Implementing Public Health Genomics in Your State: Resources from the CDC Office of Public Health Genomics

Muin J. Khoury, Dave Dotson, Ridgely Fisk Green, and Marta Gwinn

Office of Public Health Genomics

Genetic Alliance and APHA Genomics Forum Webinar
November 15, 2016
Organizing Information for Public Health Genomics: “4 Phases of Translation”

T0: Bench

T1: Bedside

T2: Recommendations / Guidelines

T3: Practice / Programs

T4: Outcomes
Organizing Information for Public Health Genomics: “4 Phases of Translation”

- **T0**: Bench
- **T1**: Research and development
  - Drugs
  - Devices (Tests)
- **Bedside**
Organizing Information for Public Health Genomics: “4 Phases of Translation”

- **Bench**: Testing, observation, and evaluation
- **Bedside**: Clinical trials
- **T2**: Epidemiologic studies
- **Recommendations / Guidelines**

_4 Phases of Translation:_

1. Bench
2. Bedside
3. **T2**
4. Recommendations / Guidelines
Organizing Information for Public Health Genomics: “4 Phases of Translation”

T0  T1  T2  T3

Bench  Bedside  Recommendations / Guidelines  Practice / Programs

“Implementation science”

Health services research
Organizing Information for Public Health Genomics: “4 Phases of Translation”
Organizing Information for Public Health Genomics: “4 Phases of Translation”

T2 – T4: <1% of published genomics research
  - Khoury MJ 2007
  - Schully 2012
  - Clyne M 2014
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**Dr Khoury’s Tweets**

[@DrKhouryCDC](https://twitter.com/DrKhouryCDC)

Using pathogen #genomics to track polio. [https://t.co/T15hVqyhQW](https://t.co/T15hVqyhQW) #WorldPolioDay

[https://t.co/C5gRQqdHwH](https://t.co/C5gRQqdHwH)

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[https://t.co/xVSpiBea1s](https://t.co/xVSpiBea1s)

From genetic counseling of individuals to cascade screening in populations: We can do this! [https://t.co/GrEKE9LFO](https://t.co/GrEKE9LFO)
[https://t.co/eU19Fa5ol](https://t.co/eU19Fa5ol)

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[https://t.co/tbKxPvkg3R](https://t.co/tbKxPvkg3R)

Is there a role for genomics in investigating sudden death? Get the latest info. #PHGKB
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[https://t.co/gCGMZ0rv2X](https://t.co/gCGMZ0rv2X)
The CDC Public Health Genomics Knowledge Base is an online, continuously updated, searchable database of published scientific literature, CDC resources, and other materials that address the translation of genomic discoveries into improved health care and disease prevention. The Knowledge Base, cosponsored by the Division of Cancer Control and Population Sciences at the National Cancer Institute, is curated by CDC staff and is regularly updated to reflect ongoing developments in the field. This compendium of databases can be searched for genomics-related information on any specific topic. We will continue to add additional features to the knowledge base and are interested in your feedback via email.

Scientific publications related to PHGKB

Database Content (Last Updated: Nov-10-2016 11AM)

- **CDC Resources**
  - CDC Information (717)
  - CDC-Authored Pub (1471)

- **Selected Insights & Reviews**
  - Human (3530)
  - Pathogen (3021)

- **Epidemiology**
  - Human (122833)
  - Pathogen (604)
Public Health Genomics Knowledge Base

- **What** are the different databases?
- **Why** did we build these databases?
- **Where** do we find content for each database?
- **How** can you use PHGKB?
What are the different databases?

- CDC Information – *web pages*
- CDC-Authorered Genomics Publications – *journal articles*
- Genomics and Health Impact Scan Database
- Guideline Database
- Tier Table
- Implementation Database
- Advanced Molecular Detection Clips
- HuGE Navigator – *genetic association studies (PubMed)*
Familial Hypercholesterolemia: New CDC Blog

This week, we feature a new blog post entitled: "what gets measured gets done: public health progress in familial hypercholesterolemia". For more information on public health implementation tool kit in FH, click here.

For latest information on FH, check our Public Health Genomics Knowledge Base.
Genomics and Health Impact Scan Database

Why did we build it?

