Northwestern Medicine
Feinberg School of Medicine

Policy Implementation

Emergent Topics in Implementation Science and GPPH

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Centers for Disease Control & Prevention (CDC): Policy Implementation

- ‘Policy’ defined as **law**, **regulation**, **procedure**, **administrative action**, **incentive**, or **voluntary practice** of governments and other institutions
  - Influence systems development, organizational change & individual behavior to promote health improvements
  - Consider policies in **different sectors and multiple levels**
  - Federal law prohibits lobbying by CDC

- CDC Policy Process
  - **Policy Implementation:** translate the enacted policy into action, monitor update, and ensure full implementation
  - Example: build capacity of states, tribes and communities to implement policy

Figure 1 Policy Process

https://www.cdc.gov/policy/paeo/process/index.html

Example of R21 Funded Grant in Policy Implementation for Young Cancer Survivors

R21: Policy Implementation Research on Health Benefit Mandates for Fertility Preservation Services to Improve Access to Care in Young Cancer Survivors

Principal Investigator

Hui-Chun Irene Su, MD, MSCE
UNIVERSITY OF CALIFORNIA SAN DIEGO HEALTH*

NOFO**

PAR-19-275

Award Number

R21#CA271184-01A1

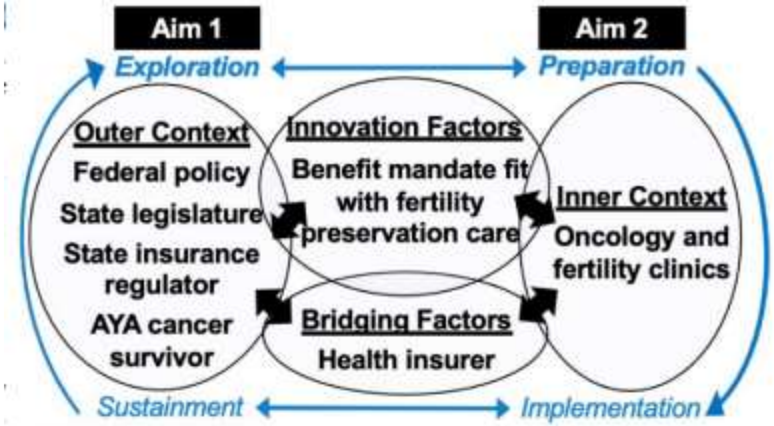
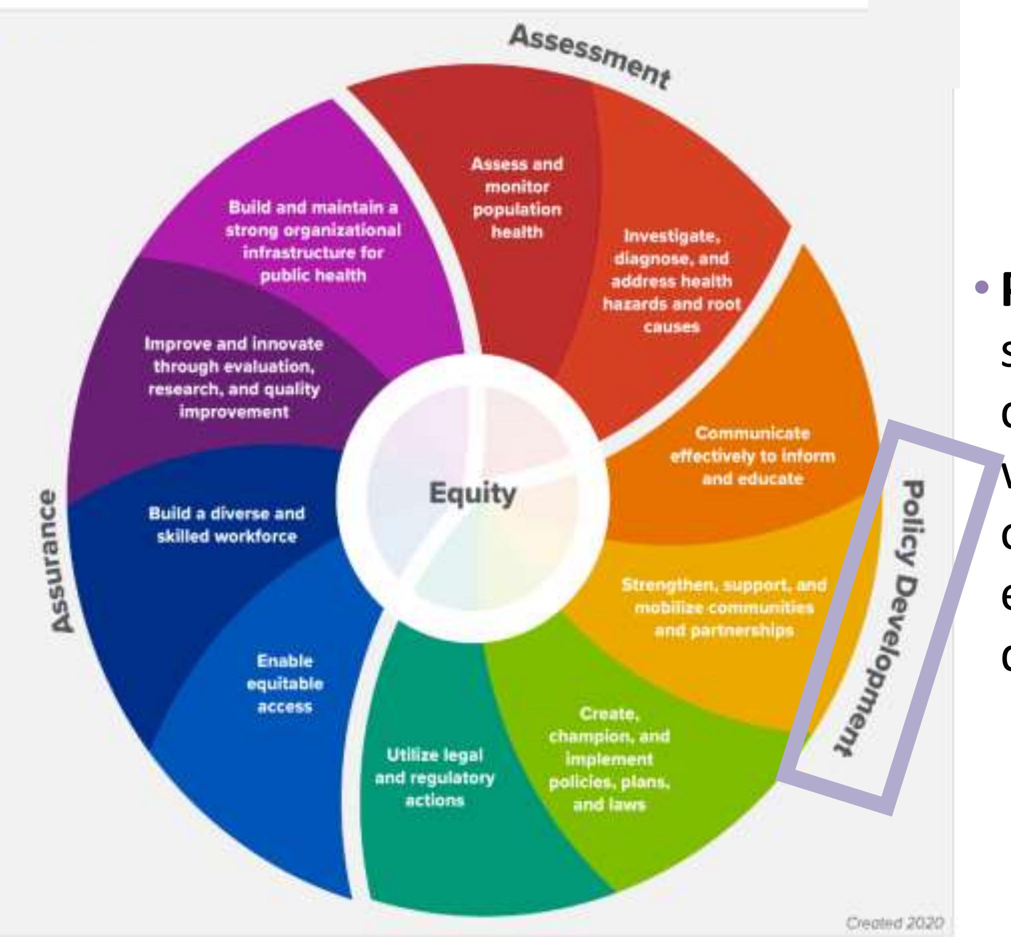


