



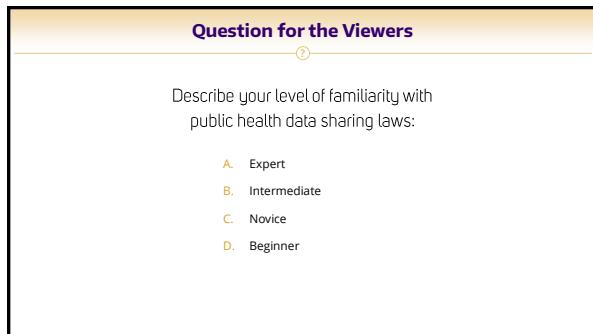
Ethical Issues in Public Health Data Use

 Rachel Hulkower, JD, MSPH
Public Health Analyst,
Cherokee Nation Assurance
CDC Public Health Law Program

 Cason Schmit, JD
Assistant Professor
Texas A&M University
School of Public Health

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Northwest Center
FOR PUBLIC HEALTH PRACTICE



Question for the Viewers

Describe your level of familiarity with public health data sharing laws:

A. Expert
B. Intermediate
C. Novice
D. Beginner



About This Presentation

 **PART I:**
PH Data
Sharing 101

 **PART II:**
Protections &
Exceptions

 **PART III:**
Ethical
Frameworks

 **PART IV:**
Data Sharing
Ethics

DISCLAIMER

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Part I: Public Health Data Sharing 101



Scenario: Disease Outbreak

Four new cases of hepatitis C virus (HCV) are diagnosed at a small, 100-bed hospital. It is quickly determined that all patients share a genetically similar strain of the virus, indicating a common source. However, it is also noted that the diagnoses occurred in close proximity to each other, the health care exposures were similar, and none of the patients had known or apparent HCV risk factors.

To prevent further HCV infections, the public health department called to the hospital and requested access to all patient electronic medical records to look for anyone suspected to be exposed, or a source. **The hospital denied access to any patient information in the EMRs without prior patient consent.**



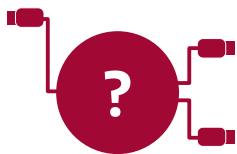
Consider: In this scenario, is it legal for the provider to disclose the health information of these individuals?

- a. Yes – public health activities like this allow providers to disclose patient data.
- b. No – the patients have not given authorization.

PH Data Sharing Guidance

How federal, state, and local public health data confidentiality laws apply to you depends on the following:

- **What** is in the data?
 - **Who** has the data?
 - **Who** wants the data?
 - **Why** is the data being released?



Common Sources of Public Health Data

- Immunization Information Systems
 - Vital statistics
 - Public health registries
 - Treatment registries
 - Disease-specific registries
 - Registries used in preventive medicine

Examples: Disease Surveillance and Reporting

- **National Notifiable Diseases Surveillance System (NNDS)**
 - Allows any PH entity to *voluntarily share* notifiable disease-related health information with the federal government
 - **State and local laws**
 - Can *require* reporting of dangerous diseases to state or local health departments

How Is PH Data Used?

- **Disease Investigations**

All state (and some local) health departments have authority to *investigate diseases and potential outbreaks*

- **Disease Control**

All state (and some local) health departments have authority to *implement disease control measures*

- **Other Uses**

Many state health departments have laws to use and release data for activities like: *treatment and coordination of care, partner notification or contact tracing, and public health research*

**Part II:
Data Privacy -
Protections &
Exceptions**



Health Insurance Portability and Accountability Act (HIPAA)

**HIPAA Privacy Protections:
The General Rule**

A **covered entity** can only use or disclose **protected health information** for **limited purposes** unless the individual authorizes the use or disclosure

45 C.F.R. § 164.502 et seq.



Covered Entities: To whom does HIPAA apply?	
Covered Entities	<ul style="list-style-type: none"> Healthcare providers "who transmit any health information in electronic form in connection with a transaction" Health plans Healthcare clearinghouses
Business Associates	Provide services on behalf of covered entities requiring the disclosure of protected health information
Hybrid Entities	Activities include "covered" and "non-covered" functions