- **Challenge:** Keeping up with genomics and family health history developments relevant to public health

- **Opportunity:** Identify the latest publications and other resources on population-based applications of genomic discoveries

- **Challenge:** Addressing misconception that genomics applies only to research or clinical practice

- **Opportunity:** Highlight public health applications of genomics—and the role of public health at the health care interface
Genomics and Health Impact Scan Database

*Where do we find the information?*

Horizon scan

- Monitor Google Alerts, PubMed queries, key websites, and other sources
- Select news stories, blog posts, scientific articles, reports, websites
- Publish online in Weekly Update
- Add to searchable database
Genomics and Health Impact Scan Database

- Indexed by category and “translation phase”

<table>
<thead>
<tr>
<th></th>
<th>T0/T1</th>
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<tbody>
<tr>
<td></td>
<td>Discovery, characterization, and development</td>
<td>Evaluation of tests and interventions</td>
<td>Implementation in practice and programs</td>
</tr>
<tr>
<td>A Original studies</td>
<td>GWAS, biomarkers, and proposed new applications</td>
<td>Clinical trials, clinical cohorts, and new data on analytic or clinical validity</td>
<td>Studies generating new process or outcome data from clinical populations; surveillance</td>
</tr>
<tr>
<td>B Research synthesis/modeling/meta-analysis/systematic reviews/narrative reviews</td>
<td>Meta-analysis and systematic reviews of gene–disease associations</td>
<td>Evidence reports</td>
<td>Cost-effectiveness analyses and national program evaluation</td>
</tr>
<tr>
<td>C Guidelines/policies/recommendations</td>
<td>New nomenclature, data sharing, and publication standards</td>
<td>Clinical practice and professional guidelines</td>
<td>Electronic health standards, reporting requirements, and ethical standards</td>
</tr>
<tr>
<td>D Tools/methods/training/education/decision support</td>
<td>Research road maps, databases, software, and training tools</td>
<td>Modeling methods, databases, and methods for systematic review</td>
<td>Clinical algorithms; provider and patient education materials</td>
</tr>
</tbody>
</table>

About Advanced Molecular Detection Clips

Clips are selected weekly from a variety of sources, including PubMed, journal tables of contents, and online media. Special emphasis is given to the use of next-generation genetic sequencing in infectious disease public health surveillance, investigation, and development of new diagnostics and interventions. The collection is not comprehensive but aims to capture highlights, while surveying a wide range of topics. CDC-authored articles are flagged. Items marked I&E address aspects of implementation or evaluation in clinical or public health practice.
Public Health Genomics Knowledge Base (PHGKB)

Global search of all databases

Search PHGKB:

Hot Topics of the Day

Last Posted: Nov-10-2016 11AM

Gene Therapy

Snapshots of Life: Lighting up the Promise of Retinal Gene Therapy
Francis Collins, NIH Director, November 10, 2016

Gene therapy for blistering skin disease appears to enhance healing in clinical trial
Stanford Medicine, November 1, 2016

Gene therapy shows promise for treating Niemann-Pick disease type C1
NIH, October 26, 2016

More information on this topic

About PHGKB

The CDC Public Health Genomics Knowledge Base is an online, continuously updated, searchable database of published scientific literature, CDC resources, and other materials.
Public Health Genomics Knowledge Base (PHGKB)

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Hot Topics of the Day

Search PHGKB: Breast cancer

Search

Announcement

A paper describing the Public Health Genomics Knowledge Base (PHGKB) is now published in Genetics in Medicine. Check out the publication.

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Search PHGKB: Breast cancer

What’s New

Last Updated: Nov 04, 2016

- Association of Polymorphisms in FCGR2A and FCGR3A With Degree of Trastuzumab Benefit in the Adjuvant Treatment of ERBB2/HER2Positive Breast Cancer
  PG Gavin et al, JAMA Oncology, November 3, 2016

- Predictive Value of FcR Polymorphisms A Further Step on the Long and Winding Road to Application
  RDolcetti, JAMA Oncology, November 3, 2016

- Validation of an Efficient Screening Tool to Identify Low-Income Women at High Risk for Hereditary Breast Cancer.
  Stewart Susan L et al. Public health genomics 2016 Oct

- Evaluation of human epidermal growth factor receptor 2 (HER2) single nucleotide polymorphisms (SNPs) in normal and breast tumor tissues and their link with breast cancer prognostic factors.
  Furrer Daniela, et al. Breast (Edinburgh, Scotland) 2016 10 191-196

- GSTP1, GSTM1, and GSTT1 polymorphisms as predictors of response to chemotherapy in patients with breast cancer: a meta-analysis.
  Kong Xiangzhen, et al. Cancer chemotherapy and pharmacology 2016 10

more
Search result statistics are organized into following six modules below. (See description about each module.)
Click on the numbers to retrieve information records if they are hyperlinked.

