Ethics of Randomized Evaluations

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Ethics of randomized evaluations

“Parachutes reduce the risk of injury after gravitational challenge, but their effectiveness has not been proved with randomised controlled trials”
Case study: Nurse home visits for mothers

• **Partner and intervention**: The Nurse-Family Partnership (NFP) provides low-income, first-time mothers intensive support through regular home visits from early pregnancy through a child’s 2nd birthday.

• **Sample and strategy**: Randomized at the individual level; almost 6,000 mothers in South Carolina, USA
Case study: Improving learning and education

- **Partner and intervention:** Pratham helps students build foundational skills in reading and math. Students are grouped by learning level rather than age or grade.
  - Several studies with variations in exact intervention or context/location

- **Sample and strategy:** Randomized at the school or village level, in schools and villages in India. Process monitoring and scale-up in many African countries, including Nigeria and Zambia.

TaRL activities taking place in a classroom in Gujarat, India. Photo: Luke Straithmann | J-PAL
Case study: Support for health care super-utilizers

- **Partner and intervention**: The Camden Coalition of Healthcare Providers provides an intensive care transition program to patients with 2+ hospital admissions in 6 months and multiple health or socio-economic challenges.

- **Sample and strategy**: Randomized at the individual level. 800 individuals in Camden, New Jersey, USA
I. Ethics in Research with Human Subjects
II. Respect for Persons
III. Beneficence
IV. Justice
V. Institutional Review Boards
VI. Case study
Ethics in research with human subjects

- Prompted by the Tuskegee Syphilis Experiment, conducted from 1932-1972
  - Enrolled 600 African-American sharecroppers, some of whom had syphilis
  - Researchers promised free medical treatment; delivered only placebos and diagnostics.
  - Did not reveal diagnosis, and actively blocked participants from effective treatment
- Had all the hallmarks of what would now be considered unethical research
  - Deception
  - Absence of informed consent
  - Dubious benefit to society as a whole, much less the study population
Belmont principles

Respect for Persons

Beneficence

Justice

International origins

- International codes and standards related to ethics of research with humans developed after WWII, including:
  - Declaration of Helsinki
  - Nuremberg Code
- These frameworks were also sources for many other countries’ ethics frameworks

Belmont Report itself is a US creation, but the principles are broadly applicable and built off of these prior codes.
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Ethical principles for human subjects research

**Respect for persons**
- Individuals should be treated as *autonomous agents*
  - Capable of making their own decisions

Respect for persons requires that we seek *informed consent*
Respect for persons in human subjects research

Elements of informed consent:

- Information: research purpose, procedures, risks & benefits
  - Do not lie or deceive
- Comprehension: information delivered to facilitate understanding
- Subjects must voluntarily decide to participate in the study
  - No coercion (threats)
  - No undue influence
Respect for persons in human subjects research

Elements of informed consent:

- Information
- Comprehension
- Voluntariness

*Concerns for children, cognitively impaired, ill
*Concerns for prisoners, vulnerable populations

- Persons with diminished autonomy are entitled to additional protection
  
  - Children, individuals with cognitive impairment, or individuals who are very ill may not be capable of deliberation or self-determination
  
  - Prisoners, or individuals vulnerable to manipulation or subject to the authority of research representatives, may not be able to make a truly voluntary decision
Challenges to informed consent

Research is never independent of the social context and history of a given setting
• Potential subjects may be overly optimistic about participation yielding benefits or feel that they must comply
• Recognize power dynamics between study team and target population
• Try to understand expectations of potential subjects

How to document consent: written vs oral consent
• Default is written documentation of informed consent—i.e., a signature or fingerprint
• When might a different process be more protective or respectful?
Send feedback via the Q&A

Include the # of the question you are responding to. Panelists will read out some responses. If comfortable, add your first name and where you’re joining us from.

1. When and how might written documentation of informed consent present a challenge?
2. Under what conditions might we find that seeking informed consent is not necessary, or would itself present an ethical challenge?
Case study: Support for super-utilizers

**Background:**
- Intake, consent, and random assignment conducted at bedside in the hospital.

**Considerations:**
- Ensuring comprehension and voluntariness

Cooper University Hospital in Camden, N.J. NYTimes: “These Patients are Hard to Treat,” Mel Evans/Associated Press
Case study: Education interventions

Background:
• Random assignment is at the community or school level.

Considerations:
• Who should provide consent?
• Who is impacted?
• Which activities require consent?

J-PAL blog: “Zambia to scale Teaching at the Right Level program to 1,800 schools”
Questions & Comments

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Beneficence

- **Do no harm**
  - Do not administer a treatment that is known to be harmful
  - Do not withhold a benefit that would otherwise be available
  - Rule becomes difficult to apply when there is ‘genuine uncertainty’ about an intervention’s effectiveness
Beneficence in human subjects research

Minimize Risks. These may include...

• Adverse effects of the intervention
• Psychological or emotional burden of responding to sensitive survey questions
• Breach of confidentiality
• Breach of privacy
Beneficence and risk: Privacy

- What might you infer about an individual who stepped into or out of this van?
- What risk of harm is associated?
Beneficence in human subjects research

Minimize Risks. These may include...

- Adverse effects of the intervention
- Psychological or emotional burden of responding to sensitive survey questions
- Breach of confidentiality
- Breach of privacy
- Risks to study personnel
Research can impose risks to research staff including enumerator and those conducting random assignment.

- Secondary traumatization, compassion fatigue, or burnout
- Dangerous work environment
  - Transportation
  - Violence
Beneficence in human subjects research

Minimize Risks. These may include...

• Adverse effects of the intervention
• Psychological or emotional burden of responding to sensitive survey questions
• Breach of confidentiality
• Breach of privacy
• Risks to study personnel

Plan in advance to minimize and mitigate risks before bad things happen.
Beneficence in human subjects research

Maximize Benefits.
- Typically, the “anticipated benefit to society in the form of knowledge to be gained from the research.”

