation.

President Bush signed the NBCCEDP Reauthorization Act on April 20, 2007 to reauthorize the program for another five years from FY'07-FY'12. The reauthorization also covers the 60/40 waiver pilot project. In addition to NBCCEDP, the Medicaid Program also provides cancer treatment resources through the Breast and Cervical Cancer Prevention and Treatment Act of 2000 and the Native American Breast and Cervical Cancer Treatment Technical Amendment Act of 2001.

Ms. Wong highlighted NBCCEDP's major accomplishments from 1991-2007. NBCCEDP funds are used to support breast and cervical cancer (B&C) programs in all 50 states, the District of Columbia, five U.S. territories, and 12 Native American tribes or tribal organizations. The law requires NBCCEDP to serve as the payer of last resort; allocate $\geq 80\%$ of funds for extramural activities and $\leq 20\%$ of funds for intramural activities; and place a 10% cap on administrative costs. Other legal requirements of NBCCEDP include 60/40 screening costs versus all other program costs; \$1/\$3 matching funds; and 30% of funds for professional education, quality assurance, public education, outreach and other program costs.

Ms. Wong provided a breakdown of the FY'07 Congressional appropriation of \$185.5 million for NBCCEDP: (1) \$158 million in cooperative agreements to all states, the District of Columbia, territories, and tribes or tribal organizations; (2) \$1.3 million to support the Information Management Services contract; and (3) \$700,000 in cooperative agreements to two American Indian/Alaska Native (AI/AN) organizations to increase screening among urban AI/AN women and strengthen partnerships for cancer prevention and control among AI/AN women. The FY'07 appropriation of \$185.5 million excluded the Well-Integrated Screening and Evaluation for Women Across the Nation (Wise Woman) Program.

NBCCEDP had an overall increase of ~\$2.3 million based on the total Congressional appropriation of ~\$198.3 million in FY'07 and ~\$200.8 million in FY'08. The overall increase was based on (1) a decrease of \$3.2 million for NBCCEDP from the FY'07 appropriation of ~\$185.5 million to the FY'08 appropriation of ~\$182.2 million and (2) an increase of ~\$5.7 million for the Wise Woman Program from the FY'07 appropriation of ~\$12.9 million to the FY'08 appropriation of ~\$18.6 million. Although the law requires $\geq 80\%$ of NBCCEDP funds to be allocated to extramural activities, these awards typically range from 82%-84%.

Another significant accomplishment of NBCCEDP has been its reach to target populations. Minimum data elements (MDEs) collected from grantees as of June 30, 2007 showed that the

total number of women who were ever screened with NBCCEDP funds was ~3 million. The screening numbers increased from 37,549 in FY'91-FY'92 to 626,018 in FY'06. However, the screening numbers declined in FY'07 to 509,469 due to the elimination of women screened with state dollars.

In terms of the distribution of NBCCEDP funds by age, ~1.1 million women received mammograms from FY'01-FY'06 in the following age groups: 3% were ≥ 65 years of age, 2% were < 40 years of age, and 29% were 40-49 years of age. Of ~1.1 million women who received Pap tests from FY'01-FY'06, 2% were ≥ 65 years of age, 8% were < 30 years of age, 37% were 40-49 years of age, and 10% were 40-49 years of age.

In terms of the distribution of NBCCEDP funds by race/ethnicity among eligible women 40-64 years of age, the reach of the program from 2003-2005 was 44% white, 32% Hispanic, 17% African American, 5% Asian/Pacific Islander (API), 1% AI/AN, and 1% multi-racial. Of all women 40-64 years of age who were screened with NBCCEDP funds from 2003-2005, 40% were white, 34% were Hispanic, 14% were African American, 6% were API, 3% were AI/AN, and 2% were unknown.

Overall, CDC allocates NBCCEDP funds to all 50 states, the District of Columbia, five territories, and 12 Native American tribes or tribal organizations to implement B&C programs. In FY'06, 374,148 women were screened with mammography and 4,040 breast cancers were detected. In FY'06, 353,014 women were screened with the Pap test and 5,082 high grade and invasive cervical lesions were detected. From 1991-2006, > 3 million women received B&C screening; > 7.2 million screening examinations were completed; 30,963 breast cancers were detected; and 100,000 pre-malignant cervical lesions and invasive cervical cancers were detected.

Ms. Wong presented data from program performance measures of grantees. Of all grantees, (1) $\geq 90\%$ are meeting MDE requirements for complete follow-up of abnormal breast or cervical screening results; (2) $\leq 25\%$ take > 60 days from screening to diagnosis in response to abnormal breast or cervical screening results; and (3) $\leq 20\%$ take > 60 or > 90 days from time of diagnosis to treatment of breast cancer, cervical CIN or cervical invasive carcinoma.

Ms. Wong announced that the House Oversight and Government Reform Committee held a hearing in January 2008 to address the screening gap in NBCCEDP. Testimonies were given by representatives of CDC, the American Cancer Society (ACS), Susan G. Komen for the Cure, the NBCCEDP Program Directors Council, and a breast cancer survivor.

In response to the hearing, DCPC is leveraging collaborations with external partners, including ACS, the Avon Foundation, WebMD Medscape, the Wise Woman Program, and Susan G. Komen for the Cure. DCPC is also enhancing internal partnerships with the Office of the Director; Associate Director for Science; Epidemiology and Applied Research Branch (EARB); Comprehensive Cancer Control Branch; Office of Program and Policy Information; and Cancer Surveillance Branch (CSB).

Ms. Wong highlighted key activities of the DCPC branches. EARB will publish a special monograph of the study on “Assessing the Burden of Human Papillomavirus (HPV)-Associated Cancers” in *Cancer* in the fall of 2008. The study was based on registry data from the National Program of Cancer Registries (NPCR) and other sources and has resulted in the development of numerous papers that are relevant to NBCCEDP and cervical cancer. The study represents a collaborative effort across DCPC and with external partners.

The current status of EARB’s other ongoing research projects is outlined below:

- A decision analysis related to cervical cancer screening in primary care, including age to start, use of HPV DNA testing and liquid-based cytology, is near completion. This project served as a collaborative effort between CDC and the Agency for Healthcare Research and Quality.
- A population-based analysis on recent trends in mammography use from 2000-2006 was submitted for publication. This project served as an update of Behavioral Risk Factor Surveillance System (BRFSS) data.
- An analysis of the characteristics of primary care physicians who participate in NBCCEDP is in progress.
- A study on the eligible population for NBCCEDP is in progress.
- A project that is piloting strategies to add HPV DNA testing to cervical cytology screening in NBCCEDP is awaiting approval by the Office of Management and Budget (OMB).
- A cost analysis of NBCCEDP is awaiting OMB approval.

EARB is collaborating with PSB and CSB on the NBCCEDP MDE Validation Project to perform a comprehensive evaluation of the validity of MDE data and compare these data to 5,600 patient medical records from six programs. The evaluation showed that measures of screening outcomes in MDEs were accurate overall. However, the assessment also emphasized the need to more clearly define some variables to facilitate uniform data collection. EARB determined that revised MDE variables and a linkage to cancer registries to obtain staging data would address this issue.

ACS issued a press release in September 2007 that showed declines in both the breast cancer rate and breast cancer mortality were due to mammography use. CSB acknowledged that the stage at diagnosis is an important quality indicator and is linking NBCCEDP and NPCR data to address a number of gaps in this area. Most notably, current staging data are submitted by multiple sources and are not standardized. Previous studies suggest that the MDE data set is under-staged compared to central cancer registries.