**CDC Resources**
- CDC Information (12)
- CDC Authored Pub (13)

**Selected Insights & Reviews**
- Human (164)
- Pathogen (1)

**Epidemiology**
- Human (5393)
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- Guidelines (23)
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Relevant Resources

- All Databases
  - CDC Information Database (666)
  - CDC-Authorized Genomics Publication Database (1348)
  - Genomics & Health Impact Scan Database (6544)
  - Guideline Database (257)
  - Tier Table Database (159)
  - Implementation Database (230)
  - Advanced Molecular Detection Clips Database (4869)

HuGE Navigator
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Guidelines Database

Why did we build it?

- **Challenge:** Finding policies, guidelines, and recommendations that include genomics or family health history

- **Opportunity:** Compile a centralized, searchable, publicly available database for policies, guidelines, and recommendations related to genomics or family health history

- **Challenge:** Relevant policies, guidelines, and recommendations are developed independently by many different groups on different schedules

- **Opportunity:** Keep updated with most recent guidelines, allow for easier cross-referencing
Guidelines Database

Search Guidelines Database: lung cancer

Records 1-8 (of 8 Guidelines) Download

Query Trace: lung cancer [original query]

National Working Group Meeting on ALK diagnostics in lung cancer. Published 2014 (Pfizer-sponsored National Working Group Meeting on ALK Diagnostics in Lung Cancer)

Systemic Therapy for Stage IV Non-Small-Cell Lung Cancer: American Society of Clinical Oncology Clinical Practice Guideline Update. Published 2015 (American Society of Clinical Oncology (ASCO))

Final Recommendation Statement: Lung Cancer: Screening, December 2013 Published 2013 (US Preventive Services Task Force)

EGFR-TK mutation testing in adults with locally advanced or metastatic non-small-cell lung cancer Published 2013 (National Institute for Health and Care Excellence)

Guideline Recommendations for EGFR Mutation Testing in Lung Cancer: Proposal of the Korean Cardiopulmonary Pathology Study Group. Published 2013 (Korean Cardiopulmonary Pathology Study Group)
Tier Table Database

**What it is:**

- Repository of genomic applications classified according to evidence
- Demonstration of a method for organizing horizon scanning results
- Potential aid to informed decision-making
- Scenario-based
- Systematic
- Subjective
- Context-dependent
# How it Works – Tier Level Criteria

## Tier 1:

<table>
<thead>
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<tr>
<td>- FDA label requires use of test to inform choice or dose of a drug</td>
</tr>
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<td>- CMS covers testing</td>
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<tr>
<td>- Clinical practice guideline based on systematic review supports testing</td>
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## Tier 2:

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<tbody>
<tr>
<td>- FDA label mentions biomarker*</td>
</tr>
<tr>
<td>- CMS coverage with evidence development</td>
</tr>
<tr>
<td>- Clinical practice guideline, not based on systematic review, supports use of test</td>
</tr>
<tr>
<td>- Clinical practice guideline finds insufficient evidence but does not discourage use of test</td>
</tr>
<tr>
<td>- Systematic review, without clinical practice guideline, supports use of test</td>
</tr>
<tr>
<td>- Systematic review finds insufficient evidence but does not discourage use of test</td>
</tr>
<tr>
<td>- Clinical practice guideline recommends dosage adjustment, but does not address testing</td>
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</table>

## Tier 3:

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

*Can be reassigned to Green or Red if one or more conditions in these categories apply*
Tier Table Database

What it is **NOT**: 

- A substitute for informed decision-making
- An endorsement or recommendation for or against anything
- A comprehensive or complete assessment of tests or scenarios
- The final word in determining what is ready to implement
Tier Table Database

**Why did we build it?**

- **Challenge:** The public and health care providers are bombarded with information on genomic tests, many with unproven utility
- **Opportunity:** Educate providers and the public about potential benefits and harms of genomic tests and the need for evidence
- **Challenge:** There is no widely agreed upon threshold level of evidence for determining whether genomic tests are ready for use
- **Opportunity:** Develop flexible method(s) for classification of tests by level of evidence to aid in research/evaluation and help define which aspects of evidence should be considered in developing thresholds
Tier Table Database

Last data update: Sep 09, 2016. (Total: 159 Documents)

Enter a search term

Search

Note: Simple Boolean operators are allowed, such as AND or OR

Search Tier Table Database:

159 records

Download

Filtered by:

