ETHICAL CONSIDERATIONS IN THE CONDUCT OF DISSEMINATION AND IMPLEMENTATION HEALTH RESEARCH

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Implementation Science Seminar
July 18, 2017
Learning Objectives

1. Discuss application of ethical principles in dissemination and implementation (D & I) science research and contrast their application to clinical research.

2. Elicit feedback to inform specific topics and content for future training seminars focused on ethical considerations in D & I research.
Definitions

◦ **Clinical Research**: focuses on establishing the evidence for a particular intervention and conducted under controlled circumstances with a well-defined participant cohort.
  ◦ Example: ?

◦ **Implementation Research**: focuses on identifying the best process to implement and sustainably scale-up research evidence through consideration of social and contextual factors, the process of implementation and the outcomes of implementation.
  ◦ Example: ?
Case Study: CPRT

- Teacher use data from clinical training informed research questions
- Teacher feedback on intervention components informed adaptation (Funding cycle #1)
  - Systematic adaptation of components
  - Pilot testing of adaptation
- Effectiveness trial of adapted intervention (Funding cycle #2)
  - Proposal included only clinical aims, but implementation data was added
  - Outcomes indicate additional teacher adaptation and training needs
- Teacher and paraprofessional use data informed research questions (Funding cycle #3)
  - Systematic identification of key components
  - Development of web-based distance training model and resources

U.S. Department of Education Grants: R324A130349, R324B07002
Differences Between Clinical And Implementation Research That Impact Application Of Ethical Principles

<table>
<thead>
<tr>
<th>Domain</th>
<th>Clinical research</th>
<th>Implementation research</th>
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<tbody>
<tr>
<td>Research participants</td>
<td>Individuals</td>
<td>Countries, institutions, communities, and individuals</td>
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<tr>
<td>Informed consent</td>
<td>Informed consent by competent individuals, assent by minors, and consent by legally authorized representatives</td>
<td>Consent may be difficult to obtain in cluster randomized trial design. There may be a need for a two level consent—consent for randomization from gatekeepers and consent for participation at the individual level. Sometimes individual consent may not be feasible. However, gatekeeper consent does not replace the need for individual consent. Ethical committee should oversee the informed consent requirement and process</td>
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<tr>
<td>Equipose</td>
<td>Clinical equipoise</td>
<td>Clinical as well as contextual equipoise (genuine uncertainty that the implementation will work in a new context as well as whether the implementation package will work at all)</td>
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<tr>
<td>Pre-requisites</td>
<td>Understanding of disease pathophysiology</td>
<td>Identification of population health needs</td>
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<td></td>
<td>Intervention aimed at disease-specific management</td>
<td>Understanding relative priority of need for intervention within local context</td>
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<td></td>
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<td>Community engagement to understand community needs; ensure scalability, and sustainability</td>
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<td>Research conditions</td>
<td>Generally controlled research environment</td>
<td>Real-life or pragmatic research environment</td>
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<tr>
<td>Research designs</td>
<td>Cross-sectional, case-control studies, Cohort studies, randomized clinical trials</td>
<td>Cluster randomized trials</td>
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<td></td>
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<td>Pragmatic, mixed methods, effectiveness implementation hybrid designs, participatory action research, quasi-experimental design, realist review</td>
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<tr>
<td>Integration within health system</td>
<td>Often, there is no a priori plan for health system integration. Findings of clinical research go through IR before integration into health system</td>
<td>R has a strong health system strengthening focus. It creates horizontal integration into the health system. There is an ethical imperative for health system integration</td>
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<td>Predominant research disciplines</td>
<td>Physiology, genetics, biochemistry, and other basic sciences, epidemiology, clinical medicine</td>
<td>Anthropology, Economics, Epidemiology, Political science, Public health, Sociology</td>
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## Differences Between Clinical And Implementation Research That Impact Application Of Ethical Principles