The NBCCEDP/NPCR data linkage will result in a number of advantages. Measures of NBCCEDP outcomes will be improved at the stage of diagnosis. Missed cancers in both the NBCCEDP and NPCR data systems will be detected. More data will be collected on women screened and additional information will be gathered for research purposes. For example, NBCCEDP/NPCR data can be used to conduct prospective follow-up studies of women

screened with NBCCEDP funds to assess long-term outcomes. More robust data can be collected on mortality rates or survival times.

In the current funding announcement, CDC required grantees to establish an NBCCEDP/NPCR data linkage. To assist grantees in achieving this goal, CDC will revise NBCCEDP data requirements and data variables, develop standardized protocols, provide software training, offer technical assistance and create other tools.

CCCB oversees funds - allocated to all 50 states, the District of Columbia, seven tribes and seven U.S. territories - to implement Comprehensive Cancer Control (CCC) Programs. At this time, 57 CCC plans have been developed and disseminated and 64 CCC programs are being implemented. Nearly all state CCC plans include B&C activities. NBCCEDP program directors participate on CCC coalitions for their respective states. Each CCC coalition has diverse representation from both public and private sectors.

Ms. Wong described several emerging issues that impact NBCCEDP and reviewed untapped opportunities to make an impact at the population level. NBCCEDP has received flat funding over the past few years and decreased funding in FY'08. New technologies will cost more, and the 60/40 pilot projects must be implemented. Issues related to funding equity and state screening dollars must be addressed. Mammography rates might be declining in the population based on data that show 30% of women in the United States are not screened. The number of uninsured persons and the overall screening population are increasing.

The law that governs NBCCEDP clearly defines a target population, but only 14.7% of the eligible population is being screened for breast cancer and 8.7% for cervical cancer. Programs and delivery systems are complex and diverse. As the nation's public health agency, CDC is concerned about all of these emerging issues.

Presidential candidates and ~21 states are considering healthcare reform and universal health coverage at this time. However, the role of NBCCEDP in healthcare reform is unclear. Each state has different eligibility and coverage requirements. Because the law requires NBCCEDP to serve as the payer of last resort, many women might not remain eligible with universal coverage. Moreover, the public health model and infrastructure established under NBCCEDP might be lost. Public health would still be an essential component to pay for clinical services even with universal coverage.

Ms. Wong concluded her presentation by outlining several actions that should be considered to increase screening at the population level and address potential implications of healthcare reform on NBCCEDP. For clinical activities, which include screening, diagnosis, treatment referral and case management; non-federal dollars should be leveraged to screen uninsured and underinsured women. Screening efforts should be increased among women who have insurance and those on Medicare.

For non-screening activities, awareness should be raised about the need for a population approach in addition to NBCCEDP. Critically important non-clinical public health activities that

support effective population-level B&C screening to achieve prevention, early detection and control should be promoted. Partnerships for a population approach should be increased. Ms. Wong informed the BCCAC members that additional information on CDC's Cancer Prevention and Control Programs could be obtained at www.cdc.gov/cancer.

BCCAC thanked Ms. Wong for presenting a comprehensive overview of NBCCEDP, including DCPC's internal and external collaborations, emerging issues that are impacting NBCCEDP, and untapped opportunities at the population level. BCCAC also commended DCPC for increasing its research efforts to strengthen NBCCEDP. However, several members were extremely concerned about continued under-funding of NBCCEDP, particularly because one in seven women will be diagnosed with breast cancer.

BCCAC's comments and suggestions to CDC on NBCCEDP are outlined below.

- Native women are underserved by NBCCEDP. The Indian Health Service (IHS) and tribes are under-funded and do not have an adequate infrastructure.
- The use of NBCCEDP dollars to subsidize Medicare, IHS, Title X and other under-funded programs is a concern.
- CDC should clearly define "case management" to clarify whether this service includes the entire continuum of care from diagnosis, treatment and collaboration with affected families. CDC also should demonstrate whether case management has produced actual outcomes.
- All programs have insufficient resources. Some state programs have strong linkages to tribes, but other programs do not have these relationships. Decreased funding results in "fights" for limited resources and an unstable safety net. Health disparities will not be eliminated with the current "nickel-and-dime" approach. A dramatic change is needed instead.
- ACS's allocation of \$15 million to a purposeful campaign for underserved populations has resulted in an abundance of "hate mail" because the majority does not care about these groups. CDC should document and widely publicize the suffering of and the problems with serving underserved populations.
- Under-insured persons often become uninsured following a cancer diagnosis. An overhaul of the healthcare system and changes from leadership are needed. Taxpayer dollars are used to support 90% of healthcare funds that are used for treatment.
- CDC should develop and broadly deliver tailored messages to all populations with an optimistic approach to change health behaviors.

BCCAC extensively discussed other issues related to NBCCEDP, including:

- The process to distribute NBCCEDP funds to grantees.
- Potential out-of-pocket expenses for mammography.
- The rationale for not applying the 60/40 split to clinical screening.
- Ineligibility of immigrant and undocumented women to receive state services and treatment funded by NBCCEDP.

- Common misconceptions about healthcare to Native American women.
- State use of funds for under-insured women.
- The decline in mammography rates.

Update on the NBCCEDP-Eligible Population Study

Dr. Florence Tangka is an Economist in EARB. She provided an update on a study that was conducted to determine whether NBCCEDP has helped to meet mammography and cervical cancer screening needs of underserved populations from 1998-2006. CDC and the U.S. Census Bureau jointly conducted and designed the study with four key objectives.

- The number of NBCCEDP-eligible women would be estimated by age and race/ethnicity at county, state and national levels.
- The percentage of NBCCEDP-eligible women who received mammography and Pap tests funded by the program would be calculated.
- The percentage of all women in the United States 18-64 years of age who received mammography and Pap tests funded by NBCCEDP would be estimated.
- The extent to which NBCCEDP provided services to women of different racial/ethnic backgrounds would be examined.

Dr. Tangka described the design and methods of the study. The data sources included:

- 1998-2006 Census data and the Current Population Survey Annual Social and Economic Supplement (CPS ASEC) to estimate the number of U.S. women 18-64 years of age and the number of women eligible for the NBCCEDP, adjusting for hysterectomy status, using the National Health Interview Survey (NHIS) and BRFSS.
- 1998-2006 NBCCEDP data to obtain the number of women receiving Program-funded mammograms and Pap tests.
- Survey, population and administrative data to obtain estimates of NBCCEDP-eligible women at the state level by race/ethnicity and at the county level.

The eligible study population included uninsured women 18-64 years of age living in households with family incomes \leq 250% of the HHS Poverty Guidelines. The overall analysis covered two years of breast cancer screening data and three years of cervical cancer screening data. CPS ASEC data were used to estimate the total number of women in appropriate age groups and calculate the number of women who were eligible for services funded by NBCCEDP at national and state levels.

NHIS and BRFSS data were used to adjust the hysterectomy status of the estimated population that was eligible for NBCCEDP cervical cancer screening at national and state levels. NBCCEDP data were used to determine the number of women who received mammograms

and Pap tests funded by NBCCEDP screening dollars. The screening rate was estimated by using the number of women screened as the numerator and the number of eligible women as the denominator. A standard error in the estimated number of eligible women was also included in the calculation.