Tier

Disease

Gene

Basis

Tier

Number of Records

Tier 1

46

Tier 2

105

Tier 3

9

Continue

Clear
### Examples of Tier 1 Genomic Applications

<table>
<thead>
<tr>
<th>Disease/Disorder</th>
<th>Test to be Assessed</th>
<th>Intended Use</th>
<th>Tier Classified</th>
<th>Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>31 core conditions</td>
<td>Newborn screening panel</td>
<td>Screening</td>
<td>Tier 1</td>
<td></td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>Parental history of hip fracture</td>
<td>Estimate fracture risk to inform osteoporosis screening</td>
<td>Tier 1</td>
<td></td>
</tr>
<tr>
<td>Familial hypercholesterolemia (FH)</td>
<td>DNA testing and LDL-C concentration measurement</td>
<td>Cascade testing of relatives of people diagnosed with FH</td>
<td>Tier 1</td>
<td></td>
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<tr>
<td>BRCA-related cancer; hereditary breast and ovarian cancer</td>
<td>Family history</td>
<td>Risk prediction for referral for BRCA genetic counseling</td>
<td>Tier 1</td>
<td></td>
</tr>
<tr>
<td>Lynch syndrome</td>
<td>Various strategies</td>
<td>Screening, cascade testing of relatives</td>
<td>Tier 1</td>
<td></td>
</tr>
</tbody>
</table>
### Tier 1 Recommendation: BRCA Testing

#### Genomic Application General Information

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<tr>
<td>Target Population</td>
<td>Women</td>
</tr>
<tr>
<td>Intended Use</td>
<td>Risk prediction for referral for BRCA genetic counseling</td>
</tr>
<tr>
<td>Application Type</td>
<td>Family history</td>
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<tr>
<td>Basis</td>
<td>Clinical Practice Guideline</td>
</tr>
<tr>
<td>Entered Date</td>
<td>05/08/2015</td>
</tr>
<tr>
<td>Last Updated Date</td>
<td>05/14/2015</td>
</tr>
</tbody>
</table>

#### Relevant evidence and sources

- **Primary Basis for Tier Classification**
  - USPSTF (2013)

- **Additional Synthesized Evidence Sources**
  - USPSTF (2013)
**Tier 1 Recommendation: Lynch Syndrome Testing**

### Genomic Application General Information

<table>
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<td>Target Population:</td>
<td>Patients with newly diagnosed colorectal cancer</td>
</tr>
<tr>
<td>Intended Use:</td>
<td>Screening, cascade testing of relatives</td>
</tr>
<tr>
<td>Application Type</td>
<td>Screening</td>
</tr>
<tr>
<td>Basis:</td>
<td>Clinical Practice Guideline</td>
</tr>
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</tr>
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<td>08/07/2015</td>
</tr>
</tbody>
</table>

### Relevant evidence and sources

- **Primary Basis for Tier Classification**
  - EGAPP (2009)
## Tier 1 Recommendation: Familial Hypercholesterolemia

### Genomic Application General Information

<table>
<thead>
<tr>
<th>Tier Classification:</th>
<th>Tier 1</th>
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<tbody>
<tr>
<td>Disease/Disorder:</td>
<td>Familial hypercholesterolemia (FH)</td>
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<tr>
<td>Test to be assessed:</td>
<td>DNA testing and LDL-C concentration measurement</td>
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<td>Target Population:</td>
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<tr>
<td>Intended Use:</td>
<td>Cascade testing of relatives of people diagnosed with FH</td>
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<tr>
<td>Application Type:</td>
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<td>Basis:</td>
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### Relevant evidence and sources

- **Primary Basis for Tier Classification**
  - NICE guidelines [CG71](2008)
# Example of a Tier 3 Genomic Application

## Genomics Application General Information

<table>
<thead>
<tr>
<th>Parameter</th>
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<tr>
<td>Tier Classification</td>
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<tr>
<td>Disease/Disorder</td>
<td>Hereditary breast/ovarian cancer</td>
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<tr>
<td>Test to be assessed</td>
<td>Routine BRCA genetic counseling, routine BRCA testing</td>
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<td>Target Population</td>
<td>Women whose family health history is not associated with an increased risk of BRCA mutations</td>
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<tr>
<td>Intended Use</td>
<td>Population screening</td>
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<td>Application Type</td>
<td>Screening Family history</td>
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## Relevant evidence and sources

- Primary Basis for Tier Classification
  - USPSTF recommendation statement

## Links to other sources

- Mammary Neoplasms [Disease]
- BRCA1 [Gene]
- BRCA2 [Gene]
Family Health History

Knowing and acting on your family health history is an important way to protect your health. Collect your family health history and share it with your doctor at your next visit.

Your doctor can use it to develop a more complete picture of your health and your risk factors for disease. Together you can work on ways to reduce that risk.