Figure: Multi-level contextual assessment (Aim 1) and preparation (Aim 2) for implementation of health insurance benefit mandate to facilitate fertility preservation in cancer survivors

- Investigating how **state laws** require **health insurance plans** to include fertility preservation benefits
- Mixed methods study of implementation of **multiple levels** including insurance regulators, insurers and clinics
  - Guided by EPIS
  - Develop implementation strategies to influence how policies facilitate uptake of fertility preservation care

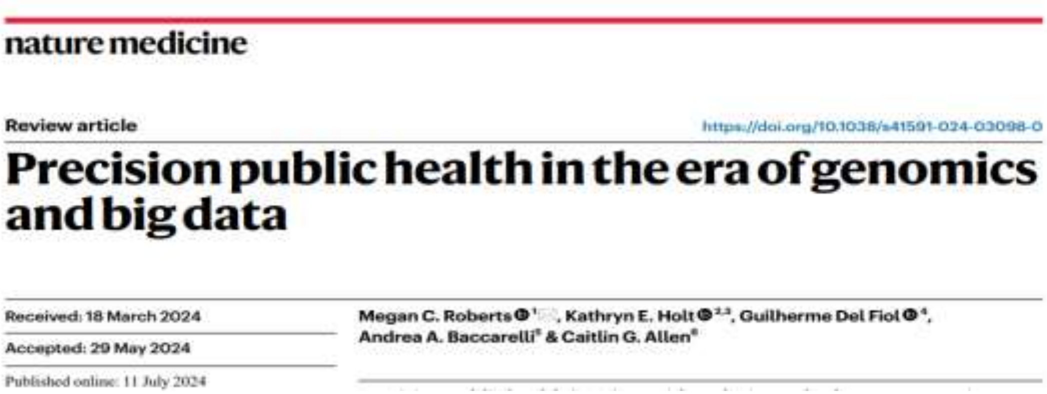
https://cancercontrol.cancer.gov/is/funding/sample-grant-applications

Precision Public Health & Policy Development: Core Public Health Function and Essential Services



- **Policy Development**: Formulation of standards and guidelines, in collaboration with stakeholders, which promote the appropriate use of genomic information and the effectiveness, accessibility, and quality of genetic tests and services