Protected Health Information: What does HIPAA protect?	
<p>Protected health information</p> <ul style="list-style-type: none"> Individually identifiable health information that is transmitted or maintained by covered entity <p>Individually identifiable health information</p> <ul style="list-style-type: none"> Created or received by a covered entity <u>and</u> Relates to the health of an individual <ul style="list-style-type: none"> Identifies the individual; <u>or</u> Reasonable to believe information can be used to identify the individual <p>45 C.F.R. § 160.103</p>	

Exceptions: When Do Covered Entities Disclose Data?	
Must Disclose	May Disclose
<ul style="list-style-type: none"> Individuals requesting access to their protected health information US Department of Health and Human Services undertaking compliance investigation, review, or enforcement action 	<ul style="list-style-type: none"> Public health activities* Law enforcement Serious threats to health or safety National security Disaster response

HIPAA Permitted Use Exception: Public Health Activities



A **covered entity** may use or disclose **public health information** to a public health authority:

"for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions"

45 C.F.R. § 164.512(b)

Image courtesy CDC

State Laws: PH Data Sharing Protections

States generally have broad legal protections for individuals' information, including:

- Vital statistics laws
- Public access laws
- Health information privacy laws

Example: Vital records information may only be released to "public agencies administering health, welfare, safety, law enforcement, or public assistance programs" "when deemed in the public interest" 470 ILCS 5/5-2-3

Example: "Disclosure of a government record shall not constitute a clearly unwarranted invasion of personal privacy if the public interest in disclosure outweighs the privacy interests of the individual." HRS §92F-14

Example: A healthcare provider may not disclose individuals' health information "to any other person without the patient's written authorization." MT ST 50-16-529, 530



State Laws: PH Information Privacy Laws

State privacy laws can dictate the following:

- **What** exact information can be shared with public health authorities
- **What** information is subject to or exempt from public records requests
- **When** information can be shared with other government entities
- **Which** government employees or agents may access information

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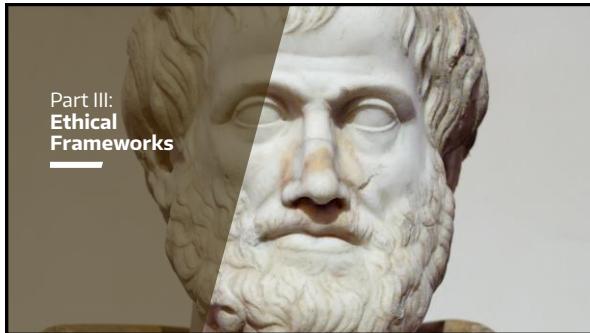
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Scenario: Disease Outbreak - Conclusions

This scenario demonstrates that we have laws which can protect the public's health and well-being. However...

- ✓ Private health information has broad legal protection
- ✓ When private health information is shared for public health reasons, context matters
- ✓ **Individual privacy and public health activities** are legal distinctions, *not necessarily* ethical ones

Part III: Ethical Frameworks



Guidance on Public Health Ethics

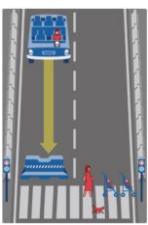
- How are ethics used to identify and resolve dilemmas about *what should be done?*
- How does *Bioethics* contrast with *Public Health Ethics*?
- Which ethical framework is more appropriate for public health and big data?

Ethics Example: The Moral Machine



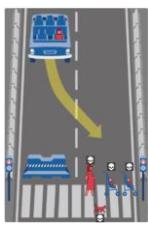
moralmachine.mit.edu

Who Should Die? Scenario 1



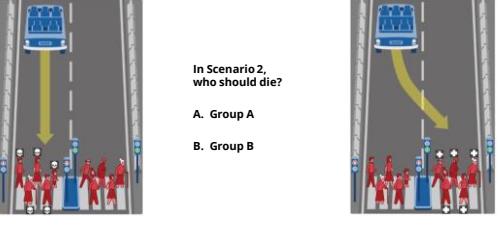
In Scenario 1,
who should die?

