

Ethical Considerations in Data Sharing

Participate Today with
PollEverywhere

Respond at **PollEv.com/schmit**

Text **SCHMIT** to **22333** once to join

Cason Schmit, JD
Assistant Professor
Program in Health Law and Policy, Director
Department Health Policy & Management
Texas A&M University School of Public Health



TEXAS A&M
UNIVERSITY

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



Moral Machine - Human Perspectives on Machine...



Watch later



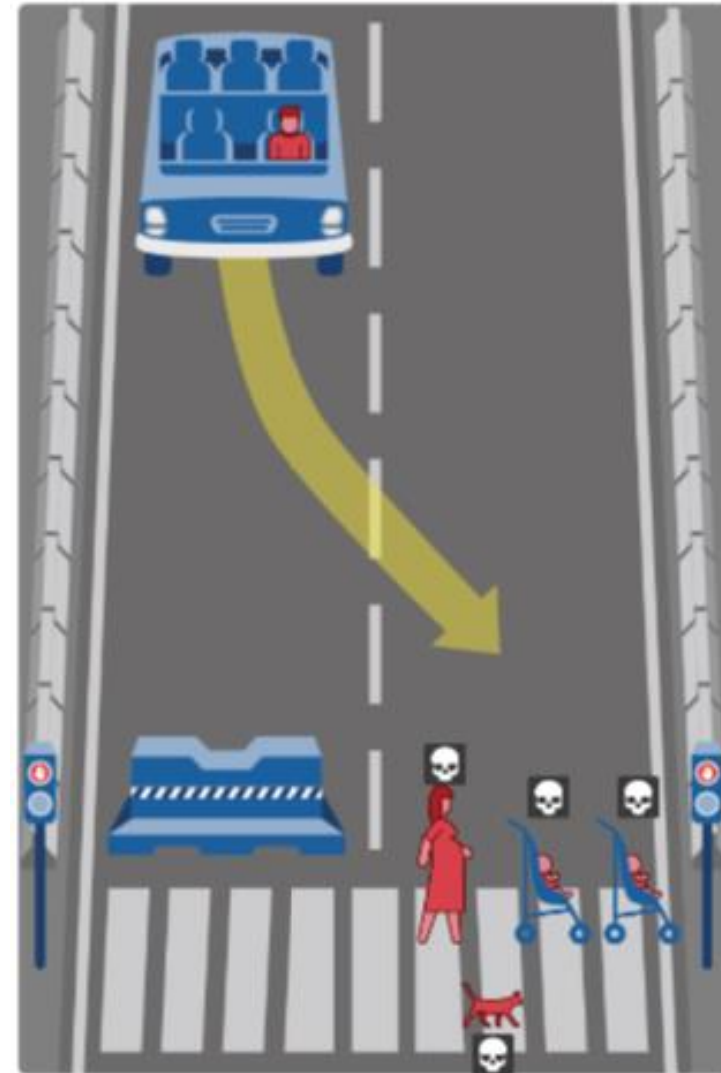
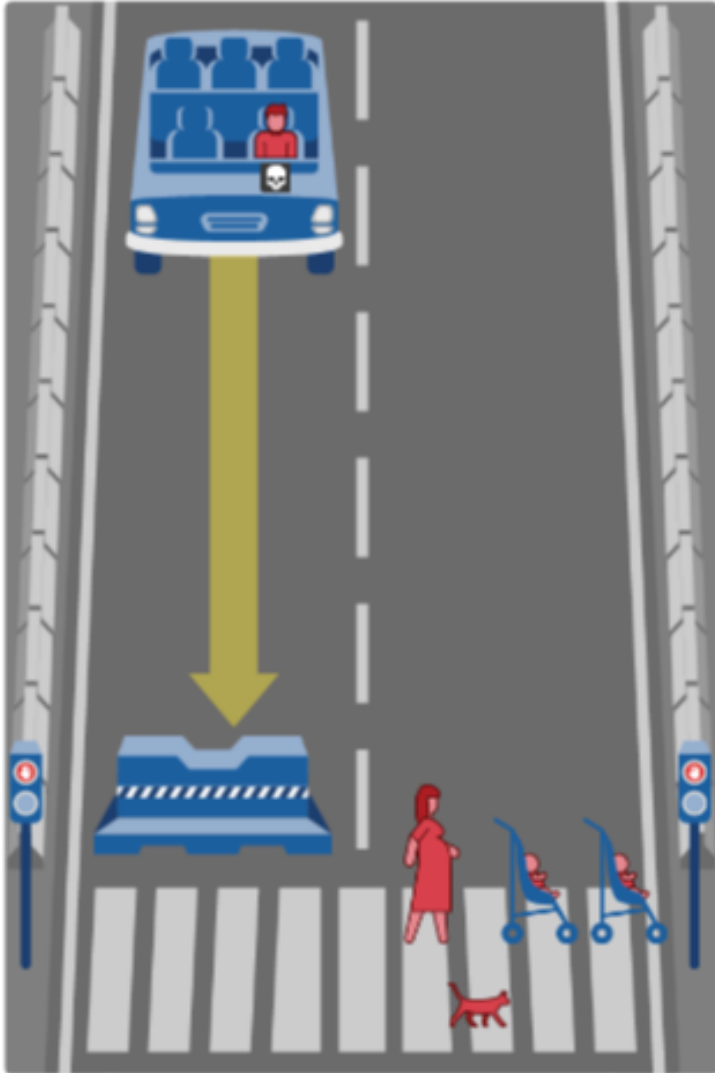
Share



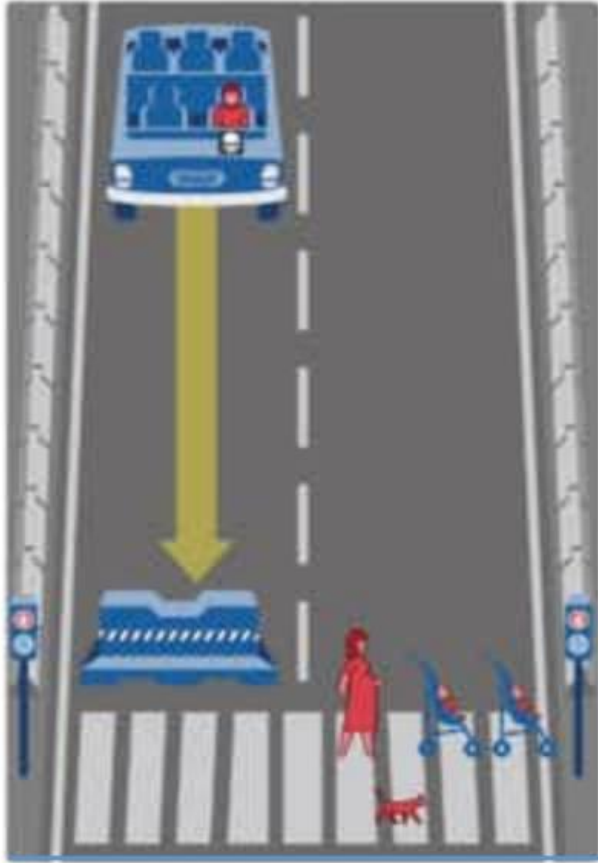
Welcome to the Moral Machine! A platform for gathering a human perspective on moral decisions made by machine intelligence, such as self-driving cars.

<http://moralmachine.mit.edu/>

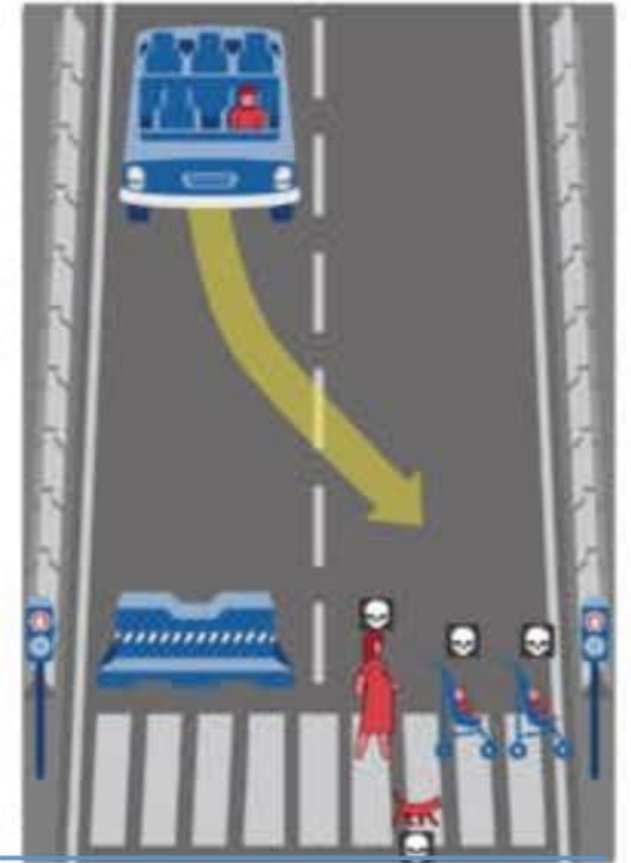
Who Should Die?