https://phgw.org/
https://www.cdc.gov/publichealthgateway/



nature medicine

Review article

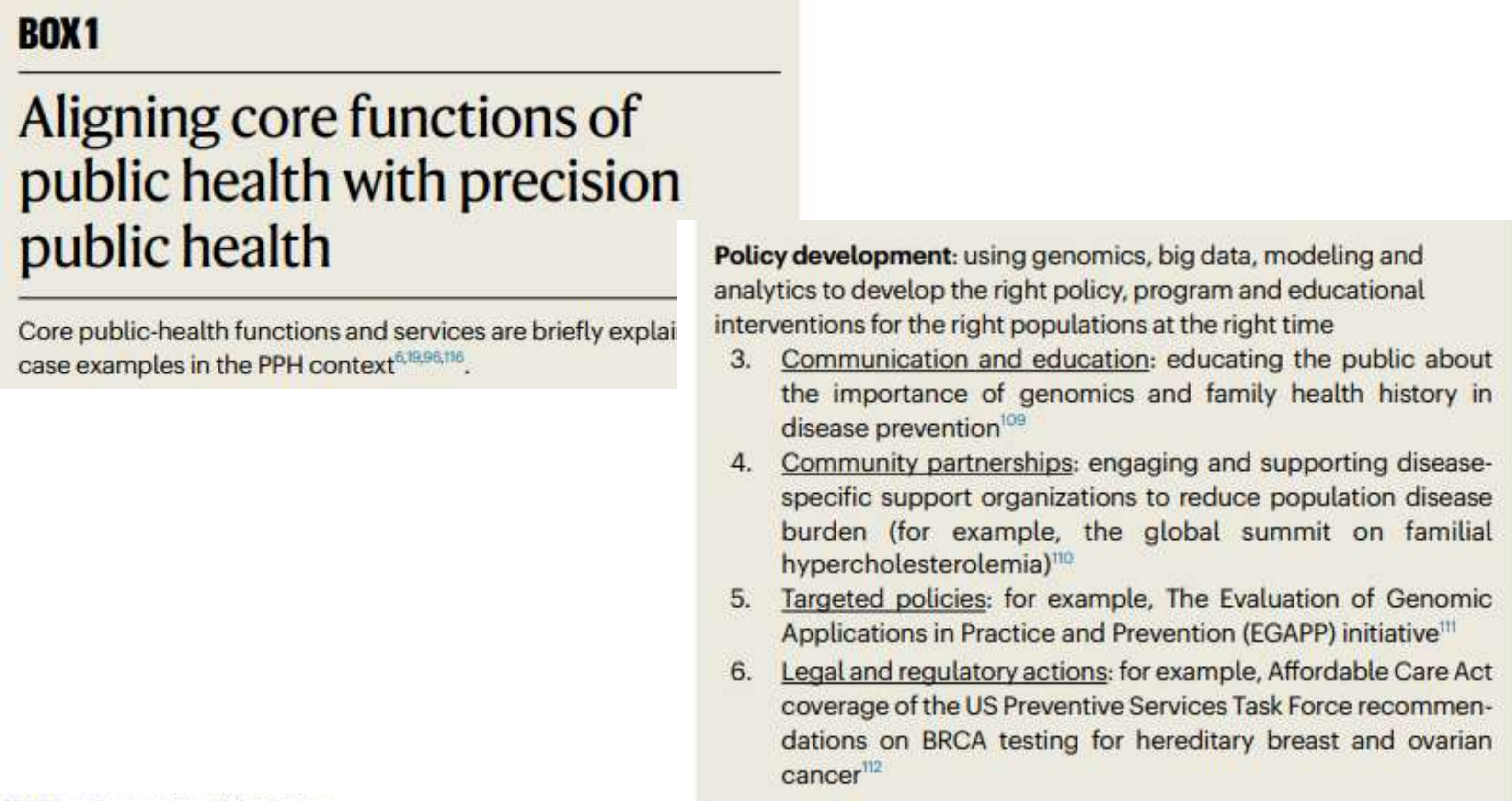
https://doi.org/10.1038/s41591-024-03098-0

Precision public health in the era of genomics and big data

Received: 18 March 2024

Accepted: 29 May 2024

Megan C. Roberts [1], Kathryn E. Holt [2,3], Guilherme Del Fiol [4], Andrea A. Baccarelli [5] & Caitlin G. Allen [6]



BOX 1

Aligning core functions of public health with precision public health

Core public-health functions and services are briefly explai case examples in the PPH context[6,19,96,116].

Policy development: using genomics, big data, modeling and analytics to develop the right policy, program and educational interventions for the right populations at the right time

3. Communication and education: educating the public about the importance of genomics and family health history in disease prevention[109]
4. Community partnerships: engaging and supporting disease-specific support organizations to reduce population disease burden (for example, the global summit on familial hypercholesterolemia)[110]
5. Targeted policies: for example, The Evaluation of Genomic Applications in Practice and Prevention (EGAPP) initiative[111]
6. Legal and regulatory actions: for example, Affordable Care Act coverage of the US Preventive Services Task Force recommendations on BRCA testing for hereditary breast and ovarian cancer[112]

Proposed Outcomes
for State Public Health Cancer Genomics Programs

ORIGINAL RESEARCH ARTICLE | Genetics inMedicine

Proposed outcomes measures for state public health genomic programs

Debra Lochner Doyle, MS, LCGC[1], Mindy Clyne, MHS, CGC[2], Juan L. Rodriguez, MPH, MS[3], Deborah L. Cragun, PhD, MS[4], Laura Senier, MPH, PhD[5], Georgia Hurst[6], Kee Chan, PhD[7] and David A. Chambers, DPhil[2]

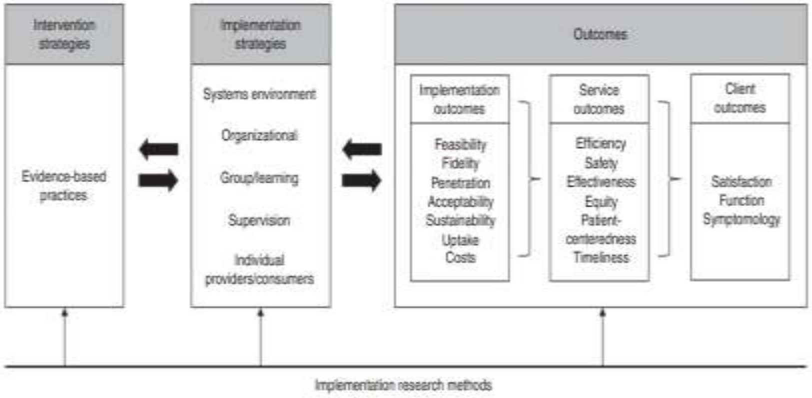


Figure 1 The implementation framework developed by Proctor et al.[2]