Dr. Tangka highlighted the key findings of the study. The population of all women in the United States 18-64 years of age was ~93.3 million in 2004-2006. Of the total population, ~9 million women or 9.6% were eligible for cervical cancer screening with NBCCEDP funds. Of the eligible population, 774,845 women were screened reflecting 8.7% of the NBCCEDP-eligible population and 0.8% of the total U.S. population 18-64 years of age. Cervical cancer screening rates of NBCCEDP substantially varied among states.

The population of all women in the United States 40-64 years of age was ~49.6 million in 2005-2006. Of the total population, ~4 million women or 8% were eligible for breast cancer screening with NBCCEDP funds. Of the eligible population, 580,141 women were screened reflecting 14.7% of the NBCCEDP-eligible population and 1.2% of the total U.S. population 40-64 years of age. Breast cancer screening rates of the NBCCEDP substantially varied among states.

In the 18-64 age group, the number of women who were eligible to receive Pap tests with NBCCEDP funds increased from ~7.5 million in 1998-2000 to ~9 million in 2004-2006. The percentage of eligible women based on all women increased from 7.2% in 1998-2000 to 9.6% in 2004-2006. The percentage of NBCCEDP-eligible women who were screened increased from 7% in 1998-2000 to 8.5% in 2004-2006.

In the 40-64 age group, the number of women who were eligible to receive mammography with NBCCEDP funds increased from ~3 million in 1999-2000 to ~4 million in 2005-2006. The percentage of eligible women based on all women increased from 6.5% in 1999-2000 to 8% in 2005-2006. The percentage of NBCCEDP-eligible women who were screened increased from 11.8% in 1999-2000 to 14.7% in 2005-2006.

Dr. Tangka summarized the conclusions of the study. NBCCEDP currently provides B&C screening services to >500,000 low-income and uninsured women, but the program is reaching only a small percentage of its eligible population. A substantial need still exists to provide services to this historically underserved population. Key findings of the study should be used to demonstrate the reach of NBCCEDP; estimate the proportion of NBCCEDP-eligible women who are screened outside of the program; direct outreach efforts; inform other studies of issues related to outreach and capacity; and guide future allocations of NBCCEDP funds.

Dr. Tangka announced that CDC would continue to collaborate with the U.S. Census Bureau to complete six major activities in the future:

- Develop state-level estimates for the NBCCEDP-eligible population that has narrow confidence intervals.
- Develop state-level estimates by race/ethnicity.
- Develop county-level estimates where possible.

- Assess the reach of NBCCEDP over time.
- Explain variations in screening rates.
- Release state and county experimental estimates on the U.S. Census Bureau web site with a link to the DCPC website.

BCCAC thanked Dr. Tangka for making an excellent presentation and also commended CDC on its efforts to conduct a comprehensive study to determine the actual performance of NBCCEDP from 1998-2006.

BCCAC's comments and suggestions to CDC on the NBCCEDP-eligible population study are outlined below.

- CDC should explore the possibility of counting women who are screened with state dollars. An undercount should only be performed when screening is paid with federal dollars and counted.
- NBCCEDP was established several years ago, but the program currently serves only 15% of eligible women.
- CDC should clarify whether estimates of eligible women include undocumented and American Indian women.
- An approach of decreasing funds to over-funded states that are not spending program dollars is politically palatable. Because small states have more costs, the budgets of these programs should not be cut and diverted to large programs.
- Outreach to the population of women with lower screening rates is more costly. A cost-effectiveness study showed that previously screened women are easier to re-screen with reminders. Outreach to women who have never been screened or had bad experiences with screening is more expensive. States should share successful strategies to screen or re-screen this population of women.
- Transparency and clarity in explaining funding decisions are important, particularly the metric of the percentage of eligible women screened. Another critical issue is the outcome equity versus the funding equity, such as states with a high rate of cervical cancer that need more funding.
- One state showed a screening rate of 1.5% among eligible women, but this percentage should not be acceptable. Due to the variation in small numbers, a threshold should be established for a "minimum funding level." For example, Program Directors have previously stated their programs had either "excess" or "no" funding.
- CDC should conduct a program review of chronically underserved states. Because some states have less funding or are generally impoverished, all programs that serve at-risk populations are under-funded.
- CDC should develop case studies to evaluate program efficiencies. This assessment would help CDC to determine the rationale for solid versus poor performance in states in terms of health care delivery, populations served and other services. The efficiency evaluation also should focus on the number of women screened and variations in age, culture and other factors.

- Overall, NBCCEDP rations care. Screening is effective for women 50-70 years of age. Screening women <50 years of age should be discontinued to place more attention on NBCCEDP. CDC should explore other screening periods to reach more women.
- CDC should make efforts to increase the percentage of rarely and never screened women.
- CDC should estimate the number of lives saved with screening women 50-64 of age. CDC also should project the number of women who would die if NBCCEDP is not expanded. The number of lives saved with screening cannot be estimated for women 40-49 years of age.

BCCAC discussed other issues related to the NBCCEDP-eligible population study, including:

- The critical need to reach more than 8.7% of NBCCEDP-eligible women with Pap tests.
- An increase in the mammography curve from 1998-2006.
- The potential impact of tribal women on changing the outcomes of the study.

Overview of the Study to Use NBCCEDP-Eligible Population Estimates to Evaluate Equity in Funding

Mr. James Gardner is a Public Health Advisor in PSB. He reported that CDC conducted a study to evaluate equity in funding by using estimates of the NBCCEDP-eligible population. The study was designed to achieve three key objectives. First, eligible population estimates would be introduced to evaluate NBCCEDP's funding history. Second, the apparent inequity in funding within NBCCEDP would be demonstrated. Third, strategies would be explored to incorporate eligible population estimates into future funding decisions.

The initial step of the study was to select and juxtapose a standard population with NBCCEDP funding amounts. Two key parameters were considered in this effort: (1) age groups of 18-64 years, 40-64 years or 50-64 years; (2) the calculation of estimates for breast cancer or cervical cancer screening; and (3) a time period of 1999-2001, 2000-2002 or 2005-2006. After careful consideration, CDC defined a "standard" NBCCEDP-eligible population as the estimate calculated for breast cancer screening; for the age group of 40-64 years; and a time period of 2005-2006 to obtain the most recent screening figures and available MDEs.

For the purposes of this study, "equitable funding" within the NBCCEDP is defined as funding that is fundamentally based on the size of the NBCCEDP-eligible population in each state, tribe or territory. The need to allocate NBCCEDP funds in areas where eligible women were located and simultaneously provide allowances for variations in cost was emphasized as well.

NBCCEDP-eligible population figures have not been available until recently. NBCCEDP was initially expected to be conducted in three phases to determine appropriation levels, implement

activities, and respond to funding requests. Funding was distributed based on the actual capacity of programs to screen women in the early years of NBCCEDP, but this ability was extremely diverse among grantees. The study showed that one result of this funding methodology was inequity in funding levels based on eligible population.

To address the inequity in NBCCEDP funding, a “theoretical” equity amount should be established for each eligible woman. For example, if the total available NBCCEDP funding is \$158 million and there are 3.9 million eligible women, then CDC has approximately \$40 per eligible woman. For purposes of discussion, the \$40 amount would be referred to as the “equity amount” per eligible woman. The equitable funding level for each program could then be determined by multiplying the \$40 equity amount per eligible woman by the total number of eligible women in a project area. However, the final methodology would need to incorporate variable cost data and other, more sophisticated, cost factors to estimate the true equity amount for each grantee.