What should the Autonomous Vehicle do? (1)

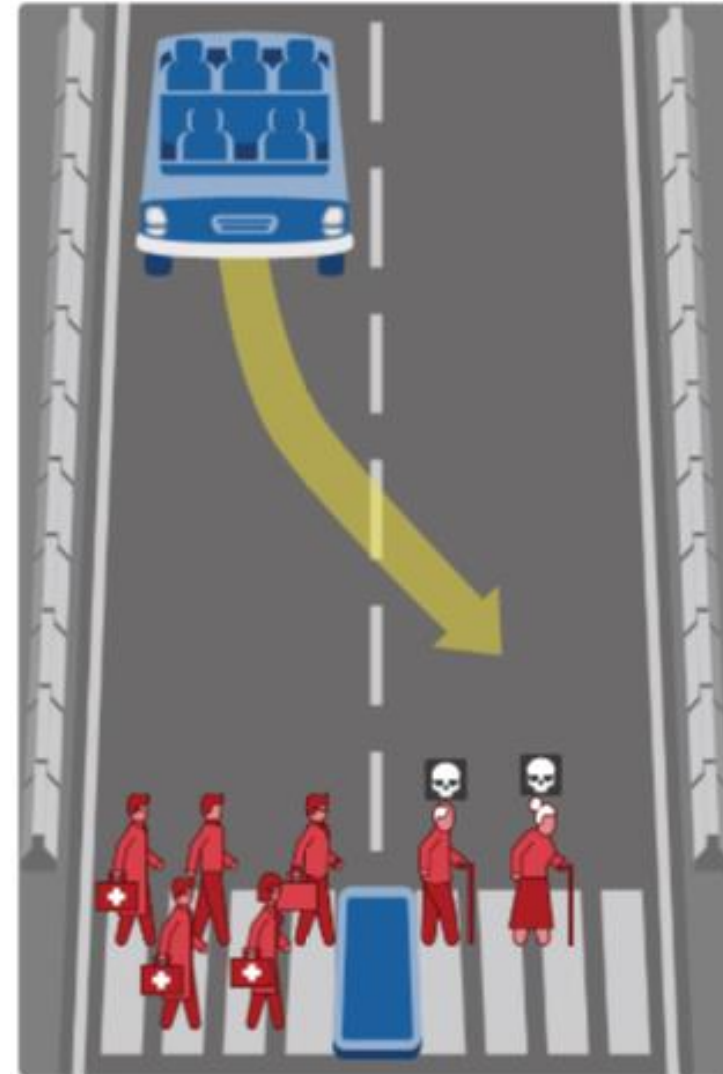
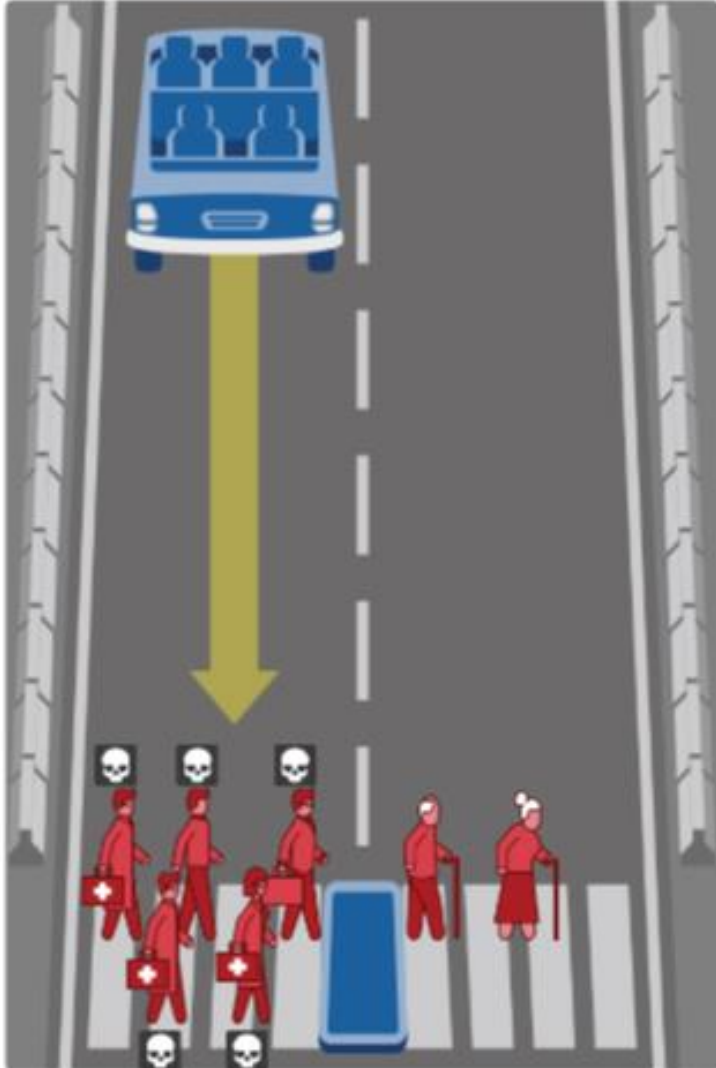


Left

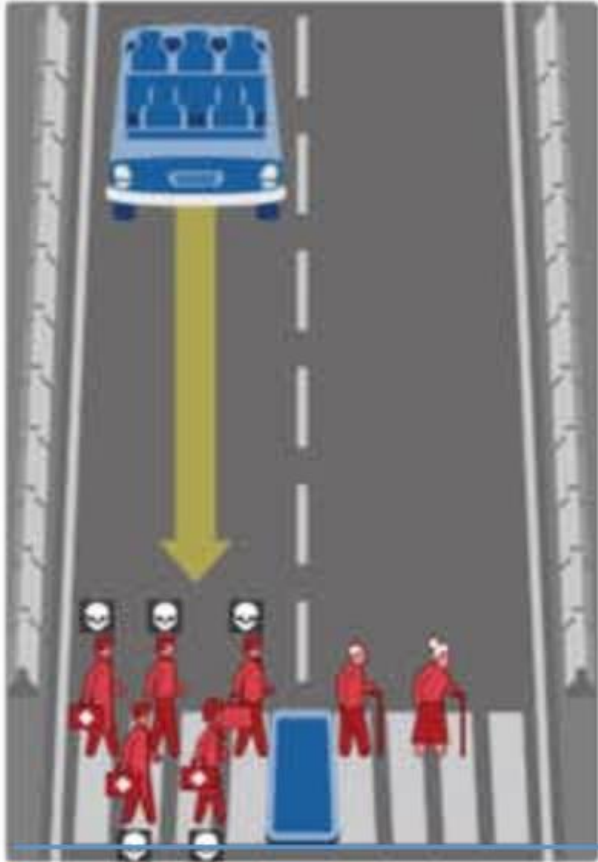


Right

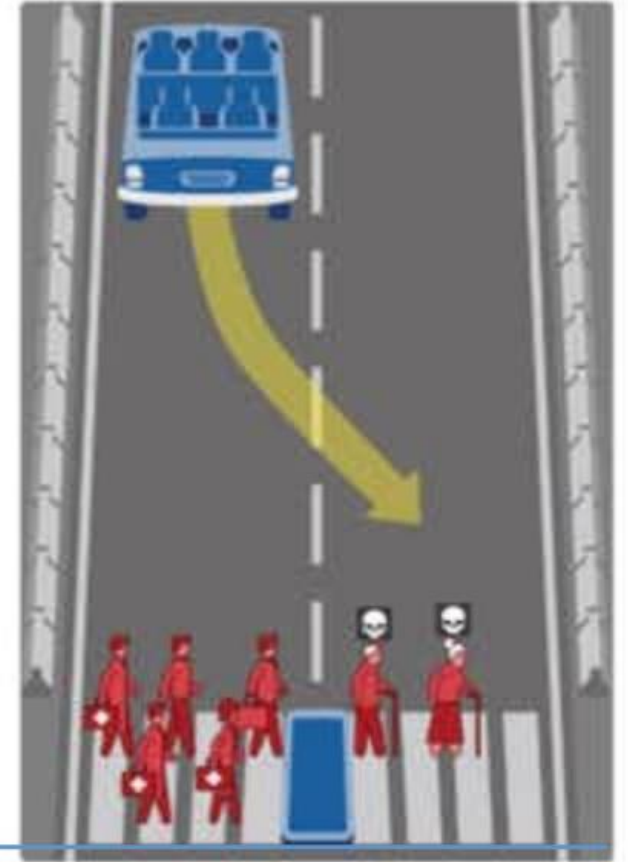
Who Should Die? (2)



What should the Autonomous Vehicle do? (2)