- Utilized modified implementation framework from Proctor et al & Silvey et al
  - Access to services (implementation outcomes)
  - Health care performance (service outcomes)
  - Public health infrastructure (client outcomes)
- Developed 38 proposed outcome measures for evidence-based approaches to delivery of genetic/genomics screening population level
  - Lynch syndrome screening for all colorectal cancers
  - HBOC family history screening
- 3 top priority outcomes for all states

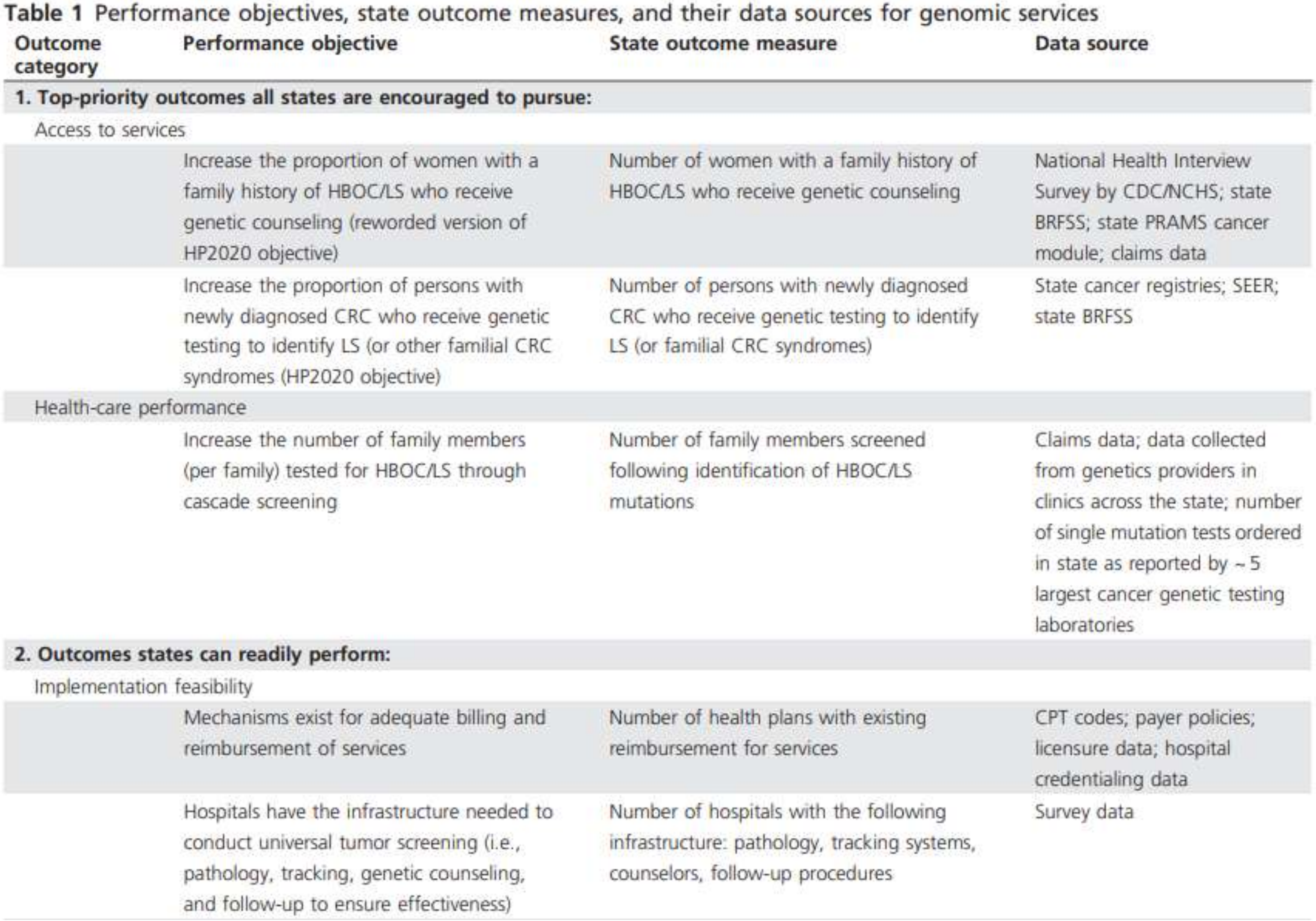


Table 1 Performance objectives, state outcome measures, and their data sources for genomic services

