Ethical Considerations in Data Sharing

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تعريف: 

المسائل الأخلاقية في مشاركة البيانات

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هيئة السياسة الصحية والإدارة
вуمنية تكساس A&M

شاركت اليوم مع روبيرليفر

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Session Objectives

- Explore how ethics are used to identify and resolve dilemmas about *what should be done*
- Compare and contrast *Bioethics* with *Public Health Ethics*
- Explore the new WHO Ethical Guidelines for Surveillance
- Discuss which ethical framework is more appropriate for public health and big data
- Make you skeptical that anything I say actually matters
  - What is ethical is not always legal; what is legal is not always ethical
Welcome to the Moral Machine! A platform for gathering a human perspective on moral decisions made by machine intelligence, such as self-driving cars.

http://moralmachine.mit.edu/
Who Should Die?
What should the Autonomous Vehicle do? (1)
What should the Autonomous Vehicle do? (2)

Left

Right
Who Should Die? (3)
What should the Autonomous Vehicle do? (3)
Who Should Die? (4)
What should the Autonomous Vehicle do? (4)
Who Should Die? (5)
What should the Autonomous Vehicle do? (5)

Left

Right
How Did You Decide?

- Utilitarianism
- Duty-based ethics
- Virtue Based Ethics
Let’s Look at Some Data Examples

- **Opportunity to Consent to Future Research**
  - Seek informed consent if data will be reused for future research

- **De-identification**
  - Protect data subjects by removing identifiers from data
More Data Examples

- Give Notice of Future Research
  - Inform participants when data will be reused for new research
- De-identification
  - Protect data subjects by removing identifiers from data
More 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

- 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

Hurricane Maria

Hurricane Maria's official death toll is 46 times higher than it was almost a year ago. Here's why

Donald Trump awards himself 10 out of 10 for Puerto Rico hurricane response

For months after Hurricane Maria devastated Puerto Rico, the official death count remained at 64 lives lost to the storm.

That changed this week when Puerto Rican governor Ricardo Rossello substantially raised the official estimate to nearly 3,000 deaths related to the hurricane, following the release of a commissioned, independent study from George Washington University.
• Knowledge of harm is centrally important for asserting individual and human rights
• “Right to be counted” issues relevant to “respect for persons”
• Do potential conflicts with consent models raise anticommons concerns?
• Special relevant for surveillance
• Reciprocity, solidarity, mutual benefit
Privacy v. Utility
More Ethical Concerns: Privacy v. Utility

• Where would you strike the balance?
Where is your balance?

- A
- B
- C
- D
- E

A B C D E
How Did You Decide?

• What ethical framework(s) did you apply?
Data Use Ethical Frameworks

Bioethics
Public Health Ethics
Bioethics

History and Context are Important!
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

  - Acknowledges the insufficiency of the bioethical model for public health

Council for International Organizations of Medical Sciences
Public Health Ethics

World Health Organization Guidelines on Ethical Issues in Public Health Surveillance
WHO Guidelines

• **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
Guideline 1. **Countries have an obligation to develop appropriate, feasible, sustainable public health surveillance systems.** Surveillance systems should have a clear purpose and a plan for data collection, analysis, use and dissemination based on relevant public health priorities.
Guideline 11. Under certain circumstances, the collection of names or identifiable data is justified.

Guideline 12. Individuals have an obligation to contribute to surveillance when reliable, valid, complete data sets are required and relevant protection is in place. Under these circumstances, informed consent is not ethically required.

Justification for collecting Identifiable data

Informed consent is not always ethically required
Ethical Data Use for Public Health

• Guideline 14. With appropriate safeguards and justification, **those responsible for public health surveillance have an obligation to share data** with other national and international public health agencies.

• Guideline 16. With appropriate justification and safeguards, **public health agencies may use or share surveillance data for research purposes**.
Belmont Report for Data

- Argument for ethical review of all data projects

- But what ethical framework do we apply?

