Building Customized Implementation Approaches for Genomics Programs at the State Level

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“Genomics will be to the 21\textsuperscript{st} century what infectious disease was to the 20\textsuperscript{th} century...Genomics should be considered in every facet of public health: infectious disease, chronic disease, occupational health, environmental health, in addition to maternal and child health”

Gerard et al. Journal Law, Medicine, Ethics 2002; vol 30 (suppl):173-176
The 3 Core Public Health Functions

- **Assessment**
  - More “precision” in measuring population health problems

- **Policy Development**
  - Developing the right intervention for the right population

- **Assurance**
  - More “precision” in delivering interventions & addressing health disparities

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Khoury et al, AJPM, 2016
HEALTHY PEOPLE 2020 (HP 2020) CANCER GENOMICS OBJECTIVES

- HP 2020 marks first time for genomics objectives
- Increase the proportion of women with a family history of breast and/or ovarian cancer who receive genetic counseling
- Increase the proportion of persons with newly diagnosed colorectal cancer who receive genetic testing to identify Lynch syndrome (or familial colorectal cancer syndromes)

http://www.healthypeople.gov/2020/topics-objectives/topic/genomics/objectives
THREE-TIER CLASSIFICATION

Green
- FDA label requires use of test to inform choice or dose of a drug
- CMS covers testing
- Clinical practice guidelines based on systematic review supports testing

Yellow
- FDA label mentions biomarkers
- CMS covers use with evidence development

Red
- FDA label cautions against use
- CMS decision against coverage
- Clinical practice guideline recommends against use of test
- Clinical practice guideline finds insufficient evidence and discourages use of test
- Systematic review recommends against use
- Systematic review finds insufficient evidence and discourages use
- Evidence available only from published studies without systematic reviews, clinical practice guidelines, FDA label or CMS labels coverage decision

*Can be reassigned to Green or Red if one or more conditions in the categories apply

https://phgkb.cdc.gov/PHGKB/topicStartPage.action
IMPLEMENTATION ‘READINESS’ OF STATE PUBLIC HEALTH DEPARTMENT AND PROGRAMS WITHIN STATE FOR PUBLIC HEALTH GENOMICS

• **How to define ‘Readiness’?**
  - No clear definition of public health genomics readiness
  - Informal ‘readiness’ developed by GPHAC
    - Awarded CDC funds for public health genomics (high-advanced)
    - Known state health department interest and/or activities in public health genomics (moderate)
    - No funding and no known interest expressed to CDC or funded states (unknown or low-beginner)

• **Consider development of GPHAC customized implementation toolkit for states based on implementation ‘readiness’**
  - Past toolkits developed based on core public health functions with examples of state public health genomics activities (CDC OPHG, ASTHO, CDD)

• **Gauge interest in public health genomics**
  - Who is ‘point person’ for public health genomics in state health department?
    - Consider Chief Medical Executive, Public Health Administration Deputy Director, Chronic Disease Director, Cancer Registrar, State Genetics Coordinator (newborn screening), Cancer Prevention & Control Program Manager, Cardiovascular Health Manager, State Epidemiologist, Medicaid Program Medical Directors, BCCEDP staff and several other possible staff
    - Not ‘one size fits all’ on who is/will be best point person to contact
    - Challenge but also demonstrates possible opportunities in several programs!
Enhancing Cancer Genomic Best Practices through Education, Surveillance, and Policy

Goal: Provide leadership and build capacity for cancer genomics activities in state public health departments

- 2003-2008: Michigan, Minnesota, Oregon, and Utah
- 2008-2011: Michigan and Oregon
- 2011-2014: Georgia, Michigan, and Oregon

http://www.cdc.gov/cancer/breast/what_cdc_is_doing/genomics_foa.htm
DEB’S UNOFFICIAL HINTS FOR APPLICATIONS FOR CDC FUNDING

• Be prepared!
  - Build internal capacity in public health genomics before CDC RFA released
  - Be familiar with current genomics literature
  - Carefully read RFA repeatedly throughout writing of proposal and read all references and links

• Document all past and current genomics activities
  - Include evaluation results and sustainability efforts!