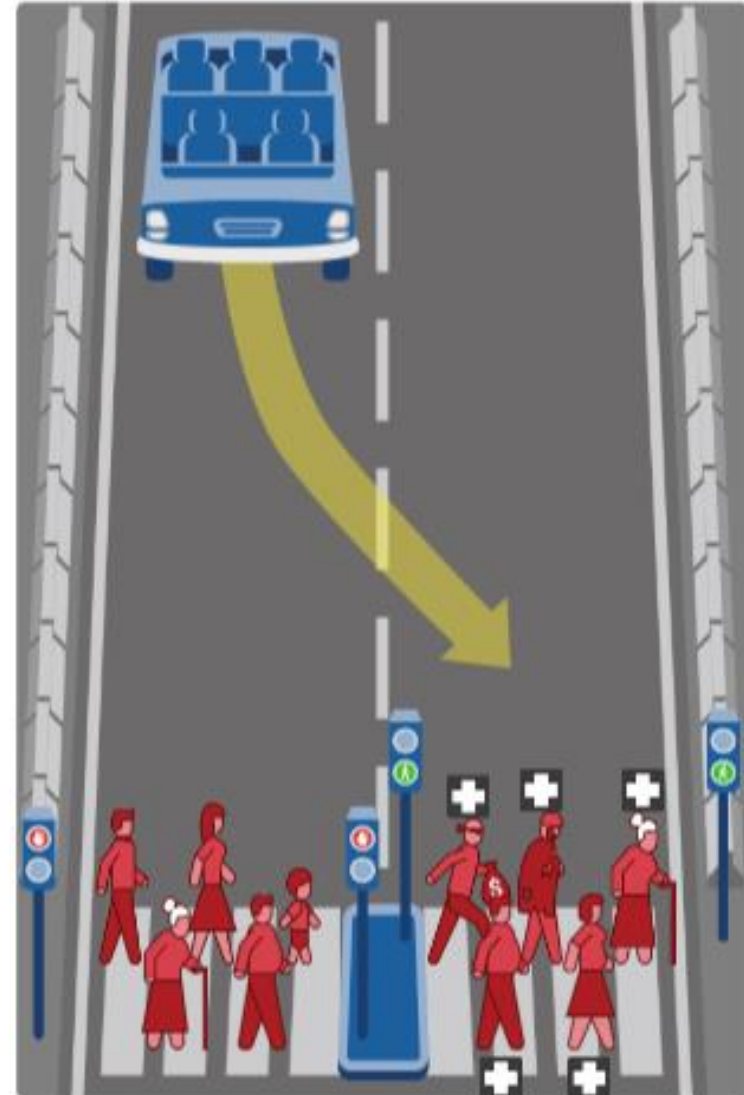
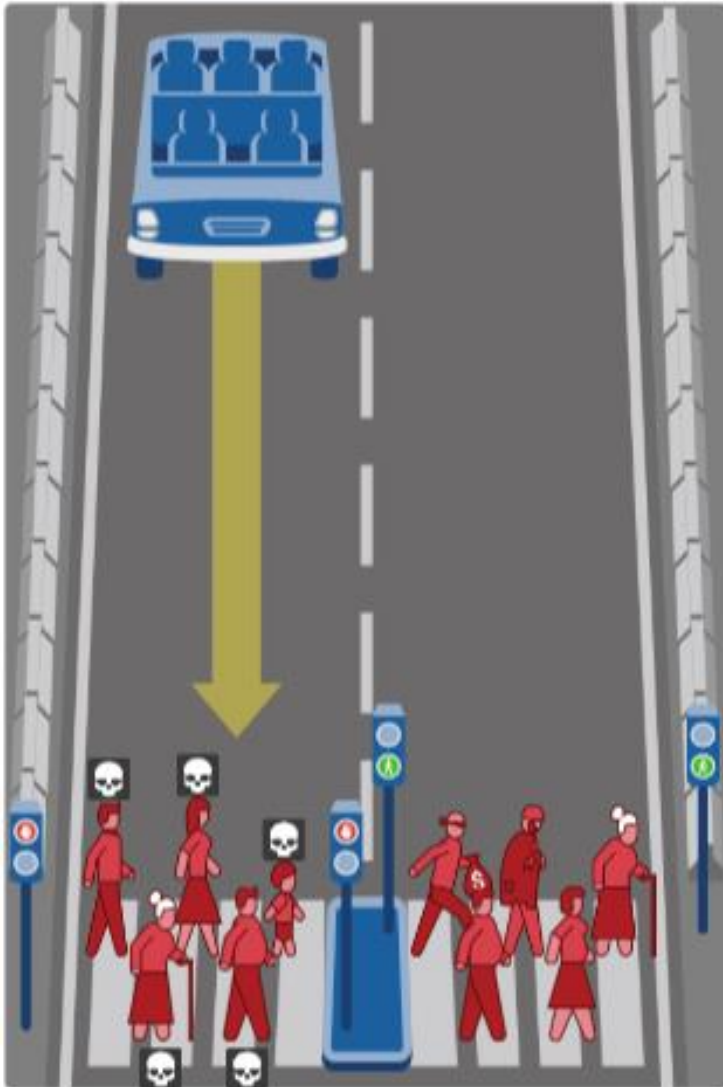


Left

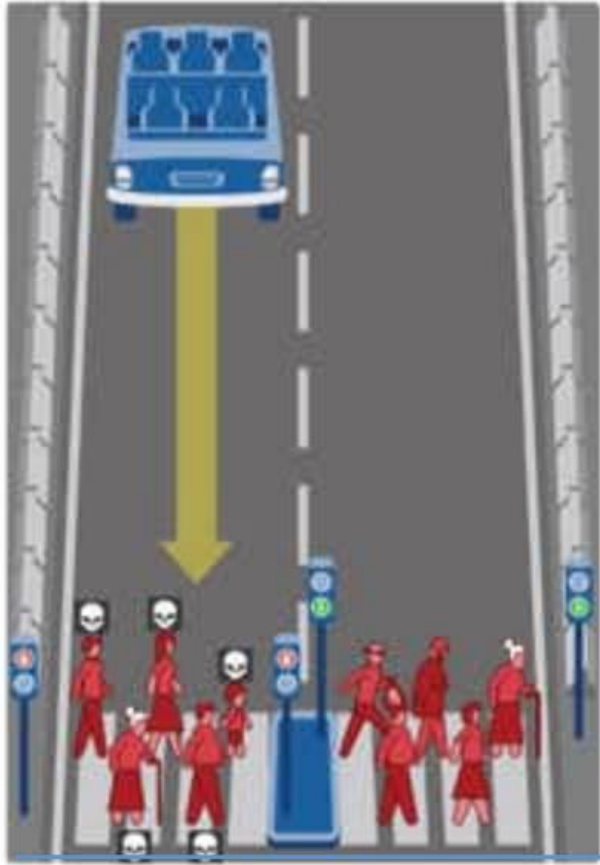


Right

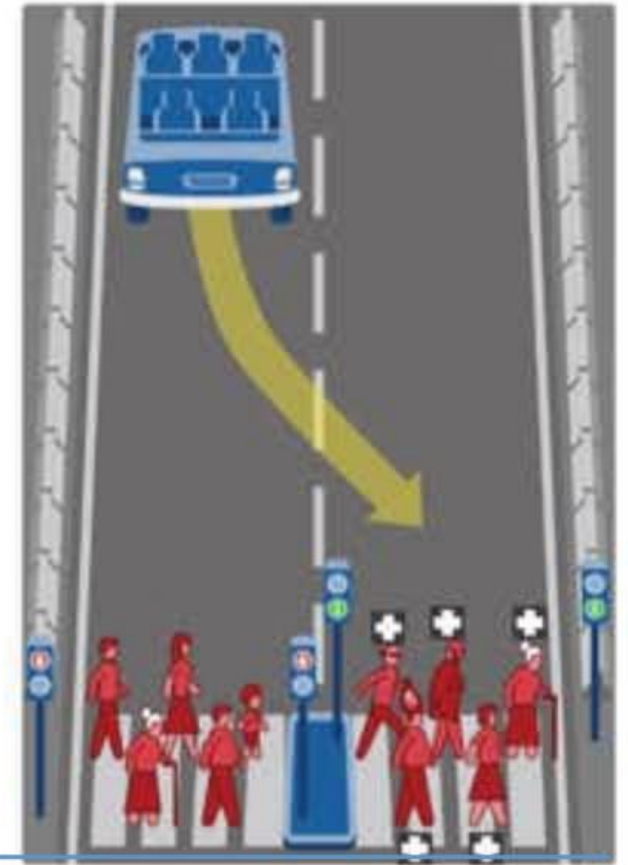
Who Should Die? (3)



What should the Autonomous Vehicle do? (3)

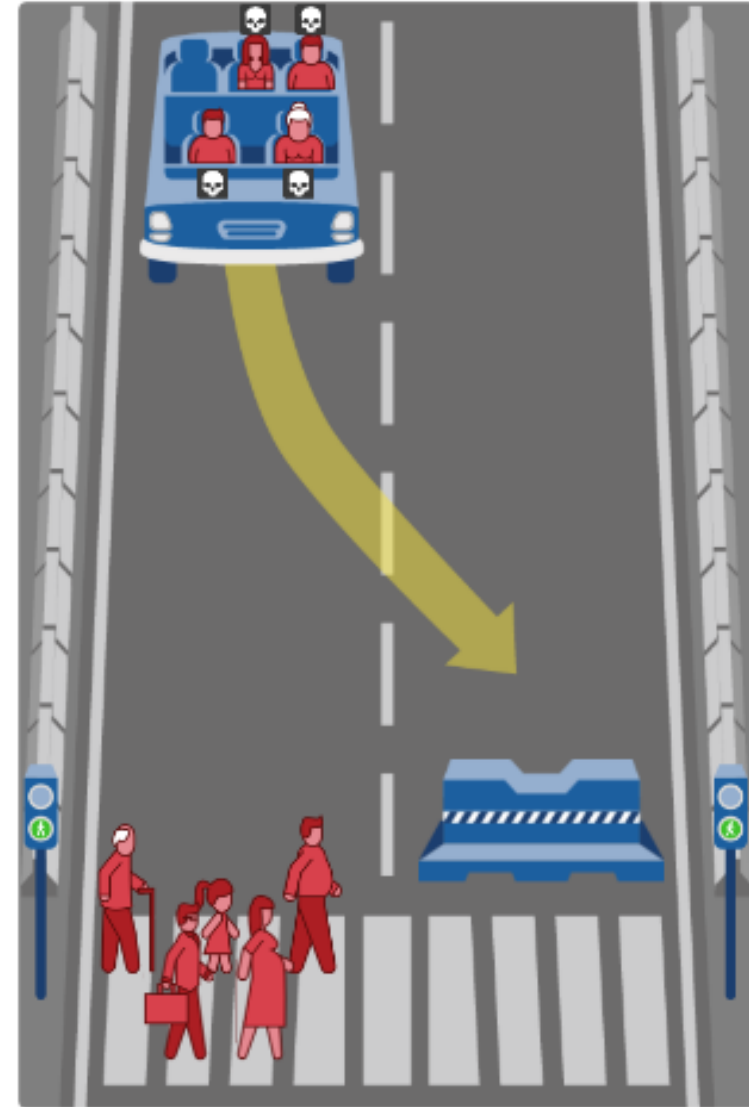
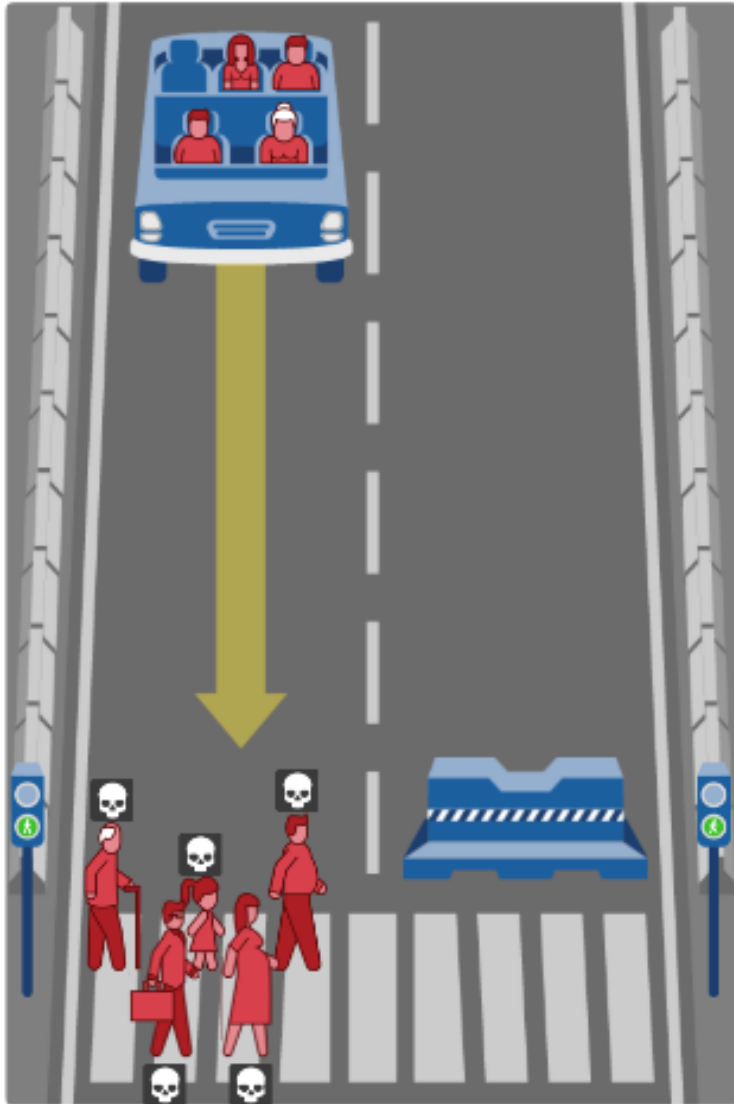