- A. The driver
- B. The pedestrians



Pedestrians

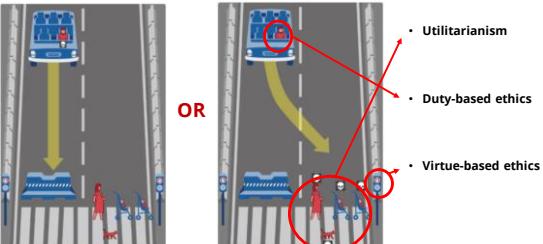
Who Should Die? Scenario 2



In Scenario 2, who should die?

A. Group A
B. Group B

How Did You Decide?

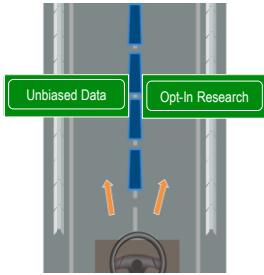


OR

- Utilitarianism
- Duty-based ethics
- Virtue-based ethics

Data Examples

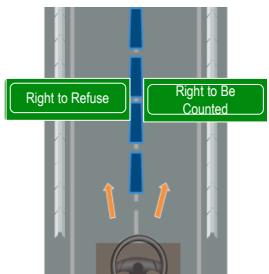
- **Unbiased data**
 - Prioritize the use of bias-free data
- **Opt-in model**
 - Give individuals choice to opt-in to secondary data research, but risk introduction of bias



More Data Examples

- Right to Refuse to Participate**
 - Right to be excluded from research/surveillance

- Right to Be Counted**
 - Right to have your circumstances counted or assessed



Love Canal, NY – Right to be Counted

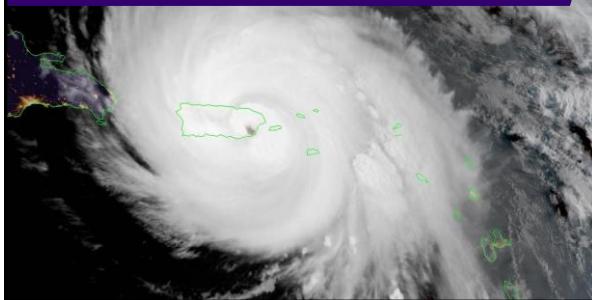
The Love Canal Disaster: 1893 – 1998

- 1950s:** Neighborhood and schools built on toxic dump
- 1970s:** Environmental contamination evidence
 - Governmental inaction frustrated community
 - Community mobilized, demanding a study of the health impact
 - Subsequent study compelled government action
- 1998:** Lawsuit settled; former residents compensated



Photo Source: EPA Flickr Page
<https://www.flickr.com/photos/usepa/2525940033/>

Hurricane Maria





What Isn't Counted Doesn't Count

The Right to be Counted – Key Takeaways:

- Knowledge of harm is centrally important for asserting individual and human rights
- "Right to be counted" issues are relevant to "respect for persons"

Do potential conflicts with consent models raise anticommons concerns?

- Knowledge from community data is a resource
- Exercise of individual rights relating to data collection and use can frustrate efforts to use that knowledge for social good

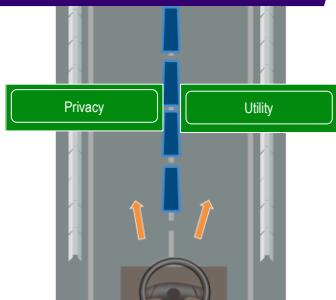
More Data Examples

Stringent non-disclosure

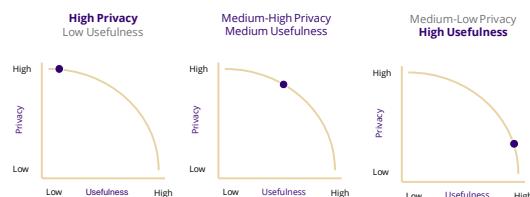
- Suppress data elements from secondary data use

Data utility

- Use more data elements to learn more from data

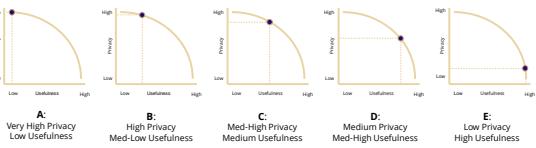


More Ethical Concerns: Privacy v. Utility



More Ethical Concerns: Privacy v. Utility

Where would you strike the balance?