• Data, data, data!
  - Importance of epidemiology, vital records, cancer registry, state-based surveys, and other data sources
  - Demonstrates need for state and activities
  - Use to identify populations in greatest need
  - Use to create measurable objectives if possible

• Be innovative
• Be logical
  - Consider using core public health functions framework
  - Consider using logic model to demonstrate

• Demonstrate strong partnerships and commitment with multi-level internal and external partners
  - Possibly include figure to show relationships (such as ‘onion’)
  - Make sure letters of support are not using same template or wording

• Use strong writer preferable with success in past CDC proposals and multiple editors
  - Consider having others with a variety of backgrounds in public health read and review before submitting
OPPORTUNITIES EXIST IN MANY PUBLIC HEALTH CHRONIC DISEASE PROGRAMS AND OTHER REALMS: ‘BEGINNER’ READINESS IDEAS

- Identify ‘champion(s)’ within state public health department and/or state external partners (academia, clinical, advocacy, industry & policy)
- Build upon existing internal and external partnerships
- Consider gaging interest through multiple venues, such as:
  - Genomics in-services with discussion
  - Convene internal genomics workgroup
  - Review of state chronic disease plans for genomics
  - Include genomics expertise on new state chronic disease plans and efforts whenever possible
  - 1:1 meetings with relevant program staff and/or external partners
  - Informal networking
  - Create workgroup of public health department to include cancer genetic clinics and/or cardiac genetic clinics, advocacy partners and/or industry
  - Engage health plans in public health genomics efforts (especially Medicaid plans)
- Build upon existing state priorities and integrate into existing programs
  - Difficult to build a stand alone program if no funding, partnerships and/or champion support
PUBLIC HEALTH GENOMICS IMPLEMENTATION TO SAVE LIVES: FROM NATIONAL VISION TO STATE SUCCESS

https://www.youtube.com/watch?v=OfjkY1ILxbE&feature=youtu.be

- 2014 video created by CDC and Genetic Alliance
- Highlights Michigan’s strategy for public health genomics
- Importance of Partnerships!

1. Set Goals by Assessing Data and Available Resources
2. Build Partnerships
3. Conduct Surveillance
4. Provide Info to Policy Makers
5. Make Education Available to the Public
6. Implement Bi-directional Reporting
7. Conduct Surveillance and Assess Results
 Proposed outcomes measures for state public health genomic programs

Debra Lochner Doyle, MS, LCGC, Mindy Clyne, MHS, CGC, Juan L. Rodriguez, MPH, MS, Deborah L. Cragun, PhD, MS, Laura Senier, MPH, PhD, Georgia Hurst, Kee Chan, PhD and David A. Chambers, DPhil

Purpose: To assess the implementation of evidence-based genomic medicine and its population-level impact on health outcomes and to promote public health genetics interventions, in 2015 the Roundtable on Genomics and Precision Health of the National Academies of Sciences, Engineering, and Medicine formed an action collaborative, the Genomics and Public Health Action Collaborative (GPHAC). This group engaged key stakeholders from public/population health agencies, along with experts in the fields of health disparities, health literacy, implementation science, medical genetics, and patient advocacy.

Methods: In this paper, we present the efforts to identify performance objectives and outcome metrics. Specific attention is placed on measures related to hereditary breast ovarian cancer (HBOC) syndrome and Lynch syndrome (LS), two conditions with existing evidence-based genomic applications that can have immediate impact on morbidity and mortality.

Results: Our assessment revealed few existing outcome measures. Therefore, using an implementation research framework, 38 outcome measures were crafted.

Conclusion: Evidence-based public health requires outcome metrics, yet few exist for genomics. Therefore, we have proposed performance objectives that states might use and provided examples of a few state-level activities already under way, which are designed to collect outcome measures for HBOC and LS.

Genet Med advance online publication 4 January 2018

Key Words: hereditary breast and ovarian cancer; implementation science; Lynch syndrome; outcome measures; public health genomics
Genomics in State Cancer Control Plans

Thank you to CDC OPHG for sharing this slide.
EXAMPLES OF MEASURABLE OBJECTIVES & STRATEGIES FROM CANCER PLAN FOR MICHIGAN, 2016-2020

OBJECTIVE 11: Increase the proportion of women with a family history of breast and/or ovarian cancer who receive genetic counseling from 8.8% to 9.7%.11

STRATEGIES:

11.1. Primary care providers should screen women who have family members with breast, ovarian, tubal, or peritoneal cancer with one of several screening tools designed to identify a family history that may be associated with an increased risk for potentially harmful mutations in breast cancer susceptibility genes (BRCA1 or BRCA2). Women with positive screening results should receive genetic counseling and, if indicated after counseling, BRCA testing.