Left

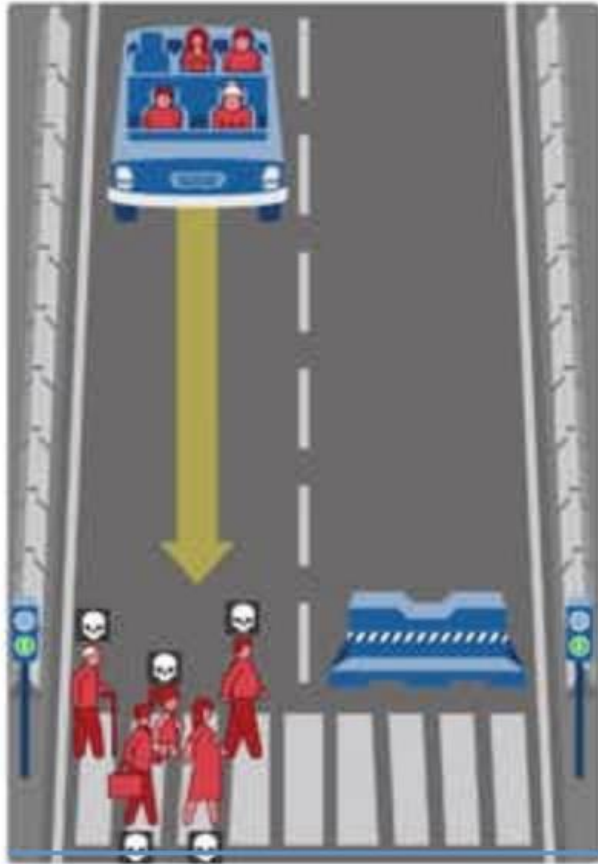


Right

Who Should Die? (4)



What should the Autonomous Vehicle do? (4)

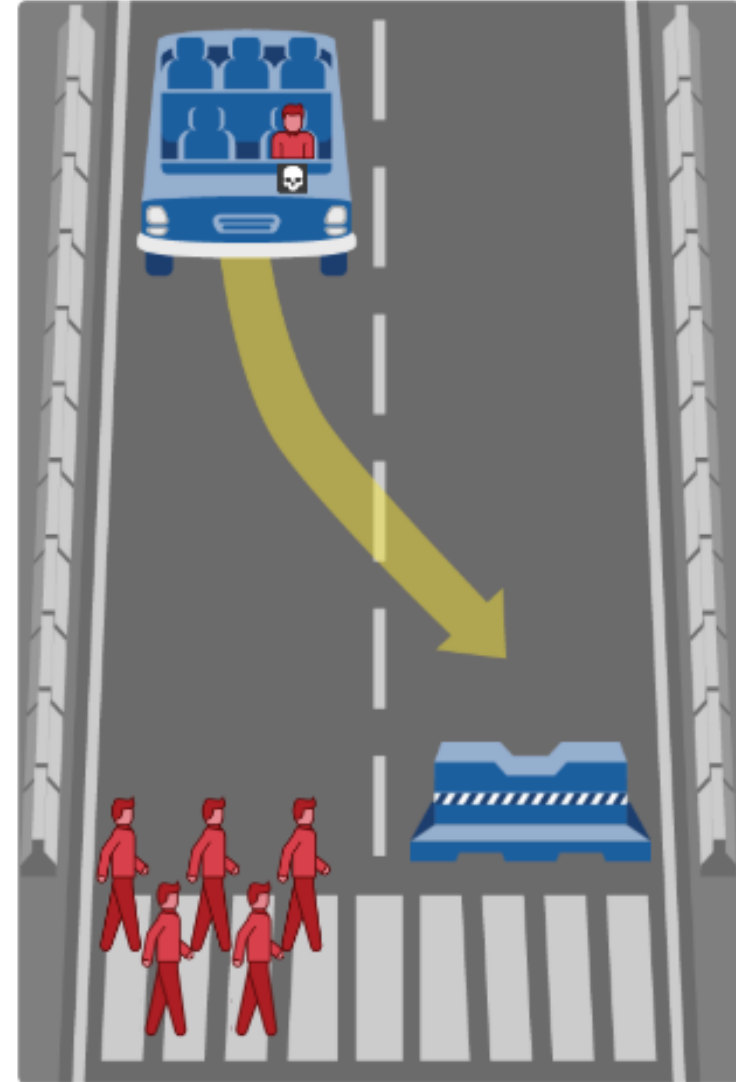
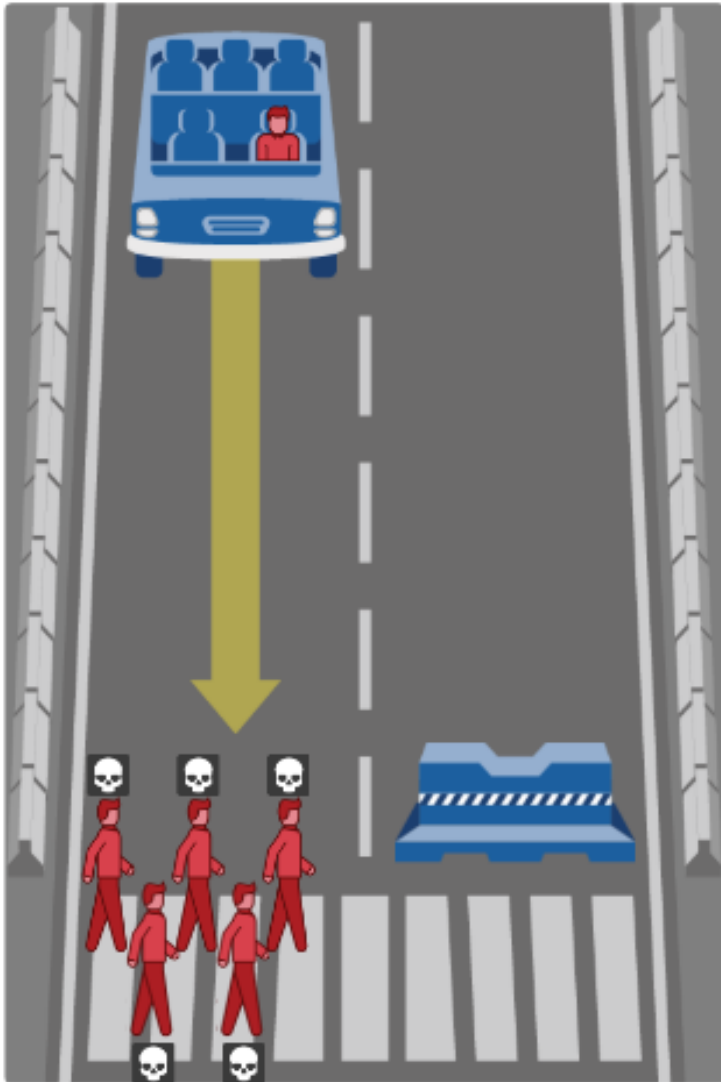


