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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"

- Smith and Pell (2003)

"Beneficiaries in humanitarian settings are often extremely vulnerable.

In such contexts, critical starting questions are: Should research be conducted at all? If yes, is an RCT appropriate?"

- Quattrochi et al. (2020)

Source: British Medical Journal (2003)

Case study: Comparing cash and mobile transfers

- **Research question:** How to most effectively deliver critical cash transfers to drought-stricken farmers.
- **Setting and partner**: In response to drought and food crisis in Niger, Concern Worldwide provided cash transfers to 10,000 households.
- **Intervention**: Eligible households in 96 villages randomized to receive:
  - Cash transfer
  - Mobile transfer

Photo: Catay | Shutterstock.com

"Payment Mechanisms and Anti-Poverty Programs: Evidence from a Mobile Money Cash Transfer Experiment in Niger," by Aker et al. (2016), *Economic Development and Cultural Change*.

Case study: Building inter-ethnic cohesion in schools

- **Research question**: The impact of a perspective-taking curriculum on students' anti-social behaviors and the integration of refugee students.

- **Setting and partner**: The Turkish Ministry of Education implemented the curriculum in two provinces on the Turkey-Syria border.

- **Intervention:** 7,000 students in 80 primary schools randomized at the school level:
  - Treatment: perspective-taking curriculum
  - Comparison: other extracurricular programs

Photo: Sule Alan

"Building Inter-Ethnic Cohesion in Schools: An Intervention on Perspective Taking," by Alan et al. (2020), HCEO Working Paper Series

I. Ethics in Research with Human Subjects
II. Respect for Persons
III. Beneficence
IV. Justice
V. Institutional Review Boards

Ethics in research with human subjects

- "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research", 1978
- Prompted by the Tuskegee Syphilis Experiment
  - Study from 1932 to 1972 to examine the effects of untreated syphilis
  - 600 African-American sharecroppers, some of whom had syphilis
  - Researchers promised free medical treatment; delivered only placebos and diagnostics
- 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
  - **Conducted on a vulnerable population without research justification**

Belmont principles

Respect for Persons

Beneficence

Justice

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978. *The Belmont Report*

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

I. Ethics in Research with Human Subjects

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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
  - Not everyone is capable of deliberation or self-determination
    - Illness, young age, or circumstances may restrict self-determination
    - Persons with diminished autonomy are entitled to additional protection
      - Prisoners
      - Refugees
      - Economically disadvantaged

- 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, and the opportunity to ask questions
- Comprehension
  - Information delivered to facilitate understanding
- Voluntary participation
  - No coercion (threats) or undue influence

Respect for persons in human subjects research

Elements of informed consent:

- Persons with diminished autonomy are entitled to additional protection
  - Children, individuals with cognitive impairment may not be capable of deliberation or comprehension
  - Prisoners may be vulnerable to manipulation or coercion
  - Refugees 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 potential benefits
- Recognize power dynamics between study team and target population

How to document consent

- Default is often written documentation of informed consent—i.e., a signature or fingerprint
- Consider situations where a different process be more protective or respectful

Case study: Cash and mobile money transfers

Background:

- Random assignment at the village level
- Program delivery and consent at the household level

Considerations:

- Consent process with low levels of literacy
- Ensuring comprehension and voluntariness

Photo: Intersect

Case study: Building inter-ethnic cohesion in schools

Background:

- Random assignment at the school level
- Curriculum implemented at the classroom level

Considerations:

- Who should provide consent?
- Who is impacted?
- Which activities require consent?

Photo: Sule Alan

Breakout discussion: Respect for persons

1. How can we ensure comprehension and voluntariness in the informed consent process in settings with low levels of literacy such as Niger?
2. Consider the case study on building inter-ethnic cohesion in schools.
   - Who should provide consent?
   - Who is impacted by the research?
   - What activities require consent?
3. Under what conditions might we find that seeking informed consent is not necessary, or would itself present an ethical challenge?
   - Alternatively, when may informed consent not be sufficient?

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Ethical principles for human subjects research

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
- **Maximize possible benefits and minimize risks**
  - Minimize the risks to *subjects*
  - Maximize the benefits to *society*
    - Findings must be *credible*
    - Findings must be *adequately disseminated*
    - There should be some *uncertainty* about the intervention's benefit (and risks)

Beneficence in human subjects research

Minimize Risks. Consider:

- 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** they materialize.