Outcome category	Performance objective	State outcome measure	Data source
1. Top-priority outcomes all states are encouraged to pursue:			
Access to services			
	Increase the proportion of women with a family history of HBOC/LS who receive genetic counseling (reworded version of HP2020 objective)	Number of women with a family history of HBOC/LS who receive genetic counseling	National Health Interview Survey by CDC/NCHS; state BRFSS; state PRAMS cancer module; claims data
	Increase the proportion of persons with newly diagnosed CRC who receive genetic testing to identify LS (or other familial CRC syndromes (HP2020 objective)	Number of persons with newly diagnosed CRC who receive genetic testing to identify LS (or familial CRC syndromes)	State cancer registries; SEER; state BRFSS
Health-care performance			
	Increase the number of family members (per family) tested for HBOC/LS through cascade screening	Number of family members screened following identification of HBOC/LS mutations	Claims data; data collected from genetics providers in clinics across the state; number of single mutation tests ordered in state as reported by ~5 largest cancer genetic testing laboratories
2. Outcomes states can readily perform:			
Implementation feasibility			
	Mechanisms exist for adequate billing and reimbursement of services	Number of health plans with existing reimbursement for services	CPT codes; payer policies; licensure data; hospital credentialing data
	Hospitals have the infrastructure needed to conduct universal tumor screening (i.e., pathology, tracking, genetic counseling, and follow-up to ensure effectiveness)	Number of hospitals with the following infrastructure: pathology, tracking systems, counselors, follow-up procedures	Survey data

- *Additional resource: Implementing Cancer Geonomics in State Health Agencies: Mapping Activities to an Implementation Science Framework, Green et al, Public Health Genomics, 2020*

Helpful Resource: Genetic Policy Hub (GPH)

- Developed by National Coordinating Center for Regional Genetic Networks
  - Supported by HRSA funding
- Includes **policy statements** from national organizations
- Includes **legislation and regulation** at state and federal level
- Includes **Medicaid coverage** policy information for each state

GPH
Genetics Policy Hub

Our Resources

25+	100+	54
Policy Topics	Proposed Legislation/Regulation	Medicaid Programs

Genetics Policy Areas

Interested in exploring how policy affects genetics patients and providers? In the Policy Area of our website, we provide a brief overview of why a specific topic (ex. newborn screening) is important to the delivery of genetics care, how policy affects the topic area, and share position statements from national organizations on the policy area.

Proposed Legislation/Regulation

Did you know that almost daily there is a piece of legislation or regulation introduced in the United States related to genetics? Policies range from coverage of specific genetic tests or services to supporting educational programs about genetic conditions. Explore what your state is currently considering by visiting our interactive map.

Medicaid Coverage of Genetic Services

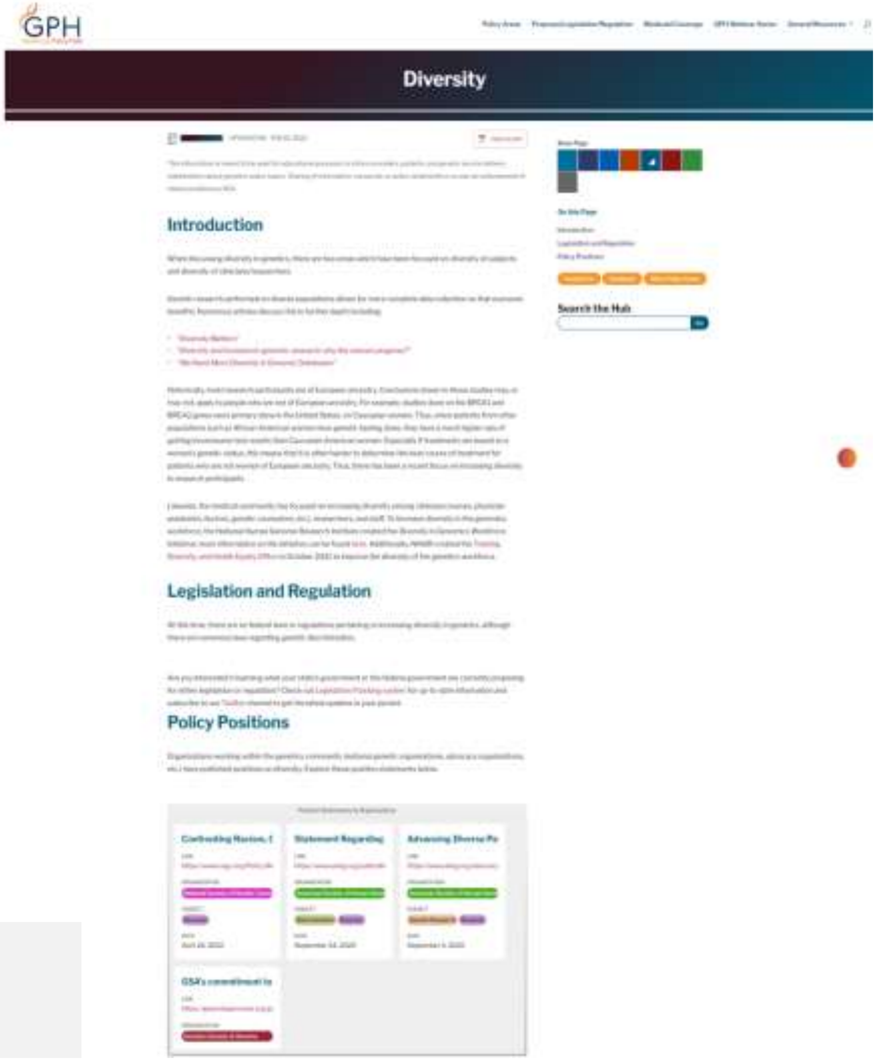
Do you want to know what your state's Medicaid program covers related to genetic services? Updated yearly, our Medicaid database includes general coverage criteria, coverage of specific genetic tests, and coverage of specific services, such as medical foods. The database collects publicly available information from each state Medicaid program.

