CDC Research and Programmatic Activities in Breast Cancer Genomics

Advisory Committee Meeting on Breast Cancer in Young Women

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Enhancing Breast Cancer Genomics Practices Through Education, Surveillance, and Policy

PROGRAMMATIC ACTIVITIES

Program Activities

- Since 2003 the Office of Public Health Genomics (OPHG) at CDC has been working with state health departments to integrate genomics knowledge and tools into state chronic disease prevention programs and core public health functions.

- In 2010 through the existing OPGH cooperative agreements, DCPC provided additional funds to two states to expand their activities in breast cancer genomics.

Program Activities

- **The Michigan Department of Community Health was provided funding to:**
  - Expand surveillance of genetic counseling and BRCA 1/2 genetic testing
  - Explore the feasibility of linking BRCA positive patients with state cancer registry data
  - Expand identification of state health insurance plans and evaluate medical policies for coverage of genetic counseling and testing, and related preventive services
  - Increase dissemination to health insurance carriers of appropriate medical policy for genetic counseling and testing, and related preventive services

Program Activities

- **The Oregon Division of Public Health was provided funding to:**
  - Expand surveillance of genetic counseling and BRCA1/2 genetic testing
  - Expand identification of state health insurance plans and evaluate medical policies for coverage of genetic counseling and testing, and related preventive services
  - Expand collection and analysis of Medicaid data on BRCA testing and follow-up procedures
  - Add questions on family history and genetic testing to the Oregon BRFSS
  - Collaborate with the state screening program to develop a conceptual model for educating and identifying high risk clients.

Program Activities

- In 2011, the Division of Cancer Prevention and Control released a new funding opportunity to continue and build upon the activities started through the OPHG cooperative agreements.
- New FOA: "Enhancing Breast Cancer Genomic Practices Through Education, Surveillance, and Policy"
- Posted June 8, 2011; closed July 25, 2011
- State and local governments or tribal organizations were eligible to apply
- Expected to fund up to 3 applicants, at $300,000 per year, for 3 years

Program Activities

- **Programs funded under the new cooperative agreement will be working in the following areas:**

- **Policy**
  - These programs will use policy interventions to promote the use of clinical best practices for genetic counseling, BRCA1/2 testing, and preventive services for those identified as high risk.

- **Education**
  - These programs will develop or expand public and provider education programs to increase knowledge on the importance of family history, appropriate risk assessment and communication, genetic counseling and BRCA1/2 testing, and preventive services for those identified as high risk.

Program Activities

- **Surveillance**
  - Programs in surveillance will track the use of genetic counseling and BRCA1/2 testing, follow-up procedures for those identified as high risk, and family medical history tools or family medical history based risk assessment tools for breast and ovarian cancer.

- **Applicants required to propose activities in 2 out the 3 areas.**

Study Team

- **CDC:**
  - Katrina Trivers, PhD
  - Juan Rodriguez, MPH, MS
  - Sherri Stewart, PhD

Health Insurance Coverage of Genetic and Prevention Services in Populations at Increased Risk for Breast and Ovarian Cancer

RESEARCH

Background

- With the advent of genetic testing, identifying individuals at high risk for breast and ovarian cancer has become a priority for clinicians and researchers.
- Several mathematical models have been developed to calculate the probability of an individual being a mutation carrier.
- Clinical practice guidelines based on personal and family history of breast and ovarian cancer have also been developed by several professional medical associations.

Background

- **In 2005, the United States Preventive Services Task Force issued a grade B recommendation that "women whose family history is associated with an increased risk for deleterious mutations in BRCA1 or BRCA2 genes be referred for genetic counseling and evaluation for BRCA testing[1]."**
  - Recommendation states that "this counseling should be done by a suitably trained health care provider[1]."
- **While recommendations and clinical guidelines for identifying high risk populations exist, several uncertainties still remain.**

1. US Preventive Services Task Force. (2005). Genetic Risk Assessment and BRCA Mutation Testing for Breast and Ovarian Cancer Susceptibility: Recommendation Statement. Annals of Internal Medicine. 143:355-361.

Background

- One of these uncertainties relates to insurance coverage and medical policy.
- It is unclear what breast and ovarian cancer genetic services are generally covered by health insurance plans and the requirements for coverage policy holders face.
- In addition, it is unclear what guidelines or evidence is used to develop these medical policies.

Background

- **In order to address these issues, DCPC investigators are conducting a systematic review of health insurance medical policies that address genetic counseling and testing for mutations in BRCA1/2.**
  - Medical policies for coverage of clinical preventive services are also being reviewed.

Methodology

- **Review being conducted at a state level**
- **Within each state, a list of health insurance companies offering health insurance coverage is compiled**
- **Criteria for inclusion into review:**
  - Company must offer comprehensive group, family, or individual health insurance coverage
  - Number of covered lives within each company must be 1% or more of the market share
- **Public plans also included in review**

Methodology

- **Once plans selected, the health plan's website is searched for their relevant medical policies.**
  - Search engines are also used to retrieve relevant websites and documents.
- **Retrieved health plan medical policies are then reviewed and abstracted into the study database.**
- **Original study methodology called for contacting health insurance companies where there was incomplete data, but this was suspended early in the study.**

Methodology

- **Medical Policies were reviewed for the following clinical services:**
  - Genetic counseling for breast and ovarian cancer susceptibility
  - Genetic testing for BRCA1/BRCA2 (BRAC*Analysis*®)
    - BRAC*Analysis* Large Rearrangement Test (BART)
  - Prophylactic mastectomy and breast reconstruction
  - Prophylactic oophorectomy
  - Cancer Surveillance:
    - Mammography
    - Breast MRI
    - Breast Ultrasound
    - CA-125
    - Trans-vaginal Ultrasound
  - Chemopreventive Drugs

Preliminary Results

- **Between September 2010 and August 2011, have reviewed medical policies for more than 200 health insurance companies in 20 states.**
- **Have seen significant variability in requirements, or conditions, for coverage.**
- **Several health insurance companies are using USPSTF guidelines as the basis for their medical policies.**
  - Some going beyond USPSTF
- **Many health insurance companies lack detailed and comprehensive medical policies for these services.**

Impact of Healthcare Reform

- **The passage of the Patient Protection and Affordable Care Act in 2010 significantly impacts these policies.**
- **The act calls for the all health insurance companies to provide full coverage (no cost-sharing) for new policy holders for grade A and B USPSTF recommendations.**
  - Essential Health Benefit
  - Grandfathered vs. new policies
  - Similarly applies to Medicare and Medicaid

Next Steps

- In the coming year will be reviewing health insurance company medical policies in remaining 28 states.
- Plan to work with state health departments and comprehensive cancer programs to improve the medical policies of health insurance carriers in their respective states.
- Have significant work to do at the national level to deal not only with issues of medical policies and insurance coverage, but also on medical billing, lack of capacity, and issues related to access.

Study Team

- **CDC**
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  - Nikki Hawkins, PhD
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Any Questions?

Thank You!

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