Beneficence in human subjects research

Maximize Benefits.

- Knowledge gains from the research are typically a key benefit to the study
- Findings must be *credible*
- Findings should be as *actionable* as possible
  - Inform concrete policy questions and decisions to scale up or down
  - Comparative cost-effectiveness

Case study: Building inter-ethnic cohesion. The Turkish Ministry of Education intends to scale-up the program upon positive results.

Beneficence and risk-benefit assessment

- Demonstrate why benefits justify the risks for the inclusion of vulnerable populations in particular, taking into account:
  - Circumstances of the specific population
  - Type and extent of risks
  - Type and extent of anticipated benefits

Beneficence and the comparison group

In a randomized evaluation, the comparison group is not offered the treatment. 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

- **Cash transfers**: No pure comparison; all participants receive a transfer (two different delivery mechanisms)
- **Inter-ethnic cohesion**: Comparison group received other extracurricular programming

Beneficence and evaluation design

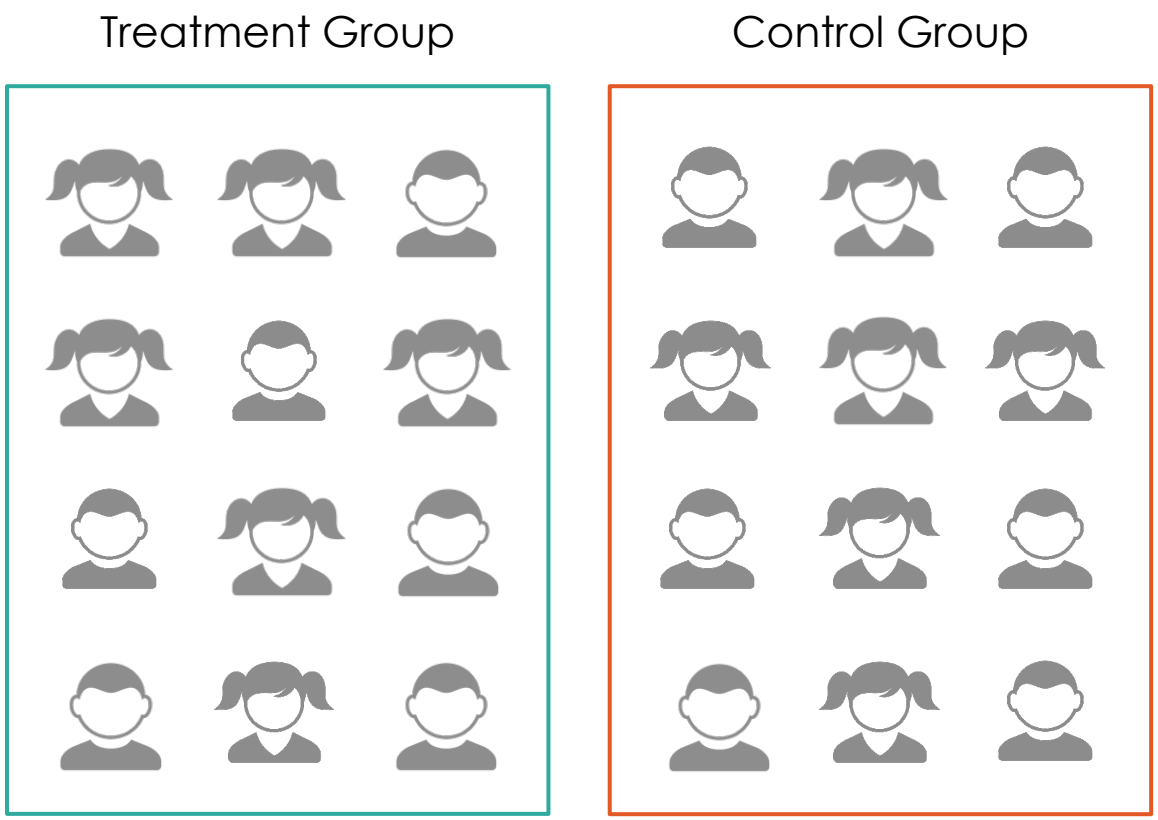
Randomized evaluations can be designed such that we are not withholding treatments that are already available, and can be designed to ensure those most in need always receive the treatment.