Left

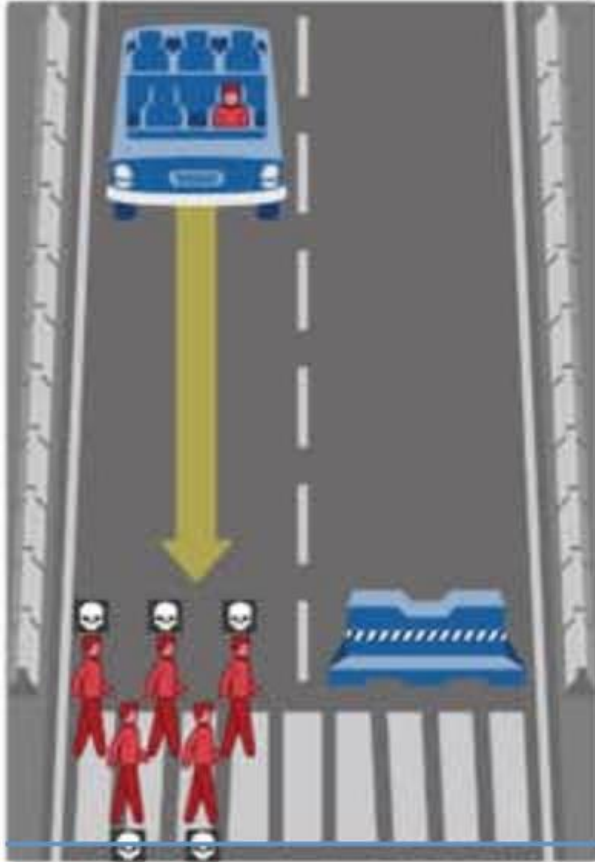


Right

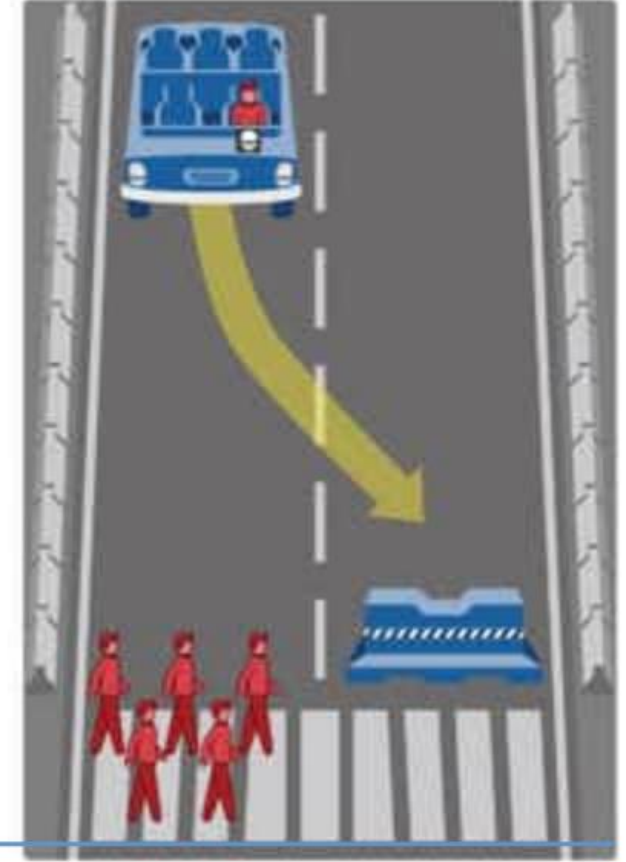
Who Should Die? (5)



What should the Autonomous Vehicle do? (5)

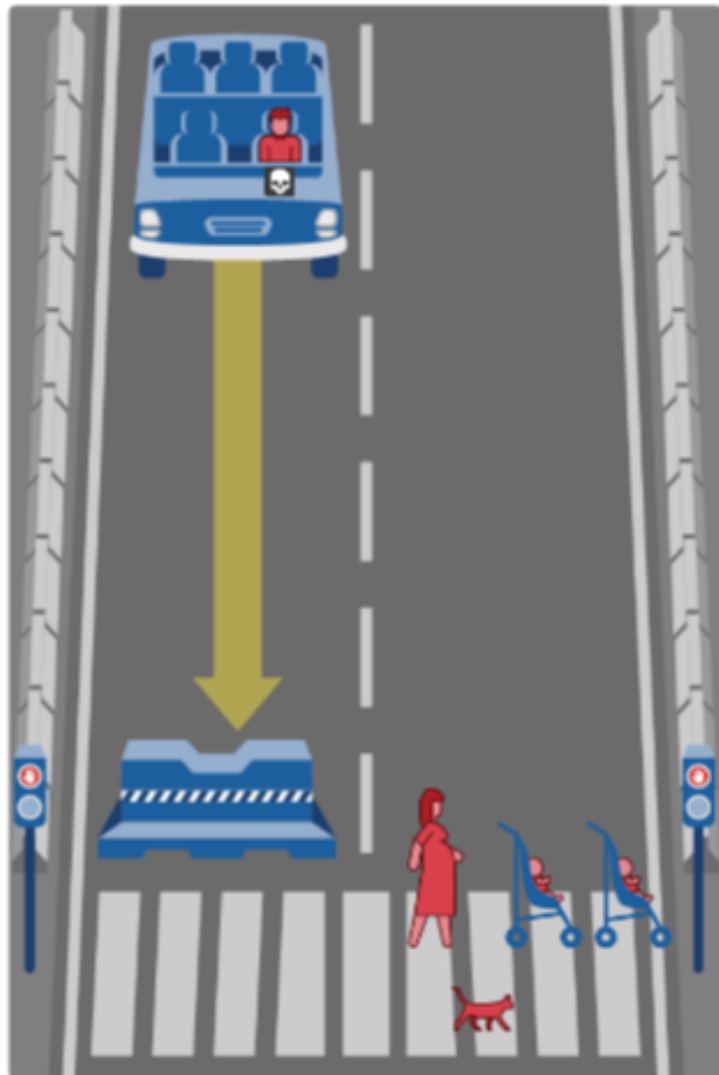


Left

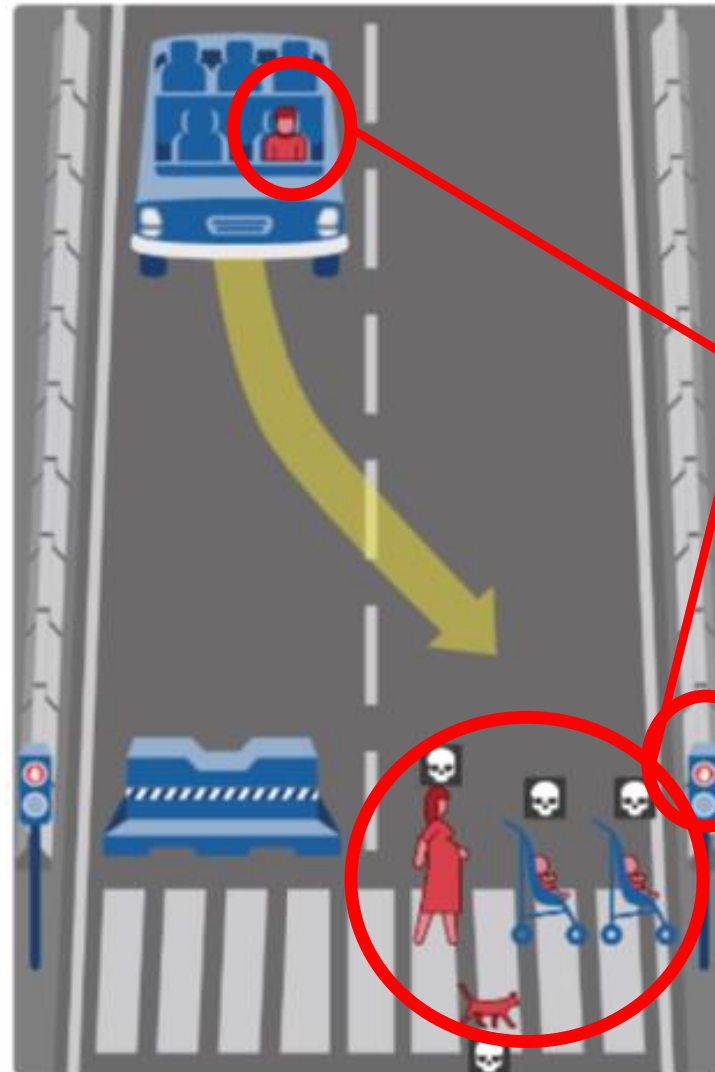


Right

How Did You Decide?