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<tr>
<th>Control groups</th>
<th>In most epidemiological designs, control groups are required. But some phase 1 clinical trials and observational studies may not require control groups.</th>
<th>Having a no intervention control group may not be acceptable. Alternative designs of quasi-experimental studies do not require a control group.</th>
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<tbody>
<tr>
<td>Boundary between research and clinical care</td>
<td>This boundary is usually clear, but may be unclear in case of therapeutic misconception especially in cancer trials.</td>
<td>Is often unclear, because the intervention is of proven efficacy.</td>
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<tr>
<td>Types of research question</td>
<td>Efficacy and safety of a therapeutic strategy in the individual.</td>
<td>Operationalization of an intervention in local context. Implementation of an intervention in local context prior to scale-up.</td>
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<td>Anticipated outcomes</td>
<td>Well-defined hypothesis at the beginning of the clinical research. Expected outcomes clearly stated.</td>
<td>Multifaceted holistic impact on health systems functioning with regard to intervention tested. Sometimes outcomes may be unexpected.</td>
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<tr>
<td>Risks assumed by:</td>
<td>Mostly, the risks are for the study participants. However, families and communities may also be affected in specific contexts.</td>
<td>Usually population level risks. Moreover, the people getting the benefits and people suffering the risks may be different.</td>
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<td>Benefits accrued by:</td>
<td>Benefits accrue to the participants, the community. The research finding may be a common good.</td>
<td>Individuals, communities, health system, institutions may benefit. The research findings may be common good. The people accruing benefits may be different from those who suffer risks.</td>
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<td>Generalizability</td>
<td>Generalizability is sometimes possible in multicentric and well-sampled studies, however most studies are specific to the target populations.</td>
<td>Generalizability may be limited by contextual factors. However, findings may be generalizable to similar contexts.</td>
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<td>Social justice implications</td>
<td>Social justice is usually not a primary consideration. However, justice considerations are required in selection of research participants. Research on vulnerable participants is often contentious because of compromised autonomy and other logistics.</td>
<td>Social justice considerations are primary. Working with vulnerable groups essential to understand implementation issues in these groups so that the intervention can reach them.</td>
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What are some of the ethical considerations specific to your project?
Ethical Considerations in Phases of Implementation Research

Planning Phase
- Responsiveness to local needs and priorities
- Equipose
- Study design
- Stakeholder and Community Engagement
- Balance between risks and benefits

Implementation Phase
- Autonomy and Informed Consent
- Privacy and Confidentiality
- Standard of Care
- Ancillary Care
- Community/Health System Empowerment

Post-research Phase
- Dissemination of research findings
- Data ownership
- Translating findings into public health action
- Scalability and Sustainability
- Benefit sharing
# Ethical Considerations in Implementation Research Designs

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<tr>
<th>IR design</th>
<th>Features</th>
<th>Example</th>
<th>Ethical concerns</th>
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| Cluster randomized trials (group randomized, place-based, community wide intervention trials) | - Random allocation of groups or "clusters" to study arms and outcomes are measured in individual subjects and at community level | - Randomization of clusters of obstetrics unit staff to education on hand washing or usual practice, measurement of rates of puerperal sepsis in women delivering at study clinics | - Different units of intervention and outcomes measurement  
- Consent before and after randomization, whom to consent?  
- Choice of gatekeepers  
- No opt-out option within cluster  
- Risk benefit balance  
- Ethics of randomization to known intervention, equipoise,  
- Identification of vulnerable groups |
| Effectiveness-Implementation hybrid trials | - Assess both effectiveness and implementation strategy simultaneously  
- Identify intervention—implementation interactions | - Evaluate impact of ITN on reduction of malaria and assess robustness of availability and uptake of ITNs in the community | - The trade-off between the scientific rigor required for effectiveness assessment and the realistic contextual considerations required for implementation is an important ethical consideration |
| Mixed-methods research | - Use of both qualitative and quantitative methods  
- Understands various perspectives  
- Rationales: "participant enrichment", "instrument validity", implementation validity", "meaning enhancement" | - Integration of HIV and TB management in single clinics—patient experience (qualitative) and adherence (quantitative) | - The trade-off between the scientific rigor required for quantitative methods and the realistic contextual considerations required for the qualitative component |
| Participatory action research | - Research question, design, and data collection in a participative manner by the research participants  
- "Bottom-up" approach | - Peer support groups to improve adherence to ARV in HIV+ subjects | - There is a need for community engagement to ensure responsiveness, sustainability, and scalability |
| Pragmatic trials | - Effects of intervention in routine practice  
- Maximise variability of settings, practitioners, patients | - Introduction of community health workers for home management of malaria | - There may be concerns of standards of care and ancillary care, which in pragmatic conditions may be ethically debatable |
| Quasi-experimental study | - Real-life conditions  
- With or without control group  
No randomization | - Open label demonstration project of effectiveness of self-reported use of pre-exposure prophylaxis for HIV | - There is a concern regarding scientific rigor of the research |
| Realist view | - Analysis of how and why an intervention works in a context combining theory and empirical evidence | - Integration of traditional healers into home management of malaria strategies | - Community engagement is of utmost importance to retain cultural and contextual sensitivity |
Future D & I Ethics Seminars

**Proposed Topics**

1. Training community providers
2. Community partnerships and collaborative research projects
3. Disseminating research findings to the community
4. Translating research findings to policy change
5. Working with vulnerable populations
   a) Refugees
   b) Indigenous populations
   c) Undocumented immigrants
   d) At-risk (HIV, substance use)
6. Global research/LMIC
7. E-health/m-health
8. **OTHERS?**

**Proposed Format**

- Quarterly or biannual presentations
  - How often?
- Format:
  - Consultation?
  - Didactic (expert presenters)?
- Include both local/national/international researchers and/or community partners pursuing services and/or D & I projects
  - Interest in presenting?
THANK YOU!