Mr. Gardner proposed three strategies that could be used to implement the NBCCEDP-eligible population into funding decisions. First, significant shifts could be made in the current 2008-2009 funding process. With no increase in appropriations, the inequity would need to be addressed using current funds. Approximately \$45 million of the current appropriation would need to be shifted from “have” to “have-not” grantees. This strategy would require addressing a potentially paralyzing political backlash to the significant funding shifts.

Second, no significant actions would be taken until the appropriation level is significantly increased. Newly appropriated dollars would be distributed to “have-not” grantees based on need until funding equity is achieved. No increase in appropriation was realized for the current fiscal year.

Third, efforts could be made to avoid making the current funding inequities worse. Grantees that have been funded above or below the equitable funding level should be clearly identified. Funding increases would not be made to “have” grantees and “have not” grantees would be protected from funding decreases, as much as possible. PSB has adopted this approach to the current funding cycle.

Overall, the study showed that 49 B&C programs were historically funded above the equitable funding level and 19 B&C programs were historically funded below the equitable funding level. Both of these categories should be considered in the formulation of funding guidance and final funding decisions.

To significantly impact the funding inequity in NBCCEDP, CDC will need to realize higher appropriation amounts while developing a methodology and designing a planning process. To achieve this goal, a subcommittee of NBCCEDP Program Directors Council representatives and DCPC expert health economists will be formed to reach consensus on the definition of “inequity” that considers variability in costs; develop a new funding allocation strategy to reverse the existing inequity; and consider the principle of “do no harm.”

Dr. Bowman added that CDC is unable to determine whether data are collected at both state and local levels. However, she emphasized that CDC makes every effort to be solid stewards of federal dollars. Dr. Bowman encouraged BCCAC to provide input to CDC on whether data that will be collected for the study would be helpful to the field.

BCCAC advised CDC to carefully consider the spending rate and population size of each individual state in its ongoing efforts to address funding distributions in NBCCEDP. Several members pointed out that the implementation of B&C programs appears to be more politically palatable in small states versus large states.

BCCAC also encouraged CDC to conduct a more detailed analysis to better inform the funding distribution strategy because many grantees expend their dollars in the first quarter of the cooperative agreement and are unable to provide services to the chronically underserved population.

BCCAC noted that data collection at the state level would not be difficult and would improve previous efforts. The members pointed out that an approach of separating breast and cervical cancers is uncertain, should not be considered, and might be burdensome in large states. BCCAC suggested that CDC explore the possibility of asking states to collect local data. Due to the importance of local data, BCCAC also recommended that CDC develop a special tool for local data collection to assist in summarizing data for state reporting. The members advised CDC to design the tool for easy use at the local level.

Update on the NBCCEDP Economic Analysis and Evaluation

Dr. Donatus Ekwueme is a Senior Health Economist in EARB. He provided an update on a multi-year study that CDC conducted to evaluate and perform an economic analysis of NBCCEDP. The study was designed to achieve eight key objectives:

- Economic cost data on NBCCEDP would be systematically collected.
- An economic analysis and evaluation of NBCCEDP would be performed by developing, designing and conducting a cost-effectiveness analysis.
- Methods contributing to the allocation of program resources would be developed.
- Threshold and scenario analyses would be conducted to determine the amount of resources required to screen 25%, 50% or 75% of the NBCCEDP-eligible population.
- The cost of treating a women diagnosed with cancer in NBCCEDP would be estimated.
- Methods used by B&C programs to deliver screening and diagnostic follow-up services would be described.
- The extent to which B&C programs use a common set of service delivery structures would be documented.

- The impact of different types of service delivery structures on the number of women screened would be determined.

Dr. Ekwueme described CDC's rationale to perform an economic analysis and evaluation of NBCCEDP. NBCCEDP is striving to reach and screen as many eligible women as possible. Given the current climate of increased healthcare costs and limited resources, emphasis is continuing to be placed on the economic analysis of NBCCEDP to determine the costs of delivering screening and diagnostic services to eligible women. CDC realized that an economic evaluation of cancer screening, prevention and other health interventions would provide a framework to help inform the decision-making process.

CDC also acknowledged that an economic analysis and evaluation of NBCCEDP would be essential to (1) support and justify programmatic activities; (2) facilitate accountability; (3) promote efficiency and equity in allocating program resources; and (4) provide useful information to assist program directors and managers in maximizing health benefits and improving the impact of the program in cancer prevention.

CDC made several accomplishments in Phase 1 of the study. A questionnaire was developed to successfully collect cost data from nine grantees. An assessment was performed to determine the average costs incurred by the nine grantees in delivering screening services. Expenditures for each NBCCEDP program component were estimated. Factors that need to be addressed to perform cost-effectiveness comparisons across programs were identified. Findings of the study were disseminated to grantees that participated in Phase 1 to be used in program planning efforts. Results of the studies will be further distributed in two publications.

Dr. Ekwueme announced that the cost analysis of NBCCEDP in selected states from 2003-2004 was published in *Cancer* in 2008. The study was designed to address three economic questions. First, what is the cost per woman served in NBCCEDP with and without in-kind contributions? For purposes of this question, CDC defined "women served" as the number of women screened within and outside of NBCCEDP and accepted for diagnostic follow-up of abnormal results. CDC also defined "in-kind contributions" as contributions that strictly represent opportunity costs. Second, what is the cost per woman served by an NBCCEDP component? Third, what is the cost per cancer detected through NBCCEDP?

The methodology of the NBCCEDP cost analysis is outlined as follows. Non-probability sampling, purposive sampling and random selection methods were applied to select and gather detailed cost and effectiveness data from nine B&C programs. CDC designed the sampling method to incorporate program diversity into the selection process. Standardized cost data collection tools were used as well.

Of 51 state-based programs, four were initially excluded based on participation in site visits. Of the 47 remaining programs, the final nine were selected from 11 centralized, 20 decentralized and 16 missed programs. Inclusion criteria were based on the total number of women screened, overall expenditures, cervical screening versus breast screening, program structure, geographic location, and size of area served.

The data collection procedures included: a standardized cost estimation questionnaire to gather FY'03-FY'04 data on costs related to various aspects of NBCCEDP; an introductory letter and questionnaire to programs; an initial conference call to introduce the study and answer questions; and follow-up telephone calls throughout the data collection process.

The data collection tools were designed to gather information on the following NBCCEDP components from each grantee: service delivery structure, program management, screening, case management, public education and outreach, data management, professional education, coalitions and partnerships, quality assurance and improvement, and surveillance and evaluation. Cost data were collected at the activity level of each of the NBCCEDP components.

CDC took several actions to ensure the quality of data collected. Several rounds of follow-up telephone calls were made to the participating programs. A comparison was made between expenses the program reported in the questionnaire and fiscal status report. A comparison was made between screening numbers and the cost of clinical services reported in the questionnaire and clinical cost worksheet. CDC found that data the programs reported in the questionnaires were accurate overall, but consultations were held to resolve any discrepancies.

Dr. Ekwueme summarized the results of the cost analysis of NBCCEDP in selected states from 2003-2004. The nine programs with or without in-kind contributions served a total of 8,131 women with a range of 1,285-19,374. Average expenditures with in-kind contributions were \$4.1 million among programs with a range of \$1.3-\$9.7 million. Average expenditures without in-kind contributions were \$3.2 million among programs with a range of \$1-\$6.3 million. The average cost per woman served with in-kind contributions was \$613.14 among programs with a range of \$282.67-\$1,096.14.