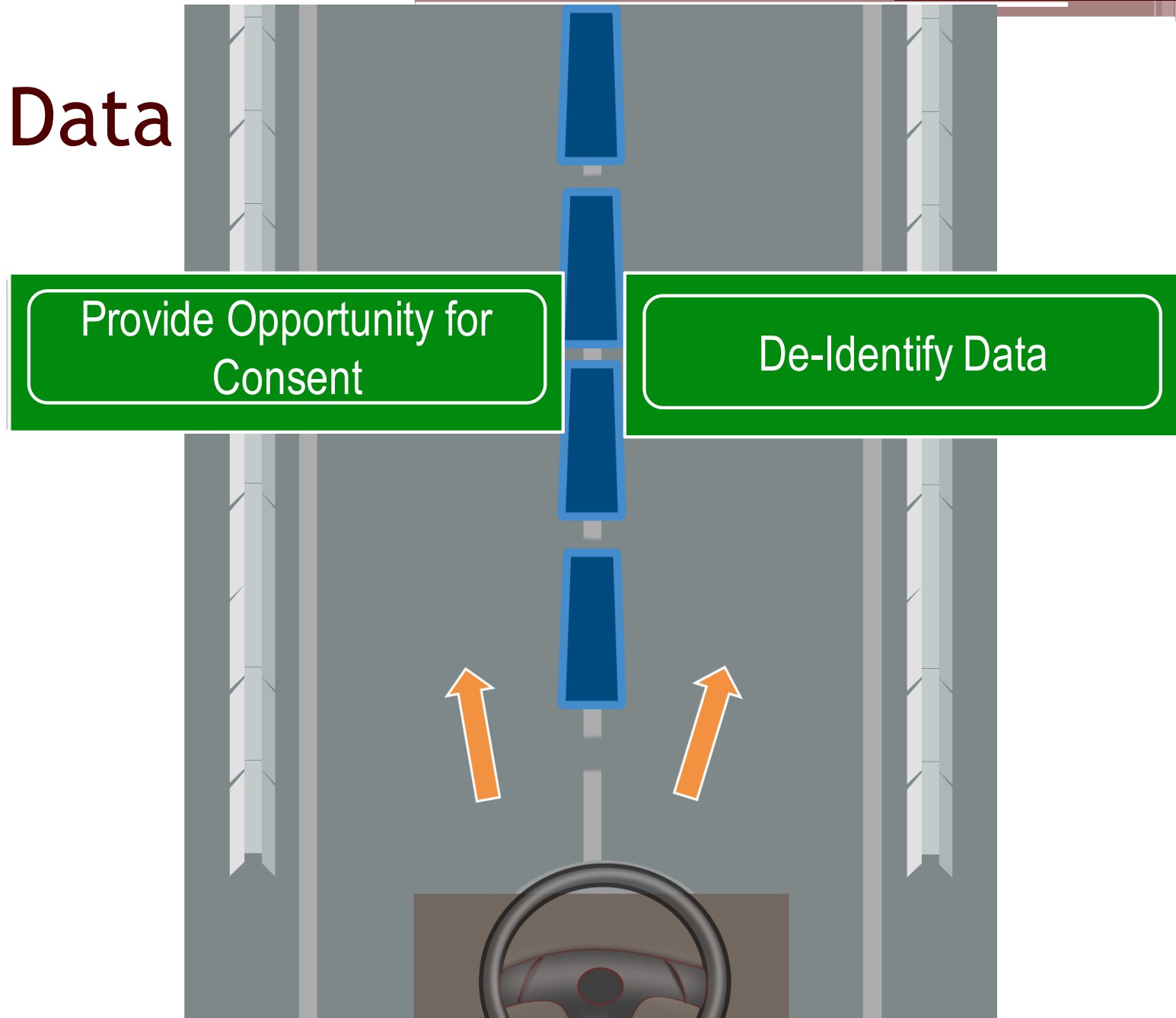
OR



- Utilitarianism
- Duty-based ethics
- Virtue Based Ethics

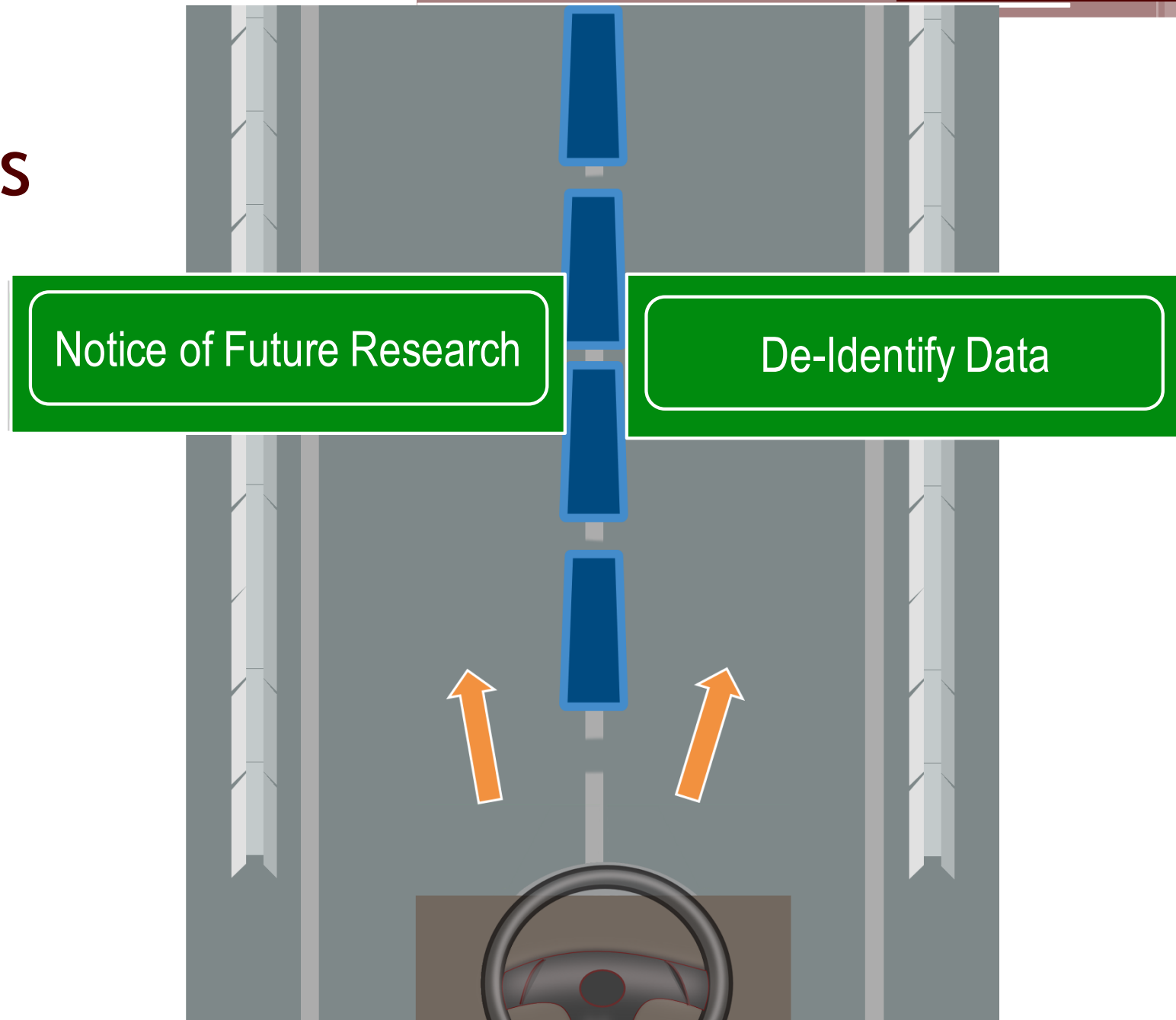
Let's Look at Some Data Examples

- 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



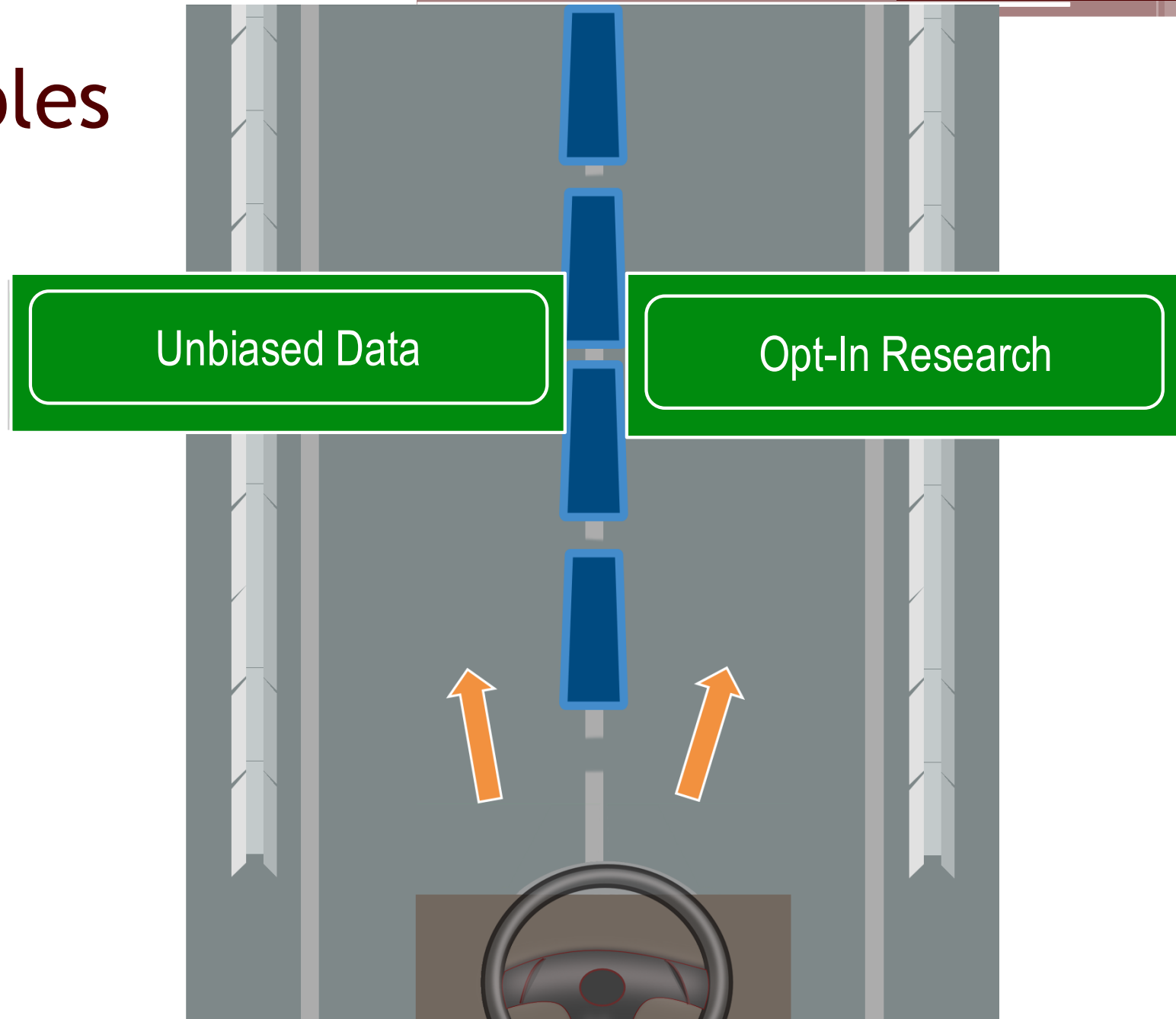
More Data Examples

- 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



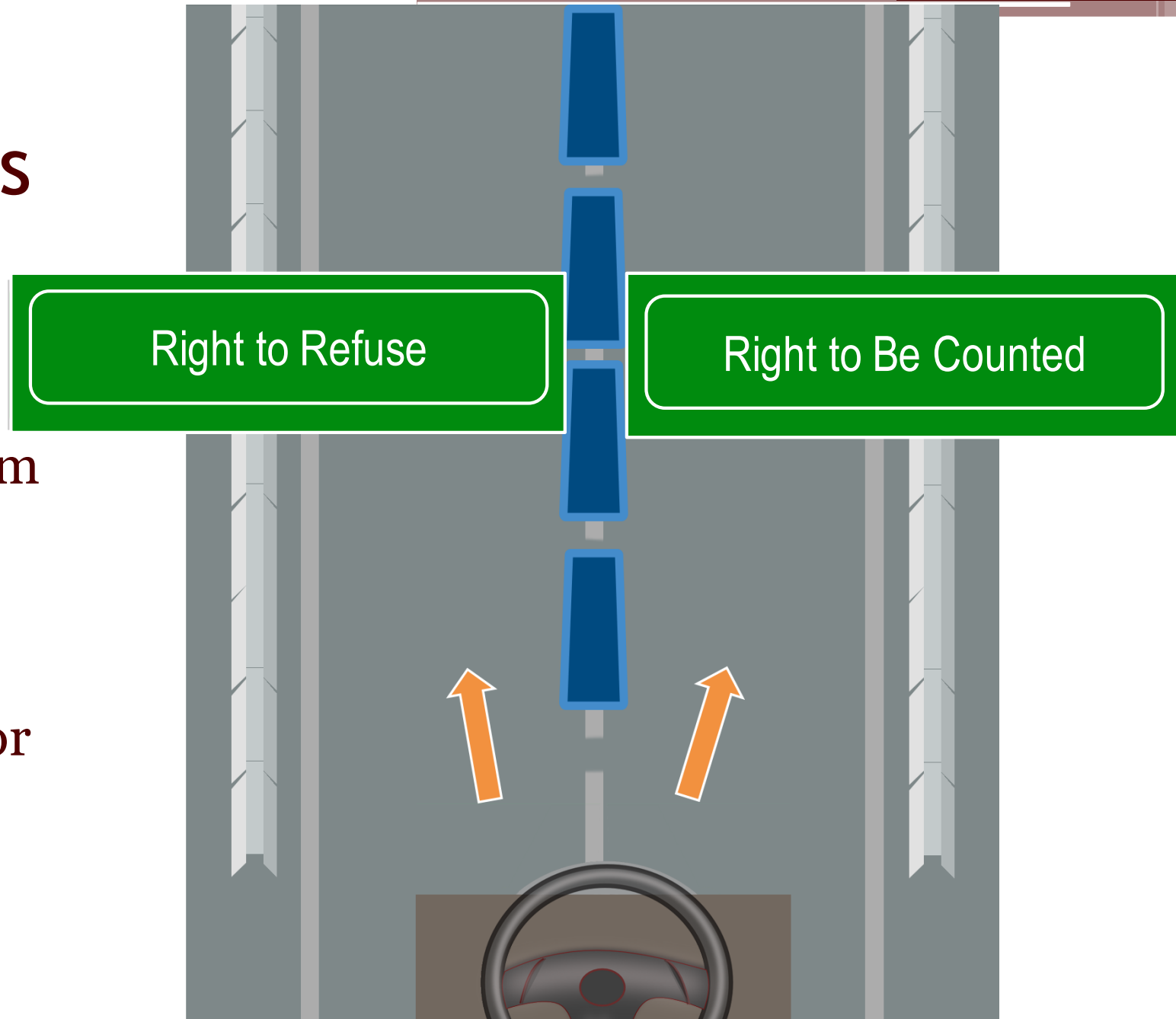
More Data Examples

- 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



<https://buffalonews.com/2018/08/04/a-history-of-the-love-canal-disaster-1893-to-1998/>

Hurricane Maria

abc NEWS VIDEO LIVE SHOWS 2020 ELECTIONS

Puerto Rico's Hurricane Maria death toll climbs to 64, as FEMA assistance tops \$1 billion

By JOSHUA HOYOS AND DAVID CAPLAN Dec 10, 2017, 2:32 AM ET

Share Tweet

Search US edition The Guardian