https://geneticspolicy.nccrcg.org/

Genetics Policy Hub (continued): Policy Positions

- Over 25 genetic policy areas
  - Includes short briefs on each topic
  - Links to relevant articles & resources
  - Links to policy positions
  - Summary of specific laws and regulations
- Policy positions from national professional organizations and advocacy organizations
  - Such as ACMG, NSGC, ISONG, ASHG, etc

https://geneticspolicy.nccrcg.org/policy-area/diversity/



GPH

Diversity

Introduction

Legislation and Regulation

Policy Positions

Search the Hub

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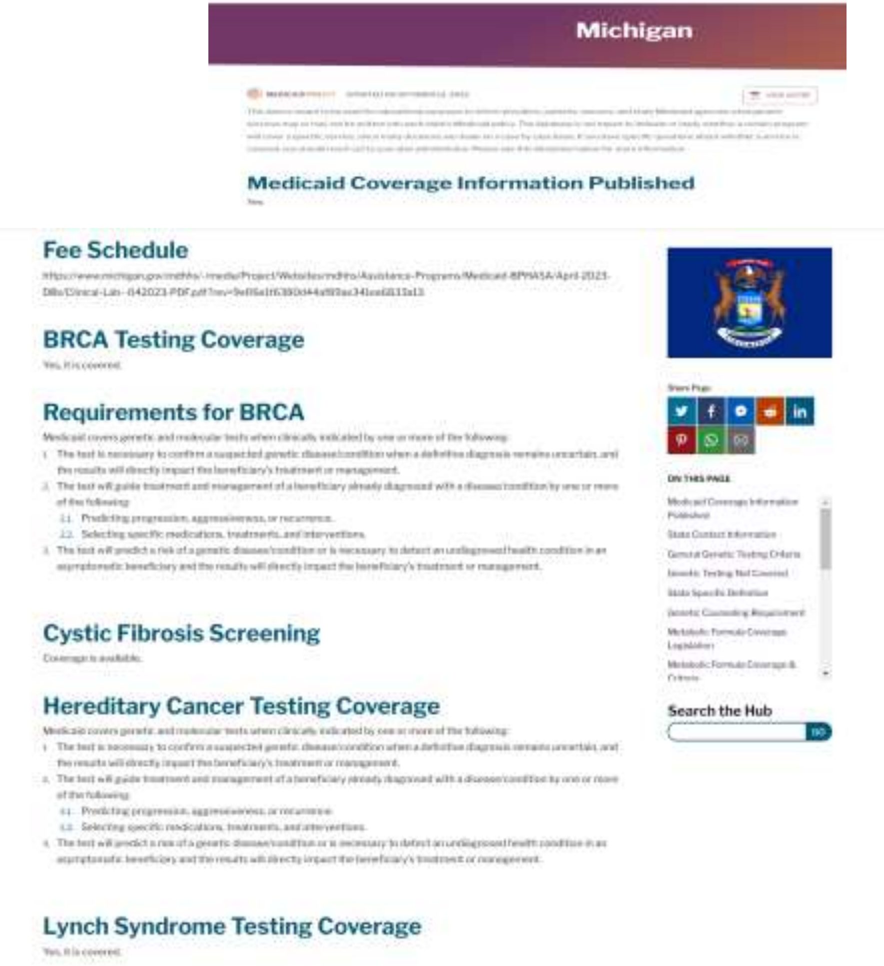
Genomics Policy Hub (continued):
State Genetic/Genomics Medicaid Policies & Legislation

https://geneticspolicy.nccrcg.org/medicaid-policy/michigan/

https://geneticspolicy.nccrcg.org/legislative-policies/



Michigan

Medicaid Coverage Information Published

Yes.

Fee Schedule

BRCA Testing Coverage

Yes, it is covered.