PATHOGEN GENOMICS
New tools are changing the landscape in the fight against infectious diseases

GENOMIC TESTING
Genomic tests are used in many diseases

EPIDEMIOLOGY
Epidemiology is a scientific foundation for public health genomics
<table>
<thead>
<tr>
<th>WHAT'S NEW</th>
<th>PHGKB</th>
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</thead>
<tbody>
<tr>
<td>Weekly summary of genomics and health impact information</td>
<td>Online searchable knowledge base on genomics and health impact information</td>
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<table>
<thead>
<tr>
<th>GENOMICS AND DISEASES</th>
<th>AMD CLIPS</th>
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<tbody>
<tr>
<td>Genomics is important for many diseases of public health significance</td>
<td>Weekly news and publications on pathogen genomics and bioinformatics</td>
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<table>
<thead>
<tr>
<th>FAMILY HEALTH HISTORY</th>
<th>IMPLEMENTATION</th>
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<tbody>
<tr>
<td>Family health history is known to be a risk factor for most diseases</td>
<td>What public health can do now to save lives using genomics</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>PATHOGEN GENOMICS</th>
<th>BLOG</th>
</tr>
</thead>
<tbody>
<tr>
<td>New tools are changing the landscape in the fight against infectious diseases</td>
<td>A blog devoted to genomic issues in research, policy and practice</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>GENOMIC TESTING</th>
<th>REPORTS AND PUBLICATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genomic tests are used in many diseases</td>
<td>CDC reports and publications in genomics</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>EPIDEMIOLOGY</th>
<th>PODCASTS AND VIDEOCASTS</th>
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</thead>
<tbody>
<tr>
<td>Epidemiology is a scientific foundation for public health genomics</td>
<td>Podcasts on genetic testing, diseases, and family health history</td>
</tr>
</tbody>
</table>

**Dr Khoury's Tweets**

- Using pathogen #genomics to track polio. [https://t.co/T15hV9yIhQW #WorldPolioDay](https://t.co/T15hV9yIhQW #WorldPolioDay)
- https://t.co/CSgRQqfHwH

What does polio eradication have to do with genetic diseases? CDC blog post [https://t.co/RXbXfj0I8 #WorldPolioDay](https://t.co/RXbXfj0I8 #WorldPolioDay)
- https://t.co/xVSpIbeaAs

From genetic counseling of individuals to cascade screening in populations: We can do this! [https://t.co/GN4E59FQ](https://t.co/GN4E59FQ) [https://t.co/eUI9HaFS](https://t.co/eUI9HaFS)

What is Hypertrophic Cardiomyopathy & what’s the role of genetics & genetic testing? #PHGKB [https://t.co/4wLq6Z1tSs](https://t.co/4wLq6Z1tSs) [https://t.co/tbKxPvkG3R](https://t.co/tbKxPvkG3R)

Is there a role for genomics in investigating sudden death? Get the latest info. #PHGKB [https://t.co/rd1Wq6UjJ](https://t.co/rd1Wq6UjJ) [https://t.co/cGmZOrv2X](https://t.co/cGmZOrv2X)
What public health can do now in human genomics to save lives and improve health

This page summarizes current information on genomic applications that are ready to be integrated into public health practice to save lives, improve health and quality of life. The focus at this time is on three Tier I applications: Hereditary Breast/Ovarian Cancer Syndrome, Lynch Syndrome and Familial Hypercholesterolemia, but information about other Tier I applications will be added in the near future. The page includes information about completed and ongoing projects spearheaded by state health departments and their partners, and recommendations from evidence based groups which can be applied at the state or local level. Please contact us at genetics@cdc.gov if you are aware of a statewide or other project not currently included which should be highlighted on this page.

Resources
- Classification of Genomic Applications by Levels of Evidence
- State Implementation Activities Clickable Map
- Public Health Genomic Tier 1 Tool Kit
- Healthy People 2020 Genomics Objectives
- Search the Public Health Genomics Knowledge Base for Implementation Resources and Information
Genomics Implementation

Tier 1 Genomic Applications Toolkit for Public Health Departments

- Tier 1 Genomic Applications and their Importance to Public Health
CDC’s Tier 1 Genomic Applications Toolkit for Public Health Departments

- Goal: Assist state and local public health departments in implementing Tier 1 recommendations using strategies from model state programs
- Hereditary Breast and Ovarian Cancer
- Lynch Syndrome/HNPCC
- Familial Hypercholesterolema
CDC’s Tier 1 Genomic Applications Toolkit for Public Health Departments

- Approaches
  - Implement bidirectional cancer registry reporting
  - Inform policy making
  - Develop surveillance indicators
  - Track Healthy People 2020 genomics objective
  - Provide education and outreach
  - Promote cascade screening
Bidirectional Cancer Registry Reporting Tools