- Encouragement design
- Expand eligibility
- Phase-in design

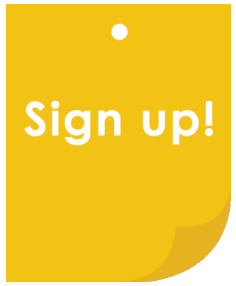
Example: Increasing food subsidy take-up

Photo: TNP2K commercial about the social protection identification card

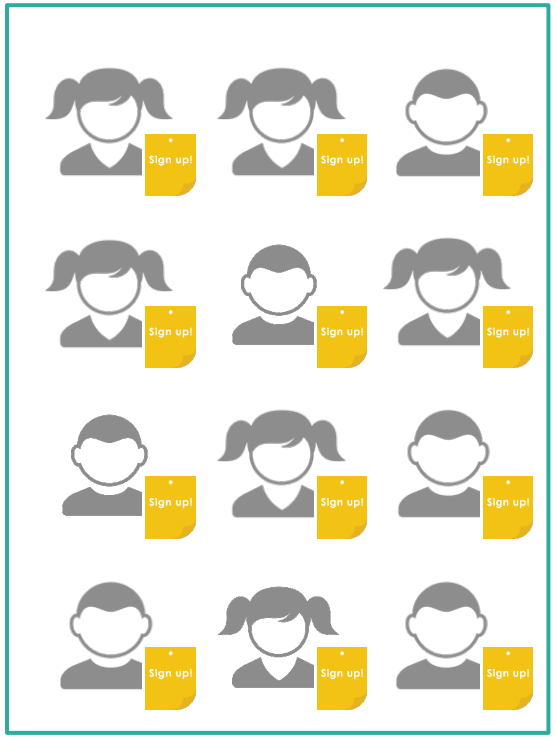
Example: Increasing food subsidy take-up



