# Ethical, Legal and Social Issues in Genomics

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# Learning Objectives

- Discuss **ethical, legal and social issues** that impact CHWs’ work in genetics clinical care and research.
- Explain how CHWs help patients build trust in genetic providers and healthcare systems.
- Describe how CHWs support informed decision-making and ensure equitable access to genetic care.

# What is Ethical, Legal, and Social Implications (ELSI) in Genomics?

- ELSI addresses how genetic science affects people and communities.
- It is about listening to communities that have been **left out, mistreated, or underserved** by biomedical research and healthcare

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Dolan *et al.* Three decades of ethical, legal, and social implications research: Looking back to chart a path forward. Cell Genomics 2022.

Ethical, Legal and Social Implications Research Program (genome.gov)

# CHW Role in ELSI

Addressing historical mistrust of genetics in healthcare

Mitigate impacts in participation in genetic testing and preventive care

Bridge gaps by informing and supporting patients

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# Examples of Ethical Issues in Genetic Testing and Screening

- What safeguards privacy and confidentiality?
- Who "owns" the information?
- Who should access the information?
- Should insurers have access?
- Who can disclosure to family members?
- When should genetic testing/screening be offered or allowed (e.g., young adolescents)?
- Is there equal access to testing?

# Genetic Discrimination

Genetic tests are usually in a person's medical records so others may have access.

Genetic test results could affect a person's insurance coverage or employment.

Members of minority communities may worry genetic info could be used against them.

Health providers must understand that some groups may mistrust the use of genetics as a health tool.

# Communication of Test Results

## 01

Test results should only be shared with people the patient has given permission to share with.

## 02

Before taking the test, the patient and provider should agree on how the results will be shared to make sure they stay private.

## 03

Test results with a person's name or other ID should NEVER be shared with anyone outside — like employers, insurance companies, or the government — without written permission from the patient.

# Duty to Warn

- Providers have a duty to warn about familial risk and to encourage discussion with relatives.
- Sometimes a provider can override patient confidentiality or consent to directly notify relatives about genetic information.
- A consultation with one or more of the following would be needed: ethics committee, legal counsel, privacy officer, etc.

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# Informed Consent Discussion Topics

- The voluntary nature of genetic testing
- Risks, limitations and benefits of testing or not testing
- Alternatives to genetic testing
- Details of the way in which the test is performed (e.g., what type of sample is required, accuracy of test, turn-around-time, etc.)
- Privacy/confidentiality of test results

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# Informed Consent Discussion Topics

- Potential consequences
  - Impact on health
  - Possible emotional and psychological reactions
  - Treatment/ prevention options
  - Ramifications for family

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# Cost of Screening

## The Affordable Care Act (ACA)

- Requires both private and public insurers to cover costs of certain cancer screenings

## *Medicare*

- Usually covers most cancer screenings in full
- Sometimes require a co-pay for the doctor's visit

## *Medicaid*

- Coverage for cancer screenings vary by state

## Navigation ideas:

- Check on free or low-cost programs through community/public health agencies
- Help patients check their state's Medicaid office or local health department

# Legal Protections

- **HIPAA** - Health Insurance Portability and Accountability Act
  - Created national standards for health privacy
  - Protects sensitive patient health information
- **GINA** - Genetic Information Nondiscrimination Act
  - Protects against discrimination based on genetic information
  - Includes health coverage and employment.

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# The Role of CHWs in Building Trust

## Be transparent and honest

- provide clear and accurate information about genetics
- explain potential benefits, risks, and limitations of genetic testing and genetic research

## Educate and empower

- provide information about genetics to your community
- help them fell more informed and confident in making decisions

## Build relationships

- listen to concerns and questions of community members
- acknowledge historical mistrust because of past discrimination and unethical practices

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# The Role of CHWs in Building Trust

## Highlight benefits for the community

Emphasize how genomics research can benefit the community as a whole

Share success stories from individuals or families who have participated in genetic research or clinical programs

## Educate individuals about protections

Reassure individuals that their data will be kept private and confidential

Share information about the Genetics Information Nondiscrimination Act (GINA)

# Workbook Activity #9

**You are working with a community member who has been referred for genetic testing to assess their risk for a hereditary condition.**

*The patient is hesitant about the test and has concerns about:*

- **Privacy**: who will have access to their genetic information?
- **Discrimination**: could this test affect their insurance or job?
- **Understanding results**: what will the results mean for them and their family?
- **Emotional impact**: how will they cope with this information?

*Reflect on this situation and provide a brief response to the following questions:*

1. How would you describe genetic testing and why it was recommended?
2. How would you address the patient's concerns about genetic privacy and data security?
3. What information would you provide about genetic discrimination and legal protections (e.g., GINA, HIPAA)?
4. What steps could you take to ensure the patient feels empowered to make their own informed decision?