- Customizable written materials
- Information for providers
- Information for patients and families
- Reporting tools
- Useful for cascade screening and other applications
Lynch Syndrome tools

Tools for Bidirectional Cancer Registry Reporting to Identify Individuals at Risk for Lynch Syndrome

The following materials were developed to support state programs using bidirectional cancer registry reporting to identify individuals at risk for Lynch syndrome. State health departments are encouraged to customize the materials to meet their needs. Materials are categorized by those intended for patients and for healthcare providers, but materials may be suitable for multiple audiences. Please note that some materials will need to be filled out with state-specific information, as noted below.

**Information for Patients**
- Lynch Syndrome: A Guide for Patients and Their Families
- Brochure on Talking to Your Family About Your Diagnosis of Lynch Syndrome
- Sample Letter for Informing Your Family Members about Your Lynch Syndrome Mutation
- List of Cancer Genetic Specialists for Your State or Region (Please note that state programs will need to complete this form.)
- What You Need to Know About Cancer Registries: Frequently Asked Questions for Patients and Their Families

**Information for Providers**
- Lynch Syndrome: Fact Sheet for Healthcare Professionals
- Evidence-based Practice Guidelines Supporting Genetic Susceptibility Testing for Lynch Syndrome
- Bidirectional cancer registry reporting to identify patients at high risk for hereditary cancer syndromes: what providers and institutions need to know. Video for educational outreach to providers and institutions in states that have bidirectional cancer registry reporting programs in place.

**Reporting Tools**
- Sample Hospital and Medical Center Cancer Genetics Data Report on Potential Lynch Syndrome-Related Cancers (Please note that state programs will need to complete this form.)
Dear [x],

I am writing to let you know that I have been diagnosed with an inherited condition called Lynch syndrome, or Hereditary Non-Polyposis Colorectal Cancer (HNPPC). People with Lynch syndrome are much more likely to get colorectal cancer and other types of cancer. Lynch syndrome runs in families and is due to errors in certain genes (known as mutations).

Because you are my blood relative, you are more likely to have Lynch syndrome and could benefit from genetic counseling and possibly genetic testing for Lynch syndrome.

If you find out that you have Lynch syndrome, you can take steps to lower your chances of getting cancer and to find cancer earlier if you do get it. These steps include preventive surgery and earlier, more frequent, and additional cancer screening. It is important to note if you have Lynch syndrome, it does not mean that you will definitely get cancer.

People with Lynch syndrome are more likely to get certain types of cancers, including colorectal cancer, endometrial (uterine) cancer, ovarian cancer, biliary tract cancer, sebaceous skin tumors, and urinary tract cancer. The attached document shows the specific mutations I have, and this mutation is one for which my family members should be tested. My parents, brothers/sisters/children (including any of these that you have), [insert any other relatives here], and [insert other relatives here] have a 50% (1 in 2) chance of having Lynch Syndrome. My other blood relatives (aunts, uncles, nieces, nephews, and cousins) might also have Lynch Syndrome. Please note that genetic testing for Lynch syndrome is not recommended for children under 18 years old, but can be considered when they reach adulthood.

The first step is to discuss this with your doctor who can provide you with more information about genetic testing for Lynch syndrome. Your doctor may refer you to a genetic counselor.

You can find the genetic counselor closest to you at www.nscrg.org.

For more information about Lynch syndrome, here are some helpful resources:
- www.cancer.net/cancer-types/lynch-syndrome
- www.cdc.gov/Features/LynchSyndrome/
- www.nshsibs.org/condition/lynch-syndrome

If you have any questions about this, please don’t hesitate to call me.

Sincerely,

[Your name]

---

Dear [xx],

I recently had genetic testing for inherited mutations (changes) in the breast cancer 1 (BRCA1) and breast cancer 2 (BRCA2) genes. These are the genes most commonly affected in breast and ovarian cancer. My test found [insert specific mutation here] mutation that causes an increased risk for breast, ovarian, and other cancers.

As one of my blood relatives, you could have the same BRCA1 or BRCA2 mutation and could benefit from genetic counseling and possibly genetic testing for this mutation. If you find out that you have the mutation, you can take steps to reduce your risk of cancer and to find cancer earlier if you do get it. These steps include preventive surgery, medications, and earlier, more frequent, and additional cancer screening. It is important to note that if you have a BRCA1 or BRCA2 mutation, it does not mean that you will definitely get breast or ovarian cancer.