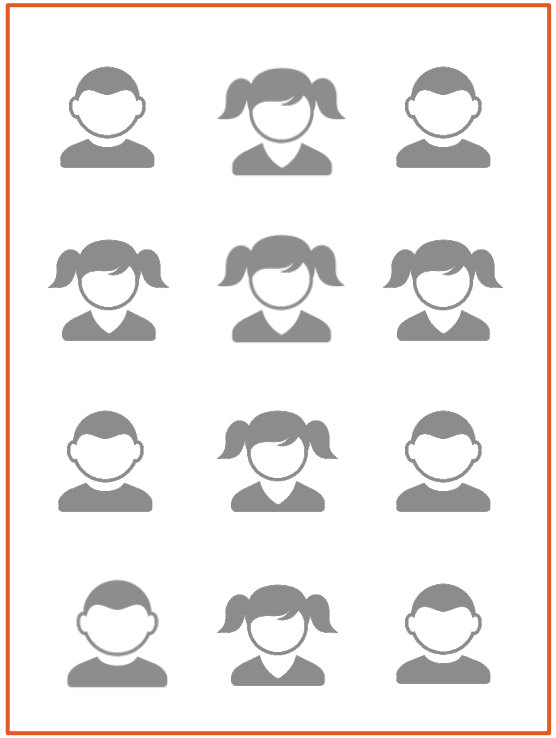
Encouragement design



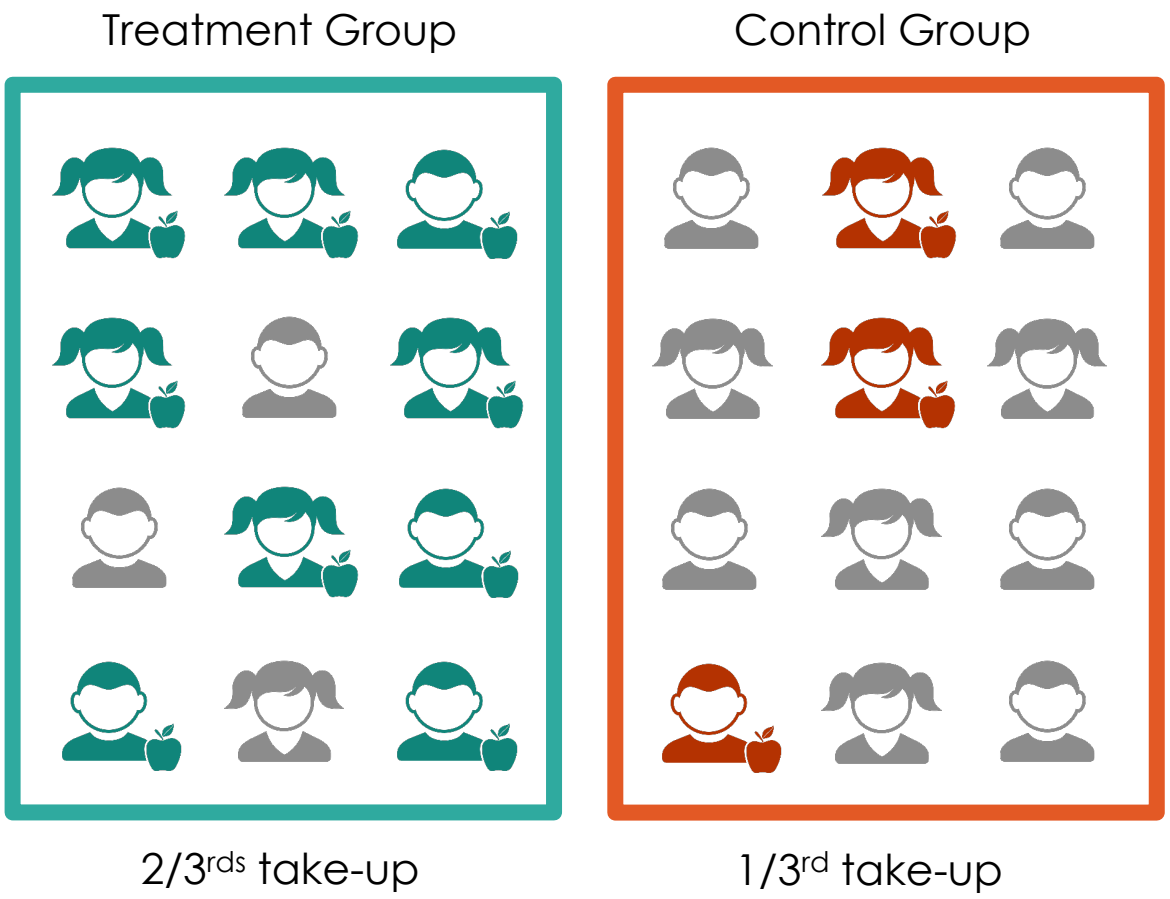
Treatment Group



Control Group



Encouragement design



Breakout discussion: Beneficence

1. Consider our two case study examples. What considerations would you use to determine whether the study should happen in the first place?
   - What would you do if the risk-reward calculation shifted in the middle of the study (e.g., the program is found to be more dangerous than originally thought)?
2. Can we justify having a control group that does not receive any form of the program? Compare the choices of treatment and comparison groups in the two case studies presented.
3. What steps can we take to minimize risk in practice?

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Ethical principles for human subjects research

Justice

- Who benefits from research? Who bears its burdens?
- Fairness in the allocation of risks and benefits between different groups of people
- 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?

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
  - Vulnerable population should not be included only for "administrative convenience"