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

Nation Aug 30, 2018 5:50 PM EDT

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

Thu 19 Oct 2017 16:46 EDT

Trump has faced criticism for his response to the crisis, including from the mayor of San Juan, Carmen Yulín Cruz, who accused the administration of not doing enough. He visited the island earlier this month and told local officials that they should be "proud" of how few people had died from the storm compared with the death toll during Hurricane Katrina, which he described as a "real catastrophe".

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.

WHAT ISN'T COUNTED DOESN'T COUNT

- 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

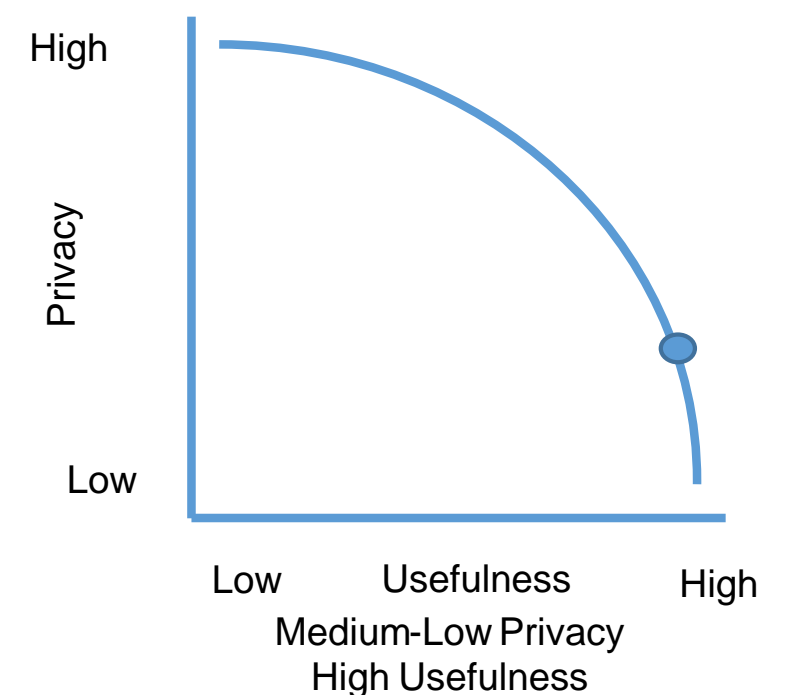
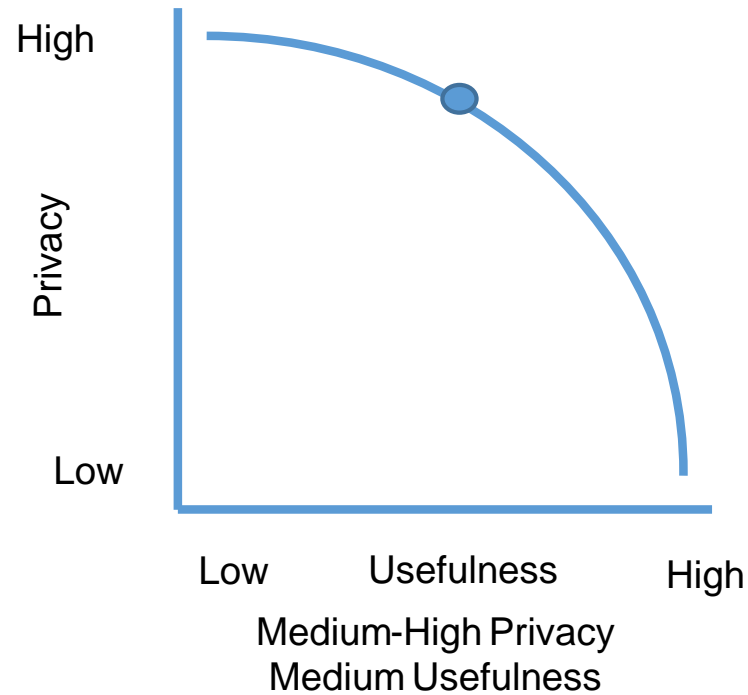
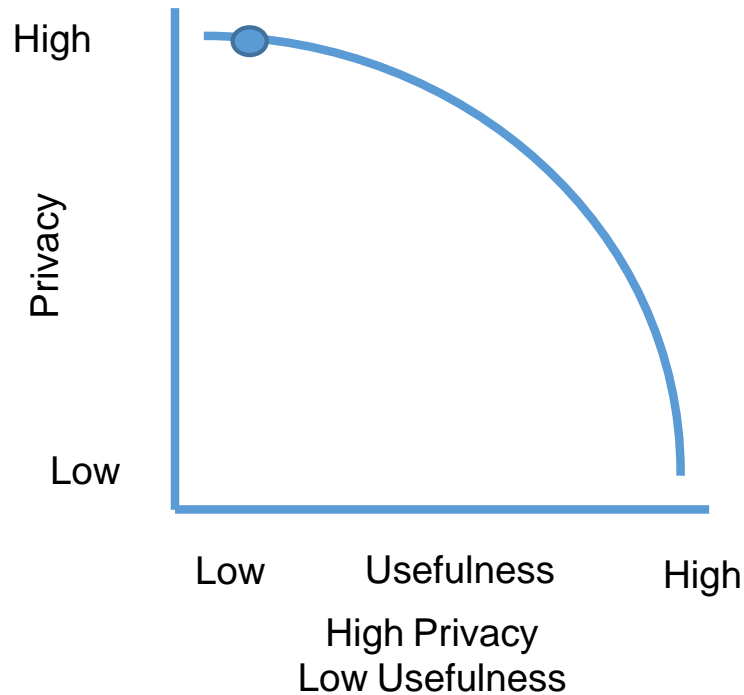