The average cost per woman served without in-kind contributions was \$472.59 among programs with a range of \$258.54-\$758.61. The median of in-kind contributions per woman served was \$140.55 with a range of \$22.22-\$337.53. The average expenditure for clinical services among programs without in-kind contributions was \$1.8 million with a range of \$0.4-\$4.6 million. The average cost per woman screened for clinical services among programs without in-kind contributions was \$246.90 with a range of \$145.44-\$349.43.

The mean number of women screened was 7,233 for breast screening and 4,745 for cervical screening. The average number of follow-up visits for abnormal results was 1,363 for breast screening and 416 for cervical screening. Costs per office visit were \$35.47 for both breast and cervical screening. The total cost of office visits was \$265,857 for breast screening and \$172,513 for cervical screening. The total cost of screening was \$445,434 for breast screening and \$74,129 for cervical screening. The total cost of screening plus an office visit was \$711,291 for breast screening and \$246,642 for cervical screening. The cost per woman screened was \$105.09 for breast screening and \$59.75 for cervical screening.

By NBCCEDP program component, screening accounted for 48.16% of funds; public education and outreach accounted for 12.06%; data management accounted for 11.79%; case

management accounted for 10%; program management accounted for 7.34%; professional education accounted for 5.65%; surveillance and evaluation accounted for 3%; quality assurance and improvement accounted for 1.68%; and coalitions and partnerships accounted for 0.48%.

In Phase 1a of the study, CDC made pilot site visits to four states to better understand the program structures of grantees, determine the impact of program costs, and identify grantees with capacity to provide cost data elements. In Phase 1b of the study, CDC developed instruments to collect cost data from grantees and recommended data collection system tools to gather cost data.

CDC compiled data from Phases 1a and 1b to conduct the following activities in Phase 2 of the study: (1) develop appropriate effectiveness measures and a cost-effectiveness model and framework; (2) create a data collection system, including a user's guide and other training documents for grantees; (3) design a framework to perform a cost-effectiveness assessment; and (4) develop a resource allocation tool to guide the evaluation of programs that use cost data and MDEs. The study protocol was approved by CDC and HHS in late 2007 and is currently undergoing the OMB approval process.

Dr. Ekwueme concluded his presentation by asking BCCAC to provide input on the following questions. Is CDC advancing toward an appropriate direction with regard to the economic analysis of NBCCEDP? Should CDC consider other quantitative study areas in addition to the economic analysis of NBCCEDP? For example, should CDC collect patient-level data to measure the burden of commitment and preferences of eligible women for cancer screening?

Mr. Gardner explained that CDC would use a web-based cost assessment tool (CAT) to collect data from grantees for the comprehensive economic analysis and evaluation of NBCCEDP. Within the tool, cost methods of programs are based on an activity-based costing approach. Cost data are collected by each program activity to obtain an accurate reflection of the value of resources or economic costs utilized in providing services under NBCCEDP. Examples of program activities included personnel, clinical screening, public education, quality assurance, data management, professional education, contracts and consultants.

The CAT will be posted on a future web site and will collect data through ten categories: grantee details, total expenditures, in-kind contributions, personnel expenditures, consultant expenditures, screening expenditures, funding for non-screening activities, costs associated with contracts, materials, travel and services, administrative costs, and allocation of resources for breast versus cervical screening. Mr. Gardner presented a demonstration of the web-based CAT system and its ten categories.

BCCAC's comments and suggestions to CDC on the NBCCEDP economic analysis and evaluation are outlined below.

- CDC should link differential investments in program components to specific outcomes, such as public education, outreach and case management. The cost

per case found is acceptable, but even nine programs would demonstrate consistency with the published literature.

- CDC should encourage programs to better define the cost of office visits. For example, the New York program conducted public education prior to receiving NBCCEDP screening dollars. Women enrolled in NBCCEDP returned to the program in response to call-backs, but other women did not return due to the absence of a call-back system.
- CDC should explore strategies to estimate the costs of treating women with stage IV cancer. The costs of identifying cancers in stage I versus stage IV, or localized versus metastasized disease, should be compared.
- NBCCEDP has a heavy focus on the number of women screened and insufficient emphasis on public education, case management, professional education and quality assurance. Stronger outreach to providers would increase the numbers of women screened.

BCCAC noted that grantees would be required to make tremendous efforts to collect and submit data to the CAT. Several members made additional suggestions for CDC to consider in the NBCCEDP economic analysis and evaluation.

- CDC should provide B&C programs with user manuals to assist in gathering information for the CAT.
- CDC should develop a simple spreadsheet to help B&C programs in inputting data into category 10 on the CAT menu: "allocation of resources for breast versus cervical screening."
- CDC should review sources of funding in states other than federal funding.
- CDC should include a methodology in the economic analysis and evaluation of NBCCEDP to estimate the cost of a woman with stage IV cancer.

Overview of NBCCEDP in the Era of Health Systems Reform

Ms. Chastity Walker is a Public Health Advisor in PSB. She explained that estimates suggest ~47 million individuals in the United States currently have no form of insurance. As a result, healthcare reform and universal coverage are being widely discussed and advocated across the country as potential strategies to control escalating healthcare costs and increase access to care.

Several states have taken the lead in developing proposals to reform healthcare systems with a goal of significantly increasing the number of persons with healthcare coverage. At this time, ~21 states have announced comprehensive reform proposals or have established commissions that are charged with developing recommendations on expanding coverage. Moreover, Maine, Massachusetts and Vermont have enacted legislation and are implementing reform plans that seek to achieve nearly universal coverage of state residents.

Current estimates show that ~18 million women 18-64 years of age are uninsured. Although a large proportion of uninsured women are from working families, an increase in the uninsured population has been observed in women of color and low-income women. Health insurance coverage is a critical factor in access to care for women because uninsured women lack adequate access to care, receive a lower standard of care when in the health system, and have poorer health outcomes. Women with health coverage are more likely to obtain needed preventive, primary and specialty care services.

The NBCCEDP is designed to increase access to and improve the quality of B&C screening nationwide and serve low-income, uninsured and under-insured women. The NBCCEDP provides cervical cancer screening for women 18-64 years of age and B&C screening for women 40-64 years of age. To be eligible for B&C screening services, women must have no health insurance and family incomes <250% of the [HHS Poverty Guidelines](#). However, the Census does not include the reporting category of under-insured women.

The NBCCEDP is a unique program that utilizes a comprehensive and coordinated public health approach to screen and monitor women for breast and cervical cancer. NBCCEDP has an eligible population of 3.7 million uninsured women and is supported by a number of key program components. Women are screened through a healthcare delivery system. Outreach, recruitment and public awareness activities are conducted to inform women of the need for screening and also to enroll eligible women into NBCCEDP.

Public education is offered to inform women about the risks of breast and cervical cancer, recommend screening intervals, and address fears that women face. Professional education and quality assurance activities are conducted to ensure the use of science-based, clinically appropriate, and high-quality screening and follow-up. Tracking and surveillance are performed for all women who are screened. Case management is provided to women with a cancer diagnosis to assure timely follow-up for diagnostic care and referrals to treatment if needed.

Ms. Walker pointed out that healthcare reform efforts have potential implications on NBCCEDP, including a decline in the number of eligible women; a reduced need for reimbursement of screening, diagnostic and other clinical services; optimized access and utilization of preventive screening tests; and possible risks to the non-clinical components of NBCCEDP.