People who inherit a mutation in the BRCA1 or BRCA2 gene are more likely to get breast, ovarian, tubal, peritoneal, prostate, and pancreatic cancer. In general, women with a BRCA4 mutation are more likely to get breast or ovarian cancer before age 50 than women without a BRCA4 mutation. Men with BRCA1 or BRCA2 mutations also have a higher chance of getting breast cancer.

The attached document shows the specific mutation that I have. This mutation is one for which my family members should be tested. People can inherit BRCA1 or BRCA2 mutations from their mother or father. Since I have the mutation, my parents, brothers/sisters/children (including any of these that you have), [insert all other affected relatives] have a 50% (1 in 2) chance of having it. My other blood relatives (aunts, uncles, nieces, nephews, and cousins) also have an increased chance of having the mutation. Please note that genetic testing for BRCA1 or BRCA2 mutations is not recommended for children under 18 years old, but can be offered to older children and adolescents with a strong family history.

If you have any questions about this, please don’t hesitate to call me.

Sincerely,

[Your name]
Why Talk to My Family?

Your family members can benefit from knowing about your diagnosis of Lynch syndrome. Talk to your family members about Lynch syndrome, so that they will know that:

- Lynch syndrome is passed through families.
- A person with Lynch syndrome is more likely to get colorectal, endometrial (uterine), ovarian, and other cancers.
- Genetic counseling and testing for Lynch syndrome can provide information about their risk.
- If they choose to be tested, they should be tested for the same mutation that you have.
- Steps can be taken to prevent colorectal and other cancers or find them earlier.

IT’S NOT EASY...

...but talking about Lynch syndrome is one of the most important things you can do to protect your family.
How Do I Talk to My Family About My Lynch Syndrome Diagnosis?

WHO: Your parents, siblings, and children are the family members who are most likely to have Lynch syndrome. Other blood relatives, such as aunts, uncles, nieces, nephews and cousins, are also more likely to have Lynch syndrome. Your healthcare provider or genetic counselor can help you figure out who in your family might have Lynch syndrome and thus would benefit from knowing about your diagnosis.

WHAT: You can share test results, letters from your doctor or genetic counselor, or other information you received about your diagnosis with your family. Giving family members information about your specific genetic mutation helps their healthcare providers know exactly which test to use and might possibly save your family money.

HOW: If you need extra support talking to your family, bring a friend. You can also ask a family member to attend your next medical appointment with you. The website http://kintalk.org can help you let your relatives know about your diagnosis and provides resources to help them learn more about Lynch syndrome. A sample letter that you can fill out and send to your family is available at www.cdc.gov/genomics/restoflink

How Do I Talk to My Children?

If you have Lynch syndrome, each of your children has a 50% (1 in 2) chance of having Lynch syndrome. Genetic testing for Lynch syndrome is typically not recommended for children younger than 18, but can be considered when your children reach adulthood.

Younger children might not be able to understand what your diagnosis means for you or for them. Children differ in the age at which they are ready to learn about this information. Answer the questions they ask. They will ask more complex questions as they grow and are ready to learn more.

Know that your children may have fears about the risk both to themselves and to you. Just as you need time and support to cope with the information and accept it, so will your children.

What if My Family Does Not Want to Talk?

Talking to some family members about Lynch syndrome might not be easy. Some might not understand why they need to know this information. Others might be nervous about receiving a diagnosis of Lynch syndrome. Remember that family members need to make their own choices about getting tested, whether or not you agree with their decisions. If family members don’t want to talk about Lynch syndrome, respect their wishes. Let them know you are available to talk if they have questions, and give them places to find information.

When family members do not want to talk about Lynch syndrome, you might feel upset or alone. Seek support from friends, healthcare providers, other family members, or people you know with Lynch syndrome.

Where Can I Find More Information?

You can find more information on Lynch syndrome at: www.ghr.nlm.nih.gov/condition/lynch-syndrome

You can find information on support groups for Lynch syndrome at: http://www.diseaseinfosearch.org/Lynch-syndrome/3371
Information for providers

Bi-directional Cancer Registry Reporting

Gregory Feero, MD, PhD
Research Director, Maine Dartmouth Family Medicine Residency

BRCAP gene-associated mutations can undergo
Reporting Tools

This report prepared by [...] provides information on the number of patients at your facility who may be at risk for Lynch syndrome (LS), also called Hereditary Non-Polyposis Colorectal Cancer (HNPCC), based on data that were reported to the central cancer registry from your institution during the time period mm/yyyy to mm/yyyy. All patients with colorectal cancer should be considered for tumor screening for Lynch syndrome. Some institutions test newly diagnosed endometrial cancers, especially those in women younger than 50.