- 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

FIRST OPINION

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

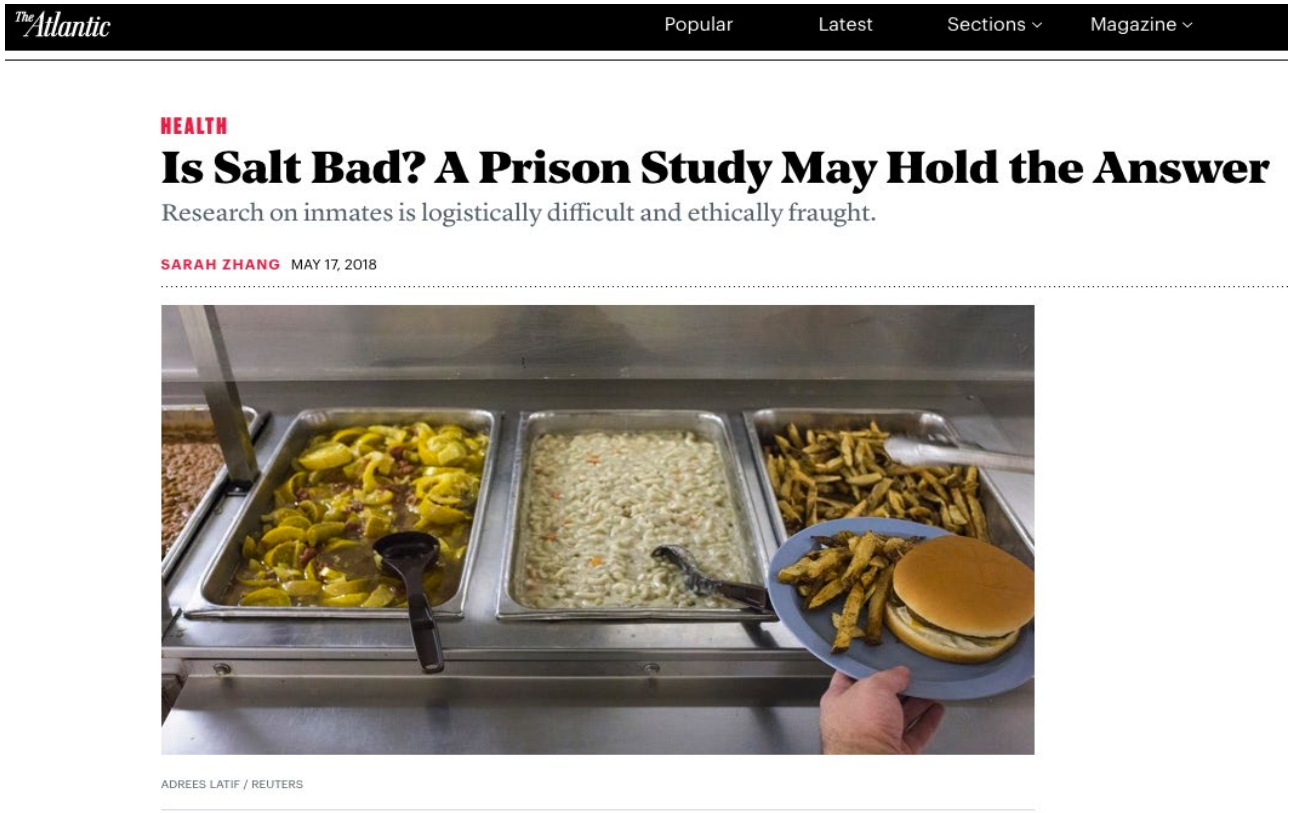
By CARLEIGH KRUBINER, RUTH R. FADEN, *and* RUTH A. KARRON / FEBRUARY 25, 2020

ADOBE

[Stat News article]

Example: Violation of the justice principle

The ethics of using prisoners to test health outcomes of low-salt diets.



The Atlantic Popular Latest Sections Magazine

HEALTH

Is Salt Bad? A Prison Study May Hold the Answer

Research on inmates is logistically difficult and ethically fraught.