Ms. Walker concluded her overview by requesting BCCAC's input on the following questions. What are the critical issues that CDC should pay attention to in the current landscape of healthcare reform? What should be CDC's role in protecting the public health infrastructure of NBCCEDP? What are the best strategies for CDC to implement to collaborate with B&C programs to ensure delivery of the highest level of quality care? What are the best approaches for CDC to take to leverage partnerships in a changing healthcare environment?

BCCAC emphasized the critical need for healthcare reform efforts to improve access to care. Several members advised CDC to encourage grantees to compile B&C programmatic data and publish studies. For example, the current status of healthcare reform activities in the United States makes a strong case to conduct a qualitative study of NBCCEDP. The BCCAC

members noted that this research might provide an opportunity to fill current data gaps. Other members raised the possibility of B&C programs developing and distributing packets of materials to describe the benefits of NBCCEDP.

BCCAC's additional comments and suggestions to CDC on the role of NBCCEDP in an era of healthcare systems reform are outlined below.

- Regardless of changes in healthcare reform, the most critical component of NBCCEDP is its infrastructure. A weak focus on infrastructure will result in usurping or eliminating this element in the future. More emphasis is placed on NBCCEDP screening rates and cost rather than its infrastructure. CDC should conduct an evaluation with experts to determine the following factors: (1) the core infrastructure needed in different situations; (2) capacity to generalize existing elements of the infrastructure; and (3) critical factors relative to the infrastructure.
- Some states might eliminate NBCCEDP from healthcare reform efforts because the program covers breast and cervical cancer screening.
- Universal coverage and healthcare reform are not equivalent. Medicare is currently a "quasi-public health benefit" because payments are only made for influenza vaccination and other prevention interventions. Influenza vaccination is free, but coverage is only 66% in the general U.S. population. Public health is a critical need because universal coverage is only one component of healthcare reform and not the entire solution.
- CDC should conduct an evaluation to identify quality and efficiency standards for NBCCEDP to lead rather than react to healthcare reform. The evaluation should focus on the current purpose and future goals of NBCCEDP. Other programs that provide similar services should be reviewed to inform the evaluation.
- CDC should modify NBCCEDP to have more flexibility in the 60/40 rule. This approach would allow CDC to test components of NBCCEDP that can be conducted differently.
- The future of NBCCEDP will vary depending on healthcare reform efforts in each state. For example, NBCCEDP is effective in Georgia, but locating rarely and never screened women is a challenge in the state. CDC should establish partnerships for NBCCEDP to better address women who are not screened.
- Women will present to programs if free services are offered, but outreach still needs to be strengthened to empower women and increase screening rates by addressing fears about cancer and navigating women through various programs and eligible services.
- Insurance does not provide access to NBCCEDP. CDC should use its existing data on the multiple components of NBCCEDP to determine items that are needed in healthcare reform. For example, other countries with socialized medicine have the same disparities as the United States and use clinical service payers rather than public health.

- Health maintenance organizations and self-referrals to care are flawed and lack coordination. Universal and interoperable electronic health records are needed to address these deficiencies.
- CDC should conduct a cost study to demonstrate the unique value of NBCCEDP in delivering quality care and highlight differences among various delivery systems. This study would be a tremendous contribution to documenting the high quality of NBCCEDP.
- CDC should conduct a qualitative study and gather anecdotes, lessons learned and experiences of programs to inform this activity. For example, New York leveraged NBCCEDP funding to identify quality assurance issues with mammography. CDC could apply New York's experience to healthcare reform.
- CDC should perform an evaluation to identify the successes and failures of NBCCEDP in the past and determine specific reasons for the lack of success in some areas. For example, a benefits package is one of NBCCEDP's key strengths.

Overview of Cancer Control PLANET

Dr. Jon Kerner is BCCAC's *ex-officio* member for the National Cancer Institute (NCI). He reported that the United States spends \$100 billion annually in biomedical and health research, but much of this worldwide investment is wasted because of dissemination and implementation failures. Consistent evidence has shown that healthcare systems and professionals fail to deliver quality of care.

NCI's research portfolio includes funded activities in five major categories: prevention, detection, diagnosis, treatment and survivorship. These projects are designed to address the entire discovery-delivery continuum of discovery, development, delivery, policy, efficacy/effectiveness, replication, knowledge synthesis, dissemination and implementation.

NCI's concerns regarding research translation and dissemination are based on four major factors. Cancer control is conducted in public health, primary care and specialty care contexts, but these settings have variable resources to integrate evidence into practice. Large numbers of surveillance and intervention studies are funded each year, but this research produces minimal evidence to demonstrate the influence of study findings on policy or practice. NCI allocates substantial resources on communication and education, but these efforts have shown limited impact on policy or practice. Demonstration programs are expensive and difficult to sustain.

NCI is making strong efforts to transfer evidence-based knowledge into public health and clinical practice. NCI is also incorporating the knowledge integration model of explicit evidence-based knowledge, informed application, tacit practice and contextual knowledge into local community applications. To advance these efforts, NCI developed the Cancer Control PLANET (Plan, Link, Act, Network with Evidence-Based Tools). The web portal provides access to data and

research-tested resources and assists tobacco control planners, program staff and researchers in designing, implementing and evaluating evidence-based tobacco control programs.

Users of the Cancer Control PLANET can locate information by cancer control topic; register on the list serve to receive monthly updates; and follow five steps to develop a CCC plan or program.

1. Program priorities should be assessed by analyzing the cancer burden on a local, state or national level. Risk factors should be evaluated to help identify high-risk populations and priorities for tobacco control and cancer control. The Cancer Control PLANET provides state cancer profiles, interactive graphs and maps, and other supporting data as resources.
2. Potential research partners that collaborate with community-based tobacco control programs should be identified. The Cancer Control PLANET provides contact information for the following groups: ACS's Regional Cancer Control Planners; CDC's Comprehensive Cancer Control Network; the Commission on Cancer State Liaisons; NCI's Cancer Information Service; cancer control research and program partners in states, territories and tribes; and local tobacco control researchers funded by ACS, CDC, NCI and the Agency for Healthcare Research and Quality (AHRQ).
3. Research on various intervention strategies should be reviewed to learn about CCC approaches with demonstrated effectiveness or ineffectiveness. The Cancer Control PLANET provides links to CDC's *Guide to Community Preventive Services* and AHRQ's *Guide to Clinical Preventive Services*.
4. Research-tested tobacco control intervention programs and products should be located and adapted to address programmatic objectives. An inventory of programs developed from scientific studies with demonstrated effectiveness should be accessed. The Cancer Control PLANET provides links to two NCI/ Substance Abuse and Mental Health Services Agency web sites. "Research-Tested Intervention Programs" and "Using What Works: Adapting Evidence-Based Programs to Fill Your Needs." These web sites provide tools to specialize CCC programs, such as promoting B&C screening, addressing barriers to screening non-adherent women, and increasing cancer control screening based on the age, race/ethnicity or setting of the target population.
5. The program should be planned and evaluated. Resources and guidelines for planning, implementing and assessing CCC programs should be reviewed. Tools to translate prevention into practice should be accessed. The Cancer Control PLANET provides state, tribe and territory implementation budgets, existing cancer control plans, and links to funding opportunities.

At the international level, Canada and Ireland offer CCC resources through PLANET portals. For countries that do not offer specific cancer control resources via a PLANET portal, links are provided to the World Health Organization and the International Union Against Cancer to obtain assistance and resources in CCC planning, implementation and evaluation. Dr. Kerner encouraged BCCAC to access the web portal at www.cancercontrolplanet.cancer.gov.