How many patients were identified at [reporting institution] and statewide?

<table>
<thead>
<tr>
<th>Cancer Site</th>
<th>Your institution</th>
<th>Entire State</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colon or Rectum (All Ages)</td>
<td># of cases</td>
<td># of cases</td>
</tr>
<tr>
<td>Endometrium (&lt; Age 50)</td>
<td># of cases</td>
<td># of cases</td>
</tr>
</tbody>
</table>

Patient names associated with the reported diagnoses can be sent to a designated person in your facility upon request. If requested, the names will be disclosed to your facility using current confidentiality rules.

What is Lynch syndrome? Lynch syndrome is a genetic condition that significantly increases an individual’s risk for colorectal, endometrial, and other cancers.

What are the benefits of identifying individuals with Lynch syndrome? Identifying patients with Lynch syndrome is important because steps can be taken to detect cancer earlier if it develops and reduce cancer risks in the future for patients and their relatives. Patients with Lynch syndrome have a higher risk for developing future cancers and can benefit from closer monitoring or special medical management. Family members of these patients might have Lynch syndrome and should consider genetic counseling and testing for the same mutation identified in the patient.

How can cancer registry data help identify individuals with Lynch syndrome? Patients with colorectal cancer at any age or with endometrial cancer (especially before age 50) are more likely to have Lynch syndrome and can be readily identified from cancer registry data.

In some states, genetic counselors have presented at Grand Rounds to educate providers about hereditary cancers.
Informing evidence-based policy making: approaches

- Educate payers about USPSTF, NCCN, and EGAPP recommendations
- Assess which health plans have policies consistent with recommendations
- Acknowledge health plans with policies that are consistent with current recommendations
Informing evidence-based policy making: approaches

- Meet with health insurance plan medical directors
- Conduct key informant interviews with health plan administrators to address barriers and facilitators to having evidence-based coverage policies
- Developing and disseminating policy guidance documents for insurers
Informing evidence-based policy making: approaches

- Incorporate genomics activities into the state cancer control plan, state cardiovascular disease prevention plan, and stroke prevention plan
- Create a list of alternative payment modalities for un/underinsured women
- Participate in Lynch syndrome screening network (LSSN)
Surveillance indicators and Healthy People 2020 objective tracking

- Behavioral Risk Factor Surveillance System (BRFSS)
- Claims data
- Cancer registry data
- Genetics services data
- Surveys of healthcare providers
- State specific data systems
Education and outreach
Examples from states

- Board-certified genetic counselors provided in-service trainings to providers
- Clinical decision support tool containing referral criteria for HBOC
- CME materials
- Partnerships between states to create and disseminate materials
Education and outreach
Examples from states

- Survey providers to identify knowledge gaps
- Develop community-specific outreach to target at-risk populations
- Awareness Days
- Communicate via in-person conferences, displays at health fairs, online modules and webinars, provider newsletters, and information at clinician’s offices
Cascade screening

- Active process to find relatives of index patient at a pre-symptomatic stage
- Inform relatives about available testing and interventions
Implementation Database

Why did we build it?

- **Challenge:** State, local, and territorial health departments need practical information that they can use to integrate genomics and family health history into their activities

- **Opportunity:** Provide a searchable database of available resources categorized by resource type, disease, and state so that health departments can find new resources and learn from other states

- **Challenge:** State, local, and territorial public health departments and policymakers want to know about genomic and family health history activities in their state and communities

- **Opportunity:** Activities can be searched by state and can also be identified through the clickable map
Implementation Database

Filtered by Location, Resource Type, or Disease

<table>
<thead>
<tr>
<th>State</th>
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<tbody>
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<td>Alabama</td>
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<td>Delaware</td>
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<td>District of Columbia</td>
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<table>
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<td>Familial Hypercholesterolemia</td>
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<td>Genetic Counseling</td>
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<td>Heart Disease</td>
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<tr>
<td>Lynch syndrome</td>
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</table>
Implementation Database

Public Health Genomics Knowledge Base (v1.0)

State Genomics Implementation Map

Click on a state to find information on public health genomics activities in that state. States have implemented genomics applications for Hereditary Breast and Ovarian Cancer syndromes, Lynch Syndrome, Familial Hypercholesterolemia, newborn screening, and more. Find relevant information from your own state or learn about what's been accomplished in other states. You can filter results by condition and resource type (data, programs, education, policy, tools, and general information). Please let us know about new efforts so that we can keep the information current.
https://phgkb.cdc.gov

genetics@cdc.gov

For more information, contact CDC
1-800-CDC-INFO (232-4636)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.