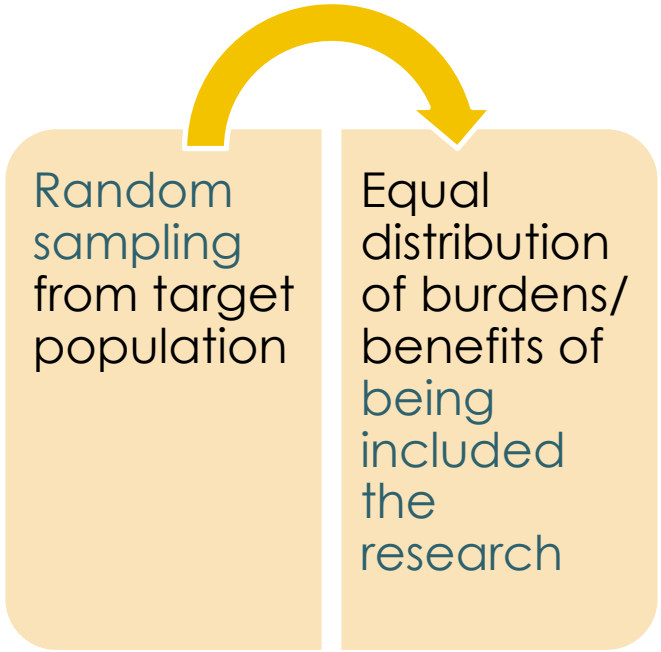
SARAH ZHANG MAY 17, 2018

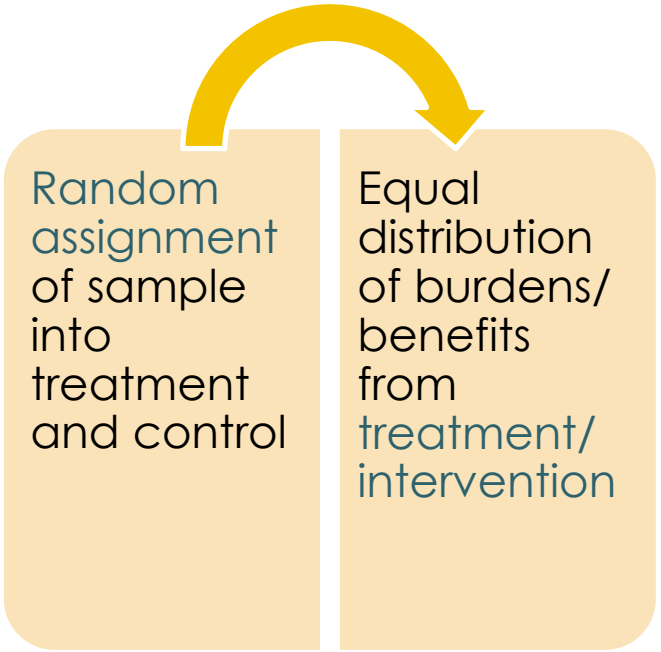
ADREES LATIF / REUTERS

[Atlantic article]

Justice and randomized evaluations

Selection of the sample, subjects, and treatment recipients





Justice and allocation of resources

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 have access
  - Randomization design: in situations with initial capacity constraints, a phase-in design may allow for greater justice

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

Breakout discussion: Justice

1. Consider randomization and a just selection of study participants for our two case studies. What concerns surrounding justice will randomization not be able to address?
2. Does justice imply an ethical obligation to share research findings with study participants and other relevant communities?

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Ethics review

- Researchers have primary responsibility for ensuring an ethical study, but they are also accountable to Institutional Review Boards
  - Countries, institutions, and funders may require research with human subjects be overseen by an independent body that protects the rights and welfare of subjects
  - Some operate at the institutional level, others at regional or national levels
- Ethical conduct of research is at the core of J-PAL's mission
  - J-PAL Research Protocols: all projects must obtain IRB approval
  - Human Subjects Research training for all research staff

IRB review process

- Research objectives, purpose, and 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
- Data confidentiality and participant privacy
- Assessment of risk (and justification, if applicable)

Photo: Shutterstock

Research ethics and research quality

- IRB review cannot substitute for researchers' responsibility to consider the ethical implications of their research and ask themselves as well as members of the communities they work in if they are comfortable with their research protocols
  - This involves carefully thinking through the research design to anticipate how subjects will feel about the research (and those carrying it out)
  - A study that is ethical in its study procedures and implementation approach is often more credible

Thank you! 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.

References on ethics and principles

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- 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/
- Lay description of research ethics: How to make field experiments more ethical, Washington Post, https://www.washingtonpost.com/news/monkey-cage/wp/2014/11/02/how-to-make-field-experiments-more-ethical/?noredirect=on&utm_term=.21c1d339fd4f
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Case study references

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- J-PAL Evaluation Summary: "Comparing Cash and Mobile Transfers in Niger"
- "Building Inter-Ethnic Cohesion in Schools: An Intervention on Perspective Taking" (Alan et al. 2020)
- J-PAL Evaluation Summary: "Teaching Students Perspective-taking to Mitigate Social Exclusion of Refugee Children in Turkey"
- "Contributions of Experimental Approaches to Development and Poverty Alleviation: Field Experiments and Humanitarian Assistance" (Quattrochi 2020)

References on prisoners as subjects

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- Paul Christopher and Michael D. Stein (March 19 2019). "Should a Prison Salt Study be Federally Funded?" Annals of Internal Medicine.
- 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

Related research resources

- Designing an intake and informed consent process: https://www.povertyactionlab.org/resource/define-intake-and-consent-process
- Data Security: https://www.povertyactionlab.org/resource/data-security-procedures-researchers