Research v. Public Health

- Common Rule research definition
  - Research means a **systematic investigation**, including research development, testing, and evaluation, **designed to develop or contribute to generalizable knowledge**

- WHO guidelines broadly define public health surveillance
  - Continuous, systematic collection, analysis, interpretation, and sharing of health–related data for advocacy and for planning, implementing, and evaluating public health practice
Other Guidance for Making Distinctions

Public Health Practice vs. Research

A Report for Public Health Practitioners
Including Cases and Guidance for Making Distinctions

May 24, 2004

James G. Hodge, Jr., J.D., LL.M.
Assistant Public Health Professor
Johns Hopkins Bloomberg School of Public Health
Executive Director, Center for Law and the Public’s Health

Lawrence O. Gostin, J.D., LL.D. (Hon).
Professor of Law, Georgetown University Law Center
Professor of Public Health, Johns Hopkins Bloomberg School of Public Health
Director, Center for Law and the Public’s Health

With the CSTE Advisory Committee

• Where do benefits accrue?
  ▫ Research → “benefit the researcher and society”
  ▫ Public health → “premised on providing some benefit to participants or the population”

• What is the intent?
  ▫ Research → “to test a hypothesis and seek to generalize the findings or acquired knowledge beyond the activity’s participants.”
  ▫ Public health → “efforts that are primarily aimed at preventing known or suspected injuries, diseases, or other conditions, or promoting the health of a particular community.”

• **Experimentation**
  ▫ “if any activity involves introduction of non-standard or experimental procedures, the activity is likely research rather than public health practice”

• **Subject Selection**
  ▫ **Research →** Selection designed to help generalize results (e.g., controls, randomization)
  ▫ **Public health →** Self selection (e.g., participants seeking services rather than research participation)
What Ethical Framework Should Apply to Big Data?

<table>
<thead>
<tr>
<th>Bioethics</th>
<th>Public Health Ethics</th>
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<tbody>
<tr>
<td>• Primary Focus</td>
<td>• Primary Focus</td>
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<tr>
<td>▫ Individual, patient, participant</td>
<td>▫ Population, Community</td>
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<tr>
<td>• Principles</td>
<td>• Principles</td>
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<tr>
<td>▫ Respect for Persons</td>
<td>▫ Common Good</td>
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<td>▫ Beneficence</td>
<td>▫ Equity</td>
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<td>▫ Justice</td>
<td>▫ Respect for Persons</td>
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<td>▫ Good Governance</td>
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Big Data Ethics Theorem

\[ \lim_{n \to N} E(x) = ? \]

\[ \lim_{n \to N} E(x) = PH_e(x) \]

- \( n \) = Sample (of \( N \) pop) size
- \( N \) = Population size
- \( E(x) \) = Ethics applied to ‘\( x \)’ situation
- \( PH_e(x) \) = Public Health Ethics applied to ‘\( x \)’ situation
Yeah, but... (the big caveat)

What is ethical is not always legal; what is legal is not always ethical
Ethical Illegal Action

- Sharing for public health purposes
  - WHO ethical guidelines argument ➔
    - Obligation to conduct public health surveillance (Guideline 1)
    - Information should be shared for public health purposes (Guideline 14).
  - But... many US laws do not contain provisions that specifically allow sharing identifiable information for public health purpose.
## Data Use Exceptions for Public Health and Research

<table>
<thead>
<tr>
<th>Federal Legal Framework</th>
<th>Data Use Exceptions</th>
<th>Public Health</th>
<th>Research</th>
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<td>42 C.F.R. Part 2</td>
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<td>WIC Confidentiality Provisions</td>
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1. Limited to educational studies
2. Several HHS components list research as a permitted purpose
3. Restricts non-governmental research
Legal Unethical Action

- What is legal is not always ethical
  - In 2016, the United Kingdom National Health Service (NHS) entered a MOU with the Home Office
    - Permitted the NHS to share identifiable health information with the “express purpose of supporting [the Home Office’s] strategic priorities.” (e.g., immigration enforcement).

7.2 Home Office staff may make requests to NHS Digital to establish if they hold certain non-clinical information (defined at Annex A) in relation to immigration offenders, and if so for that information to be provided to the Home Office for the express purpose of supporting its strategic priorities and solely where in accordance with one or more of the purposes set out within section 261(5) (c), (d) and (e).
One more thing...

- Democratic deliberation is a tool for resolving ethical issues
Big Ideas

- Ethical frameworks guide decision-making
  - but they also influence the questions we ask

- Public health ethics is a better fit for population-level data projects

- Seriously... the WHO Guidelines are awesome...
Questions?
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