Requirements for BRCA

Medicaid covers genetic and molecular tests when clinically indicated by one or more of the following:

1. The test is necessary to confirm a suspected genetic disease/condition when a definitive diagnosis remains uncertain, and the results will directly impact the beneficiary's treatment or management.
2. The test will guide treatment and management of a beneficiary already diagnosed with a disease/condition by one or more of the following:
   - 2.1. Predicting progression, aggressiveness, or recurrence.
   - 2.2. Selecting specific medications, treatments, and interventions.
3. The test will predict a risk of a genetic disease/condition or is necessary to detect an undiagnosed health condition in an asymptomatic beneficiary and the results will directly impact the beneficiary's treatment or management.

Cystic Fibrosis Screening

Coverage is available.

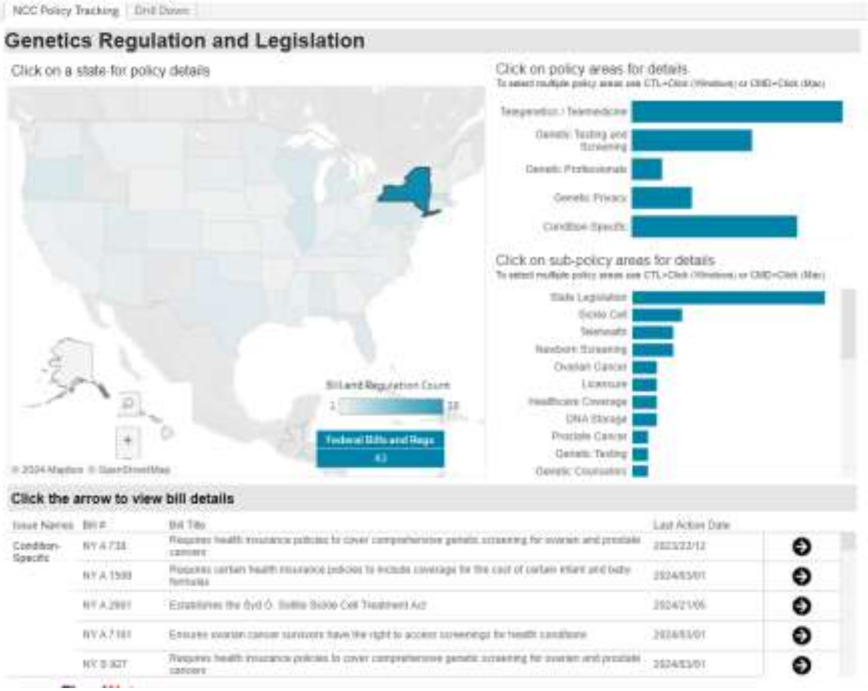
Hereditary Cancer Testing Coverage

Medicaid covers genetic and molecular tests when clinically indicated by one or more of the following:

1. The test is necessary to confirm a suspected genetic disease/condition when a definitive diagnosis remains uncertain, and the results will directly impact the beneficiary's treatment or management.
2. The test will guide treatment and management of a beneficiary already diagnosed with a disease/condition by one or more of the following:
   - 2.1. Predicting progression, aggressiveness, or recurrence.
   - 2.2. Selecting specific medications, treatments, and interventions.
3. The test will predict a risk of a genetic disease/condition or is necessary to detect an undiagnosed health condition in an asymptomatic beneficiary and the results will directly impact the beneficiary's treatment or management.

Lynch Syndrome Testing Coverage

Yes, it is covered.