11.2. Promote cascade genetic screening for individuals with a family history of breast and/or ovarian cancer.

11.3. Clinicians should engage in shared, informed decision making with women who are at increased risk for breast cancer about medications to reduce their risk. Clinicians should offer to prescribe approved risk-reducing medications for women who are at low risk for adverse medication effects.

OBJECTIVE 22: Increase the percentage of Michigan residents with a personal history of breast or ovarian cancer that are offered appropriate genetic counseling from 3.6% (ovarian) and 3.3% (breast) to 4.0% and 3.6%.22

STRATEGIES:

22.1. Promote patient education on underlying genetic/heritable causes of common cancers and the importance of genetic counseling and testing when recommended.

22.2. Promote and support the efforts of Michigan providers to meet national standards on genetic counseling and testing as recommended (e.g., NCCN, ACOG).

22.3. Promote provider education on the importance of genetic counseling and testing, understanding of underlying genetic/heritable causes of common cancers, and the importance of genetic counseling and testing when recommended.

22.4. Increase the number of health plans that have cancer genomic best practices for hereditary breast and ovarian cancer and Lynch syndrome as recommended by USPSTF, NCCN, ESAPP, and Michigan Law.

OBJECTIVE 23: Increase the percentage of newly diagnosed colorectal cancer patients who are screened for Lynch Syndrome from 2% to 2.2%.23

STRATEGIES:

23.1. Promote patient education to increase understanding of underlying genetic/heritable causes of common cancers and the importance of genetic counseling and testing when recommended.

23.2. Promote and support the efforts of Michigan providers to meet national standards on genetic counseling and testing as recommended (e.g., NCCN, ACOG).

23.3. Promote provider education to increase compliance with national standards on genetic counseling and testing, understanding of underlying genetic/heritable causes of common cancers, and the importance of genetic counseling and testing when recommended.

23.4. Increase the number of health plans that have cancer genomic best practices for hereditary breast and ovarian cancer and Lynch syndrome as recommended by USPSTF, NCCN, ESAPP, and Michigan Law.

PUBLIC HEALTH GENOMICS OPPORTUNITIES EXIST IN MANY PUBLIC HEALTH PROGRAMS: IDEAS FOR ‘BEGINNER OR MODERATE’ READINESS STATES

- **Family History**
  - Often included as risk factor in chronic disease risk assessment and/or clinical management
    - Create/enhance existing public awareness and provider education materials
    - Create/enhance risk assessment clinical tools
    - Existing family history data if exists; create new and/or improved data collection
    - Prioritize public health interventions for those with significant family history (i.e. breast MRI; Healthy Homes and asthma)
  - Likely included in some Family Planning Clinics for breast health
    - BRSQ Tool!
    - Need for education of providers and clients
    - Consider partnering with BCCCP and/or Family Planning to promote BRCA risk assessment with appropriate referral and follow-up
  - **PRAMS Component D**
    - Additional funding provided for family history of breast and ovarian cancer questions

- **Early Age of Onset**
  - Be thoughtful about what conditions and age cut-offs to use
  - Data available now!
  - Analyze trends over time and by geography
  - Cancer Registry data
  - Hospitalization data
  - Look at trends over time and by geography
  - Mortality data
    - SDY Registry
    - Funding through Child Death Review
    - https://www.sdyregistry.org/

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**Evaluating and improving the implementation of a community-based hereditary cancer screening program**

Authors: Samantha Greenberg, Beverly H. Vash, Mardie Posniman, Deb Duquette, Kari Mallon, Monica Harvin

The Sudden Death in the Young Case Registry: Collaborating to Understand and Reduce Mortality

Consider using precision public health approach to promote national efforts to ‘right population(s)’ with personalized approaches.

Promote HP2020 objectives.