With no further discussion or business brought before BCCAC, Dr. Ramirez recessed the meeting at 4:50 p.m. on March 4, 2008.

Discussion on the NBCCEDP Strategic Planning Process

Dr. Ramirez reconvened the BCCAC meeting at 8:40 a.m. on March 5, 2008 and yielded the floor to the first presenter.

Ms. Wong led the BCCAC members in a discussion regarding the opportunities and priorities for the NBCCEDP strategic planning process. The BCCAC members made a number of suggestions for CDC to consider in this ongoing effort.

- CDC should identify no more than four priorities to guide the strategic planning process. These priorities should be designed to be transparent, clear and simple.
- CDC should carefully consider the political implications of spending NBCCEDP dollars.
- CDC should gather extensive input from partners, organizations and other external groups to inform the strategic planning process.
- CDC should consider the following issues in the strategic planning process:
 - the emerging technology of digital mammography;
 - entitlement to NBCCEDP services;
 - different thresholds among states;
 - effective strategies to increase the number of NBCCEDP-eligible women; and
 - budget constraints.

Overview of Screening Challenges for NBCCEDP

Dr. Herschel Lawson is the Senior Medical Advisor in DCPC. He described the five major challenges to NBCCEDP. First, the proportion of the eligible population served should be increased. Second, disparities in health outcomes among minority populations should be reduced. Third, a strong and competent provider base should be maintained. Fourth, the use of new screening technologies should be introduced to NBCCEDP. Fifth, NBCCEDP clinical

policies should be developed, communicated, and remain relevant as science and technology evolve.

The public law governing the use of improved screening procedures contains the following language: "The Secretary may not make a grant unless the grantee involved agrees that if any screening procedure superior to a procedure described becomes commonly available and is recommended for use, the grantee will utilize the superior procedure rather than the described procedure."

Dr. Lawson reported that CDC developed a framework to assess specific technologies. Criteria for the assessment were based on available scientific evidence, the existing public health infrastructure, programmatic factors, and the public health impact of the technologies. CDC also used reimbursement decision criteria in the assessment to determine whether the technology (1) reduced breast cancer morbidity and mortality; (2) decreased overall health disparities; and (3) and sustained or enhanced overall public health benefits, quality of care and program operations.

Additional factors that CDC considered in the technology assessment included the ability of policies to: be consistent across B&C programs, allow flexibility in implementation across local communities, and accommodate differences across B&C programs. CDC also acknowledged the need to consider related policies established by the Centers for Medicare and Medicaid Services, Food and Drug Administration and other federal agencies.

For cervical cancer screening, CDC evaluated three technologies: conventional cytology, liquid-based cytology, and HPV DNA testing as an adjunct to cervical cytology screening. For breast cancer screening, CDC evaluated five technologies: conventional film mammography, full-field digital mammography (FFDM), computer-assisted detection, magnetic resonance imaging, and ultrasound.

The characteristics of each technology were assessed, including its accuracy, reproducibility, interval, cost, and population impact. Public health factors related to the clinical setting, provider, patient and programs were evaluated as well. Key findings of the technology assessment are outlined below.

FFDM has different image file storage requirements and is capable of enhancing digital mammography images. However, FFDM is more expensive than other technologies. Multiple exposures and more radiation are needed for women with large breasts due to the screening surface size of older equipment. To date, insufficient data have been produced demonstrating the role of FFDM in reducing disease incidence or improving cancer survival.

The sensitivity and specificity of FFDM are equal to conventional film mammography only. The Digital Mammographic Imaging Screening Trial (DMIST) found FFDM to be more sensitive for peri-menopausal women and those with dense breasts. The DMIST cost-effective analysis showed that FFDM was not cost-effective compared to film mammography. Age targeted FFDM screening was found to be more cost effective than either all-FFDM or all-film

mammography. DMIST results demonstrated ~\$27,000 per quality-adjusted life year, but this estimate increased among women 40-49 years of age.

The policy of reimbursing at the Medicare rate for conventional film mammography was reevaluated after the DMIST findings were released. No change in policy was recommended based on issues related to access, penetration of the technology in the community, the cost of >\$60 per examination, reproducibility, and priorities of a patient population that is primarily >50 years of age. The availability of FFDM in certified facilities has dramatically increased from 413 in June 2003 to 2,743 in February 2008. The proportion of all facilities with FFDM also increased from 6.8% in June 2003 to 31% in February 2008.

Overall, the use of FFDM is increasing by 6% each month. However, regional differences in the penetration of FFDM exist. Programs have made multiple inquiries about accelerating problems with access to mammography services. The challenges associated with FFDM include a number of radiology facilities that are now entirely digital, particularly those serving NBCCEDP-eligible women. Moreover, some providers insist on using FFDM for all screening mammograms. Programmatic concerns also have been raised regarding the loss of providers, direct-to-consumer marketing, cost-benefit issues, and perceptions of a two-tier healthcare delivery system.

Dr. Lawson noted that CDC is taking several actions to meet these challenges. U.S. Preventive Services Task Force recommendations are followed when feasible. The scientific literature and practice patterns are regularly monitored. Involvement is being maintained in developing and refining community screening guidelines and policies. Close attention is being paid to the needs and concerns expressed by B&C programs.

Partnerships are being established with other government agencies at federal, state and local levels, professional organizations, Cancer Prevention Research Centers, and community-based organizations. Efforts are being made to obtain additional resources to meet the needs of greater numbers of NBCCEDP-eligible women. An expert workgroup will be reconvened to reevaluate the status of NBCCEDP policies on FFDM.

Dr. Lawson highlighted results of a program survey that was administered to determine the current impact of FFDM. The average number of providers was 251 among six responding B&C programs. Of all respondents, 34% were fully FFDM; 33% reported problems with contracts due to reimbursement rates for conventional mammography; 50% reported problems due to excess paperwork; 67% reported problems with contracts due to reimbursement rates for FFDM; and 50% reported that providers refused service due to the FFDM reimbursement rate.

Clinical scientific consultants found no additional evidence of effectiveness to support FFDM, but they acknowledged that an argument could be made to either continue with the current policy or decide to cover FFDM. The consultants also concluded that the replacement of conventional equipment is resulting in a rapid move to all-digital and a proactive decision about FFDM reimbursement might be indicated.

Dr. Lawson summarized activities that CDC will conduct to guide the future direction of NBCCEDP. The percentage of eligible women screened through NBCCEDP will be increased. The efficiency and cost-effectiveness of NBCCEDP will be strengthened. Cancer screening among never and rarely screened women will be increased.

Partnerships will be established to expand the reach of NBCCEDP. The use of currently available resources will be maximized. Clear public health guidance will be provided to grantees and the public. Plans will be made to meet program needs associated with an expansion if additional resources become available. Integration strategies with other chronic disease programs will be explored.

Dr. Lawson concluded his overview by requesting BCCAC's input on the following questions. Should NBCCEDP fully reimburse for FFDM at this time? Based on current funding considerations, would this change negatively impact the overall effectiveness of NBCCEDP or result in positive outcomes? Should the use of FFDM be phased in over time? What are potential alternatives to FFDM?