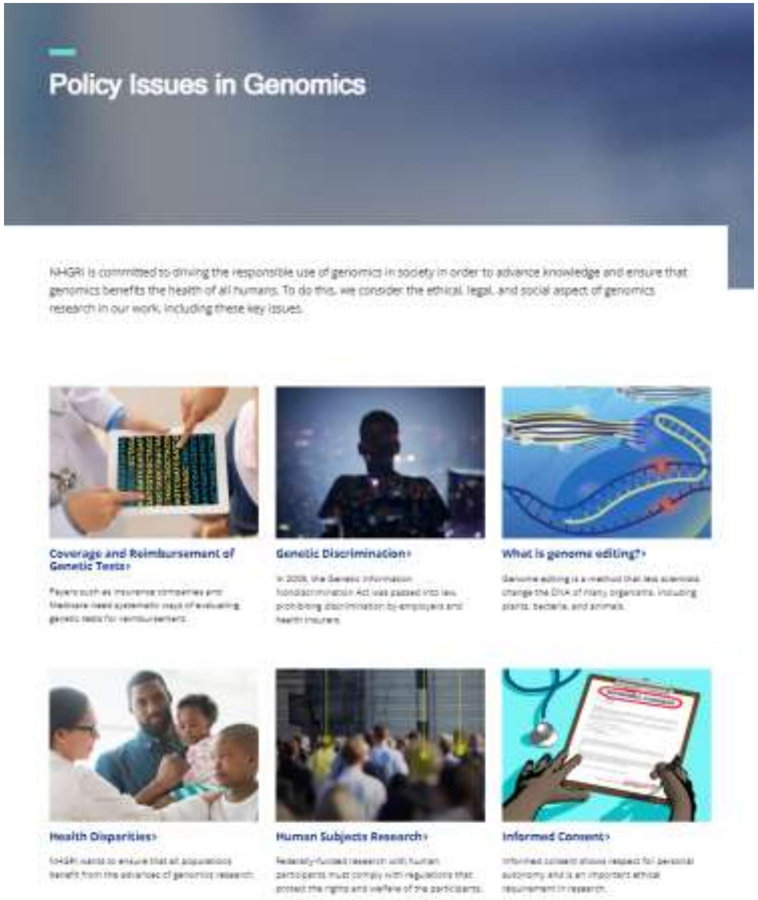
Genetics Regulation and Legislation

Click the arrow to view bill details

Issue Names	Bill #	Bill Title	Last Action Date	
Condition-Specific	NY A 738	Requires health insurance policies to cover comprehensive genetic screening for ovarian and prostate cancers	2023/22/12	➔
	NY A 1599	Requires certain health insurance policies to include coverage for the cost of certain infant and baby formulas	2024/03/01	➔
	NY A 2881	Establishes the Syd O. Sickle Cell Treatment Act	2024/21/06	➔
	NY A 7181	Ensures ovarian cancer survivors have the right to access screenings for health conditions	2024/03/01	➔
	NY S 327	Requires health insurance policies to cover comprehensive genetic screening for ovarian and prostate cancers	2024/03/01	➔

Policy Issues in Genomics: National Human Genome Research Institute (NHGRI) Resource

- Multiple up-to-date resources on policy issues related to ethical, legal and social (ELSI) aspect of genomics research
  - **Coverage & reimbursement of genetic tests**
  - **Genetic discrimination**
  - Genome editing
  - Health disparities
  - Informed Consent
  - Intellectual property in genomics
  - Investigative genomics
  - Population descriptors in genomics
  - Privacy in genomics
  - Regulation of genetic tests
  - Synthetic biology



Policy Issues in Genomics

NHGRI is committed to driving the responsible use of genomics in society in order to advance knowledge and ensure that genomics benefits the health of all humans. To do this, we consider the ethical, legal, and social aspect of genomics research in our work, including these key issues.

Coverage and Reimbursement of Genetic Tests›

Payers such as insurance companies and Medicare need systematic ways of evaluating genetic tests for reimbursement.

Genetic Discrimination›

In 2008, the Genetic Information Nondiscrimination Act was passed into law, prohibiting discrimination by employers and health insurers.

What is genome editing?›

Genome editing is a method that lets scientists change the DNA of many organisms, including plants, bacteria, and animals.

Health Disparities›

NHGRI wants to ensure that all populations benefit from the advances of genomics research.

Human Subjects Research›

Federally-funded research with human participants must comply with regulations that protect the rights and welfare of the participants.

Informed Consent›

Informed consent shows respect for personal autonomy and is an important ethical requirement in research.

https://www.genome.gov/about-genomics/policy-issues

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NHGRI Resource (continued): Genome Statue and Legislation Database

- Contains statues and bills introduced in 2002-2024 U.S. state legislative sessions
  - Search by topic(s)
    - AI & Genomic Data
    - Biomarker testing
    - Coverage and reimbursement
    - Genetic data storage (medicine and industry)
    - Genetic discrimination
    - Gene patents
    - Genetic data & law enforcement
    - Neonatal sequencing
    - Pharmacogenomics
    - Privacy
    - Use of residual newborn screening specimens
  - Search by state(s)
  - Search by bill status
    - Died
    - Enacted
    - Statute
    - Introduced
    - Pending
    - Passed House
    - Passed Senate
  - Updated monthly

International Public Health Genomic Policy Considerations: Example of Genetic Discrimination

Annual Review of Genomics and Human Genetics

Looking Beyond GINA: Policy Approaches to Address Genetic Discrimination

Yann Joly,[1] Charles Dupras,[1] Miriam Pinkesz,[1] Stacey A. Tovino,[2] and Mark A. Rothstein[3]

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[2] William S. Boyd School of Law, University of Nevada, Las Vegas, Nevada 89154, USA

[3] Brandeis School of Law and School of Medicine, University of Louisville, Louisville, Kentucky 40202, USA

https://gdo.global/

- Worldwide review of laws, policies and strategies to prevent genetic discrimination
- Significant variability among continents & countries
  - **North America & Europe-** extensive policy-making activities
  - **Australia, Asia, and South America-** moderate policy-making activities
  - **Middle East & Africa-** minimal policy-making activities
- Four broad categories of countries:
  - Broad human rights-based prohibition
  - Specific legal prohibitions in specific domains
  - Moratorium with government oversight in specific domains
  - Traditional legal protection

Questions?

Thank you!