Part IV: Data Sharing Ethics



The History and Context of Bioethics is Important



Nazi Germany
Human experimentation
early - mid 1940s



The United States Public Health Service
Tuskegee Study
1932 - 1972

Photo Sources: National Archives: <http://www.archives.gov>

Bioethics (Belmont Report, Common Rule)

Respect for Persons

- Treat individuals as autonomous agents
- Persons with diminished autonomy are entitled to protection

Beneficence

- Do not harm
- Maximize benefits and minimize harms

Justice

- Who ought to receive the benefits of research and bear its burdens?

Bioethics is an Awkward Fit for Public Health

CIOMS International Guidelines for Ethical Review of Epidemiological Studies (1991)

- Acknowledges the insufficiency of the bioethical model for public health



Source: Council for International Organizations of Medical Sciences
http://cioms.ch/wp-content/uploads/2017/01/1991 INTERNATIONAL GUIDELINES.pdf

WHO Guidelines: Overview

✓ Common Good

- Some benefits are fundamentally shared

✓ Equity

- Equitable conditions for humans to flourish
- Unfair risk distribution may require balancing resources

✓ Respect for Persons

- When possible, involve individuals in decisions affecting them
- Engage individuals in when considering population interventions

✓ Good Governance

- Accountability, transparency and community engagement

WHO Guidelines: Ethical Data Uses for Public Health

- Obligation to conduct public health surveillance (*Guideline 1*)
- Justification for collecting identifiable data (*Guideline 11*)
- Informed consent is not always ethically required (*Guideline 12*)
- Obligation to share data with public health (*Guideline 14*)
- Appropriate to use data for research purposes (*Guideline 16*)
- Inappropriate to share identifiable data with agencies likely to take action against individuals (*Guideline 17*)

Which Framework Should Apply?

Is the activity research or a public health activity?

- Historically, this has been a challenging distinction (partially addressed in recent Common Rule revisions)

What about big data analytics?

- Ongoing, systematic, data collection, and analysis of large number of individuals



Big Data Ethics Theorem

$$\bullet \quad n = \text{Sample (of } N \text{ pop) size}$$

$$\bullet \quad N = \text{Population size}$$

$$\bullet \quad BD_e(x) = \text{Big data ethics applied to 'x' situation}$$

$$\bullet \quad PH_e(x) = \text{Public Health Ethics applied to 'x' situation}$$

$$\bullet \quad \lim_{n \rightarrow N} BD_e(x, n) = ?$$

$$\bullet \quad \lim_{n \rightarrow N} BD_e(x, n) = PH_e(x)$$



Yeah, but...

Remember the following
big caveat:



**What is ethical is not always legal;
What is legal is not always ethical**

Action Items

- ✓ Data sharing practices are informed by the law **and** ethics. Understand the distinction!
- ✓ Consider which ethical frameworks guide your decision-making as a practitioner
- ✓ Use **public health ethics** for population-level data projects
- ✓ Refer to the **WHO Guidelines** (seriously...they are awesome...)

QUESTIONS?

To ask a question, please click the icon in the Zoom toolbar to open your Q&A Pod.

Resources

US Department of Health and Human Services Office for Civil Rights
HIPAA and Public Health Fact Sheet:
https://www.healthit.gov/sites/default/files/12072016_hipaa_and_public_health_fact_sheet.pdf

World Health Organization
Guidelines on Ethical Issues in Public Health:
<https://www.who.int/ethics/publications/public-health-surveillance/en/>

Massachusetts Institute for Technology
The Moral Machine:
<https://moralmachine.mit.edu/>