BCCAC expressed concerns that B&C programs are not being reimbursed for either the use of FFDM or issues related to access. Several members raised operational and programmatic issues for CDC to consider in the decision-making process of potentially changing the policy for NBCCEDP to fully reimburse for FFDM. The BCCAC members advised CDC to consider:

- Differences in existing capacity among radiological facilities.
- Variations in training among film radiologists in properly using equipment, particularly in rural areas.
- The potential for excess paperwork among B&C programs that use FFDM.
- Differences between FFDM and other technologies due to the need for radiologists to be present.
- The potential loss of follow-up of NBCCEDP-eligible women.
- The critical need for communities to have reasonable access to technologies and also to be reimbursed for FFDM at this time.
- The inability of some B&C programs to switch to FFDM due to fixed budgets.
- The lack of additional evidence to demonstrate the cost-effectiveness of FFDM at this time.
- Decreased access to film mammography over time.
- The need to consider Medicaid or Medicare legal issues.

Update on CDC Breast Cancer Research Projects

Dr. Lucy Peipins is the Behavioral and Applied Research Team Lead in EARB. She provided an overview on the "Time and Distance Barriers to Mammography Facilities in the Atlanta Metropolitan Area" study that CDC conducted in collaboration with the Agency for Toxic Substances and Disease Registry and the Georgia BCCEDP.

CDC acknowledged that research on barriers to mammography screening primarily has focused on access to health care in terms of cost. However, these studies have not produced sufficient knowledge on geographical availability and accessibility. Although geographical distance has been documented in rural areas as a barrier to breast cancer screening, spatial accessibility in urban areas also pose a challenge, particularly for minorities and low-income urban residents who depend on public transportation.

In an effort to fill these data gaps, CDC performed an analysis of spatial accessibility to mammography facilities in the Atlanta metropolitan area. The overarching goal of the study was to quantify time and distance barriers to mammography facilities from census tracts where the population would most likely use public transportation in Atlanta, Georgia. CDC selected the study site because Atlanta is the ninth largest metropolitan area in the United States and is in the top ten percent of geographical areas for growth of African Americans, Asians and Latinos.

CDC formulated several research questions to guide the study. What is the mean and range of the distribution of travel time and distance using public transportation from selected census tracts to mammography facilities in the Atlanta metropolitan area? Is there variation in this distribution by time of day or day of the week? Is there variation by socioeconomic status or race/ethnicity? What are the census tracts in which travel times pose the greatest barriers?

Dr. Peipins summarized the design and methodology of the study. The population included 282 census tracts in Fulton and DeKalb Counties where the Metropolitan Atlanta Rapid Transit Authority operates. Geographic information system (GIS) tools were used to perform an ecologic descriptive analysis. Geographic data layers included public bus, road and rail networks; bus stops and timetables for train and bus routes; mammography screening facilities; and census tracts characterized by a vulnerability index using 2000 U.S. census data.

U.S. census variables were used to determine specific factors in the vulnerability index, such as the percent of households without a private automobile or access to a vehicle; the percent of households living below the [HHS Poverty Guidelines](#); the percent of unemployed civilians; and the proportion of persons ≥ 25 years of age without a high school education. Each variable was ranked from highest to lowest for all census tracts. A percentile rank was calculated for each variable in each tract. Ranks of all variables for each tract were summed for the overall percentile rank.

The average time from the geographic center of randomly selected census tracts via the most direct route of public transportation to the closest mammography screening facility was calculated. Distributions of travel times, including means, medians and ranges, were estimated for each of the selected census tracts. Different time periods, such as morning, afternoons and Saturdays, were included because journey times are potentially dynamic.

Travel time and distance were stratified by race/ethnicity because a study demonstrated racial/ethnic disparities in travel time for low-income residents. GIS tools were used to overlay a

map of mammography clinics in the Atlanta metropolitan with bus stops. The actual time and distance to mammography facilities were calculated for each of the selected census tracts.

CDC used results of the assessment of vulnerability for Fulton and DeKalb Counties to develop and present a poster on “Transportation-Based Characterization of Census Tracts in the Atlanta, Georgia Metropolitan Area: Implications for Barriers to Mammography Screening.” These findings also were used to develop the vulnerability index; characterize the 282 census tracts in the Atlanta metropolitan area; and explore correlations between the vulnerability index and other variables, such as poverty and access to a private vehicle.

Dr. Peipins summarized key findings of the study. The correlation between census tracts with no available vehicle and those in which the vulnerability index was applied was 0.912. The correlation between census tracts with poverty and those with no access to a vehicle was 0.834. An alternative census characterization showed a difference between the geographic distribution of women ≥ 45 years of age living in poverty and census tracts with the vulnerability index and access to a private vehicle. A strong correlation was seen between census tracts with access to a vehicle and those in which both the vulnerability index and poverty/age variable were applied.

Dr. Peipins noted that CDC hopes the results of the study will contribute to the ongoing characterization of barriers to mammography with an ultimate goal of increasing screening rates in the United States. Moreover, CDC expects to apply significant outcomes of the study to achieve the following objectives.

Census tracts that have particularly long travel and time constraints will be identified. Information from the study will be used to identify areas that need more accessible referrals to screening facilities. Results of the study will assist in identifying women who may be eligible to participate in the Georgia BCCEDP. Maps and tables will be provided in .pdf formats to the Georgia BCCEDP for further distribution to field staff. Findings of the study will contribute to an economic cost analysis of time and distance barriers to mammography screening.

BCCAC thanked Dr. Peipins for presenting a comprehensive overview of CDC’s study on time and distance barriers to mammography facilities. Several members acknowledged that the study is an important step and presents a tremendous opportunity to fill current research gaps. The BCCAC members made a number of suggestions for CDC to consider in its ongoing efforts to refine the study.

- CDC should consider expanding the study beyond the Atlanta metropolitan area. For example, the New York City subway system was found to be effective for women in urban areas with no access to a private vehicle to reach mammography facilities.
- The study design and methods should be revised to include white women in urban areas who are not being screened.
- The study should reflect a more extensive review of the current literature, such as studies conducted by Dr. Paul Hahn, a journal on interval screening that was

recently published, and community-based research on time and distance barriers to mammography facilities.

- The study should be stratified by additional variables, such as 366 days that are required for reimbursement with Medicare, Medicaid or private insurance.

Dr. Lisa Richardson gave a brief summary of the Barriers to Mammography study funded by the Susan G. Komen for the Cure Foundation. This project will be funded as a contract to examine barriers to on time use of screening mammography noted in several analyses recently conducted by CDC (Blythe Ryerson, *et al.*) and NCI (Nancy Breen, *et al.*). The BCCAC members expressed concern that the project would repeat studies conducted in the past and might waste resources that could be better utilized elsewhere.

Dr. Richardson responded to these comments by explaining the unique nature of the recent findings. The subpopulation of interest for this study is women who have previously undergone mammography, but have discontinued. According to results reported by Dr. Breen, all sociodemographic groups were affected, including white, upper-income and insured populations.

Dr. Richardson concluded by noting that current and past messages around mammography use may not resonate with women today. The focus group research findings will be used to inform interventions and possible public health campaigns to reverse secular trends noted in mammography screening prevalence.

Closing Session

BCCAC applauded Ms. Debra Younginer, the Designated Federal Official, and other CDC staff for distributing meeting materials and making other logistical arrangements to convene an extremely productive meeting. The members also commended Dr. Ramirez for her outstanding efforts in chairing a successful meeting.

With no further discussion or business brought before BCCAC, Dr. Ramirez adjourned the meeting at 11:47 a.m. on March 5, 2008.

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

Date

Amelie G. Ramirez, Dr.P.H., M.P.H.
Chair, Breast and Cervical Cancer Early
Detection and Control
Advisory Committee