Privacy v. Utility

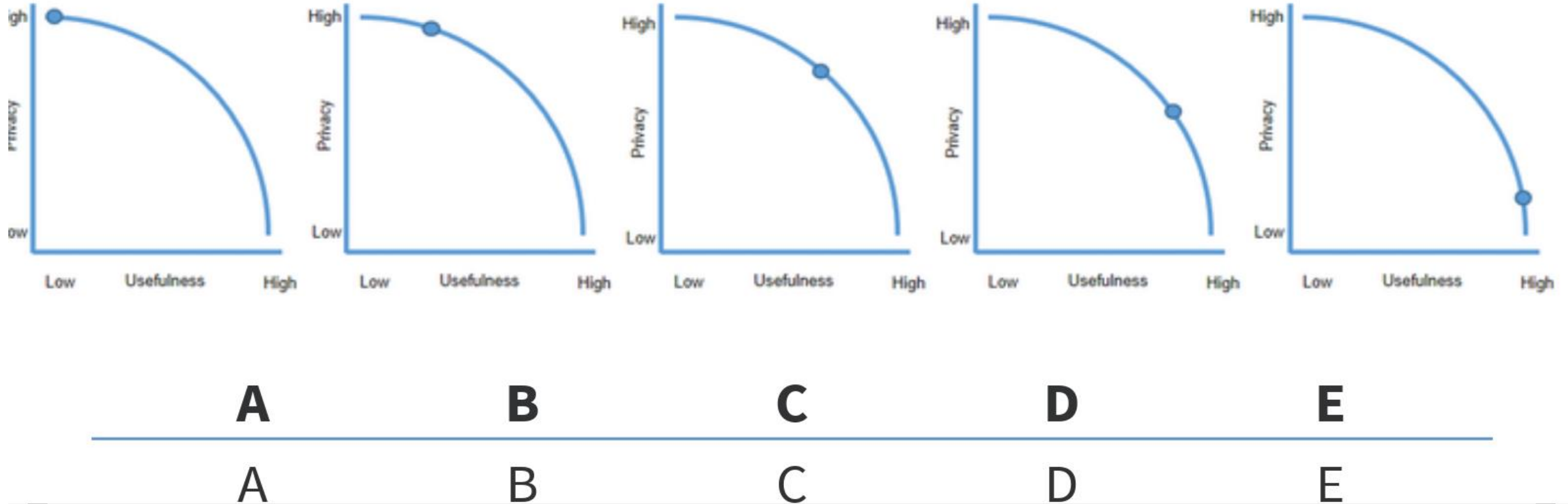


More Ethical Concerns: Privacy v. Utility

- Where would you strike the balance?

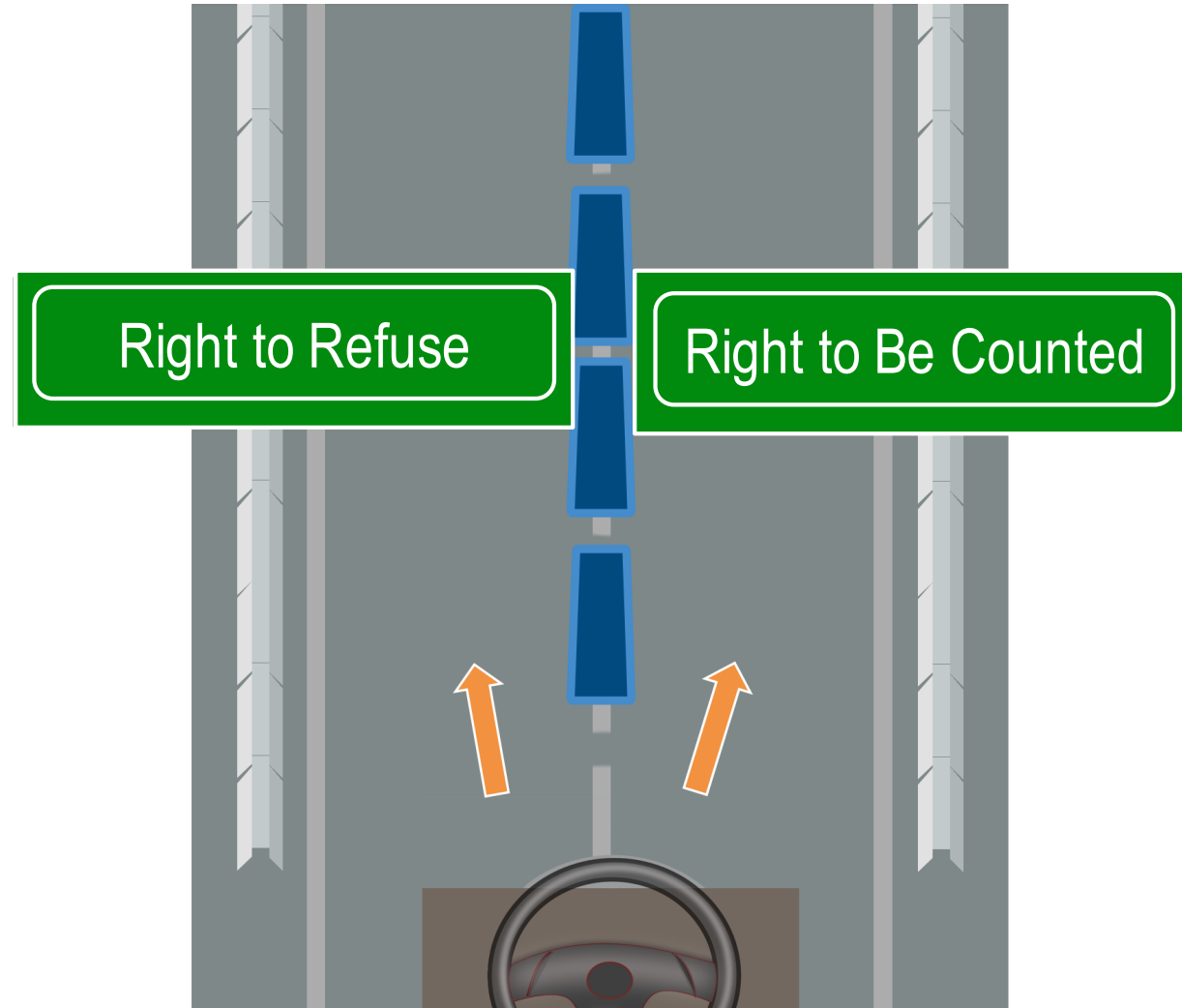


Where is your balance?



How Did You Decide?

- What ethical framework(s) did you apply?





WHO guidelines on ethical issues in public health surveillance

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

- CIOMS International Guidelines for Ethical Review of Epidemiological Studies (1991)
 - Acknowledges the insufficiency of the bioethical model for public health





WHO guidelines on ethical issues in public health surveillance

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

Ethical Data Use for Public Health

- 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.

Obligation to conduct public health surveillance

WHO guidelines on ethical issues in public health surveillance



WHO guidelines on ethical issues in public health surveillance

Ethical Data Use for Public Health

- Guideline 11. Under certain circumstances, **the collection of names or identifiable data is justified.**

Justification for collecting Identifiable data

- 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.**

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.

Obligation to share data with public health

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

Use data for research purposes

WHO guidelines on ethical
issues in public health
surveillance

Belmont Report for Data

- Argument for ethical review of *all* data projects
- *But what ethical framework do we apply?*

Parasidis E, Pike E, McGraw D (2019) A Belmont Report for Health Data. N Engl J Med 380:1493–1495.
<https://doi.org/10.1056/NEJMp1816373>



The NEW ENGLAND
JOURNAL of MEDICINE

Perspective

A Belmont Report for Health Data

Efthimios Parasidis, J.D., M.B.E., Elizabeth Pike, J.D., LL.M., and Deven McGraw, J.D., M.P.H., LL.M.



Article

Metrics

5 References 2 Citing Articles 1 Comment

Comments open through April 24, 2019

LEGAL SAFEGUARDS FOR HEALTH DATA ARE LIMITED IN SCOPE IN THE UNITED States. The Health Insurance Portability and Accountability Act (HIPAA) covers identifiable health information held or transmitted by health plans, health care providers and clearinghouses, and their business associates. However, HIPAA doesn't apply to various other companies or products that regularly store and handle customer health information, including social-media platforms, health and wellness apps, smartphones, life insurers, retailers, credit-card

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



Council of State and Territorial Epidemiologists

Leaders in Applied Public Health Epidemiology

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

Enhanced Guidance - *Hodge, Gostin (2004)*

- **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.”*

Enhanced Guidance (cont.) - *Hodge, Gostin (2004)*

- **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?

Bioethics

- Primary Focus
 - Individual, patient, participant
- Principles
 - Respect for Persons
 - Beneficence
 - Justice

Public Health Ethics

- Primary Focus
 - Population, Community
- Principles
 - Common Good
 - Equity
 - Respect for Persons
 - Good Governance



Big Data Ethics Theorem

- $\lim_{n \rightarrow N} E(x) = ?$
- $\lim_{n \rightarrow N} E(x) = PH_e(x)$
- 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.



Federal Legal Framework	Data Use Exceptions	
	Public Health	Research
42 C.F.R. Part 2	No	No
Child and Adult Care Food Program	No	No
CIPSEA	No	Yes
Confidentiality of certain (VA) medical records	Yes	Yes
VA Medical Quality Assurance Records	Yes	Yes
FERPA	No	Yes ¹
Head Start	No	Yes
HHS Privacy Act Regulations	No	Yes ²
Higher Education Act	No	Yes ³
HIPAA	Yes	Yes
Homeless Management Information Systems	No	Yes
IDEA, Part B	No	Yes ¹
IDEA, Part C	No	Yes ¹
Medicaid Information Safeguards	No	No
NSLP and SBP	No	No
Protection of Pupil Rights Amendment	No	No
SNAP	No	No
Special Milk Program	No	No
Summer Food Service Program	No	No
Title X	No	No
VA Claims Confidentiality Statute	Yes	Yes
WIC Confidentiality Provisions	No	No

Data Use Exceptions for Public Health and Research

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



BIOETHICS FOR EVERY GENERATION

Deliberation and Education in
Health, Science, and Technology

Presidential Commission
for the Study of Bioethical Issues

May 2016

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...

WHO guidelines on ethical issues in public health surveillance

Questions?

schmit@tamu.edu



TEXAS A&M
UNIVERSITY