Join existing public health genomics groups (examples below at no cost):
- Federal and non-federal family health history group
- APHA Genomics Forum
- GPHAC
- LSSN
- National DNA Day newsletter
- CDC OPHG Weekly Update

- Happy 20th birthday!
Already several existing resources created by state and/or federal agencies for public and providers for HP2020 BRCA objective

Consider innovative implementation and dissemination approaches

Utilize precision public health framework

https://www.knowbrca.org/
Connect with national and local chapters of relevant advocacy organizations
  - Beginning and all levels of readiness

Promote awareness days through state public health venues
  - Examples include proclamations, press releases, Twitter and Facebook messages
    - Beginning and all levels of readiness

Create new precision public health initiatives and activities
  - Consider partnering on funding opportunities
  - Develop new resources (public awareness campaigns, patient videos, new sources of support, ‘hot topics’)
    - Moderate and advanced levels

IMPORTANCE OF PARTNERING WITH KEY ADVOCACY ORGANIZATIONS

http://www.facingourrisk.org/get-support/PNP/index.php

https://thefhfoundation.org/
### Example of Advocacy Group Metrics Related to Public Health Genomics

**http://50statesofteal.org/**

#### Score: 9/10

New York scored higher than all states and the District of Columbia.

<table>
<thead>
<tr>
<th>New York’s Result</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Insurance Coverage: New York has expanded Medicaid.</td>
<td></td>
</tr>
<tr>
<td>Access to and Use of Well-Woman Services: 18.8% of New York women report having no health care provider (national average = 18%).</td>
<td>✓</td>
</tr>
<tr>
<td>Access to Oral Contraceptives: New York covers family planning services for women up to $223$% of the federal poverty limit.</td>
<td>✓</td>
</tr>
<tr>
<td>Access to Genetic Services: New York Medicaid covers genetic counseling and BRCA testing.</td>
<td>✓</td>
</tr>
<tr>
<td>Access to Gynecologic Oncologists: New York has 0.55 practicing gynecologic oncologists per 100,000 people.</td>
<td>✓</td>
</tr>
<tr>
<td>Access to Affordable Cancer Therapies: New York has a state law requiring oral chemotherapy parity.</td>
<td>✓</td>
</tr>
<tr>
<td>Use of Palliative Care: 75% of hospitals had palliative care programs (national average = 63%).</td>
<td>✓</td>
</tr>
<tr>
<td>Protection from Genetic Discrimination: NY Requires life, disability, and long term care insurers obtain written informed consent before requiring genetic testing of applicants.</td>
<td>✓</td>
</tr>
<tr>
<td>End of Life Care: 47.9% of cancer patients receive hospice services (National Average = 63.4%).</td>
<td>✗</td>
</tr>
<tr>
<td>Outcomes of Ovarian Cancer: NY had a Mortality of Incidence rate of 0.60 (National Average = 0.66).</td>
<td>✓</td>
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</table>
CURRENT FUNDING OPPORTUNITY WITH POTENTIAL FOR PARTNERSHIPS FOR STATE PUBLIC HEALTH GENOMICS

<table>
<thead>
<tr>
<th>Department of Health and Human Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>Part 1. Overview Information</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Participating Organization(s)</th>
<th>National Institutes of Health (NIH)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components of Participating Organizations</td>
<td>National Cancer Institute (NCI)</td>
</tr>
<tr>
<td>Funding Opportunity Title</td>
<td>Traceback Testing: Increasing Identification and Genetic Counseling of Mutation Carriers through Family-based Outreach (U01 Clinical Trial Optional)</td>
</tr>
<tr>
<td>Activity Code</td>
<td>U01 Research Project – Cooperative Agreements</td>
</tr>
<tr>
<td>Announcement Type</td>
<td>Now</td>
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<tr>
<td>Related Notices</td>
<td>None</td>
</tr>
<tr>
<td>Funding Opportunity Announcement (FOA) Number</td>
<td>PAR-18-616</td>
</tr>
<tr>
<td>Companion Funding Opportunity</td>
<td>None</td>
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<tr>
<td>Number of Applications</td>
<td>See Section III. 3. Additional Information on Eligibility.</td>
</tr>
<tr>
<td>Catalog of Federal Domestic Assistance (CFDA) Number(s)</td>
<td>90.393</td>
</tr>
<tr>
<td>Funding Opportunity Purpose</td>
<td>The purpose of the Funding Opportunity Announcement (FOA) is to support pilot research projects using a “Traceback” approach to genetic testing women with a personal or family history of ovarian cancer and reaching out to family members to identify unaffected individuals at increased risk for cancer in different clinical contexts and communities, including racially/ethnically diverse populations.</td>
</tr>
</tbody>
</table>

Key Dates
‘HOT TOPIC’ FOR ALL STATES TO CONSIDER REGARDLESS OF READINESS

https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm599560.htm
THANK YOU!

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