- Learn what works and scale up or down as appropriate
  - Funding
  - Disseminating results

Case study: Improving education. Pratham’s “teaching at the right level” approach has been scaled up to improve learning opportunities for over 60 million students in India and Africa.
In a randomized evaluation, the Control or Comparison group is not offered the intervention offered to the Treatment group. That doesn’t mean they are denied services otherwise due.

**Standard of care:** Comparison group receives the status quo; is not denied access to care to which they are entitled

- **Support for super-utilizers:** Comparison group eligible for standard care from hospital (discharge plan)
- **Home visits for mothers:** Comparison group received a list of relevant resources and services (also received by treatment group)
Randomized evaluations can be designed such that we are not withholding treatments that are already available, and can be designed to ensure those most in need always receive the treatment.

- Encouragement design
- Expand eligibility
Case study: Increasing SNAP take-up
Case study: Increasing SNAP take-up

Treatment Group

Control Group
Encouragement design

Sign up!

Treatment Group

Control Group
Encouragement design

Treatment Group

Control Group

3/4\textsuperscript{ths} take-up

1/4\textsuperscript{th} take-up
Eligibility cut-off or targeting criteria
Eligibility cut-off or targeting criteria

- Eligible
- Ineligible

People vs Income
Expand eligibility and randomize among the newly eligible
Expand eligibility and randomize among the newly eligible
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**Justice**
- Who benefits from research? Who bears its burdens?
- Fairness in the allocation of risks and benefits
- No one group should bear all the risk while another reaps all the benefits

→ Will the target population benefit from subsequent applications of the research?
“Injustice may appear in the selection of subjects, even if individual subjects are selected fairly by investigators and treated fairly in the course of research. Thus injustice arises from social, racial, sexual and cultural biases institutionalized in society. Thus, even if individual researchers are treating their research subjects fairly, and even if IRBs are taking care to assure that subjects are selected fairly within a particular institution, unjust social patterns may nevertheless appear in the overall distribution of the burdens and benefits of research. Although individual institutions or investigators may not be able to resolve a problem that is pervasive in their social setting, they can consider distributive justice in selecting research subjects.”
Justice and randomized evaluations

Selection of the sample, subjects, and treatment recipients

Random sampling from target population → Equal distribution of burdens/benefits of being included the research → Random assignment of sample into treatment and control → Equal distribution of burdens/benefits from treatment/intervention
If resources are scarce and in high demand, randomization may be a fair way to allocate resources, even in the absence of a study.

• How should we select among the eligible?
• “First-come, first-serve” may not ensure that those who are most in need would have access

What if we want to target resources to those most in need?

• Do we know how best to target program?
• Randomization design: create criterion for ‘need,’ admit everyone below some threshold and randomize everyone above.
Admit everyone below threshold, randomize above
Admit everyone below threshold, randomize above.
Admit everyone below threshold, randomize above
Admit everyone below threshold, randomize above
Justice and representativeness

Study population should represent the population experiencing the problem, and the population that stands to benefit

• Convenient, manipulable: not a valid justification for sample selection

• Sub-populations or those who are difficult to reach:
  – Don't exclude unless they do not stand to benefit from the research
  – Important to examine heterogeneous effects

It may be more costly to do this!
Justice and representativeness

In the race for coronavirus vaccines, don’t leave pregnant women behind

By CARLEIGH KRUBINER, RUTH R. FADEN, and RUTH A. KARRON / FEBRUARY 25, 2020
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Researchers have primary responsibility for ensuring an ethical study.

Many countries, institutions, and funders also require that research involving human subjects be overseen by an independent body that protects the rights and welfare of those subjects.

Ethics review
Ethics review

• Institutional Review Board (IRB), Research Ethics Committees (RECs), etc
• Some operate at the institutional level
  – universities, hospitals, research orgs
• Others at the regional or national levels
• If you are doing research in another country, need approval by review boards in home institution and in study region
IRBs review study protocol, risk assessment and all study-related documents

- Research objectives and purpose
- Research methods
- All materials subjects come in contact with:
  - questionnaires, recruitment flyers, apps, experimental tools, etc
- Study participants
  - Sample selection method, number of subjects
- Recruitment process and informed consent
- Assessment of risk (and justification, if applicable)
- Data confidentiality and participant privacy
Thank you! More Questions?
Credits

• Created by Anja Sautmann, based partly on slides by Lindsey Shaughnessy, Marc Shotland, Rohit Naimpally, and others. The original presentation benefited from conversations with Laura Costica, Laura Feeney, and Nilmini Herath. Laura Costica shared her IRB talk and inspired several slides.
• Updated by Laura Feeney with assistance from Stephanie Lin and Clare Sachsse.
Related research resources include…

References on ethic and principles

• The Markkula Center for Applied Ethics, Santa Clara University, specifically: https://www.scu.edu/ethics/ethics-resources/ethical-decision-making/a-framework-for-ethical-decision-making/
• The Stanford Encyclopedia of Philosophy, specifically: https://plato.stanford.edu/entries/capability-approach/
• Laura Feeney/J-PAL’s resources on ethics and practicalities of informed consent: “Define intake and consent process”
• Ethics and communication: http://blogs.3ieimpact.org/not-lost-translation-ethical-research-communication-inform-decision-making/
References on prisoners as subjects


• Allen M Hornblum (1997): They were cheap and available: prisoners as research subjects in twentieth century America.

• Common Rule regulations on research with prisoners as subjects: Subpart C, Title 45, Part 46, of the Code of Federal Regulations.

• HHS FAQs on research involving prisoners as subjects
References on compensation


