Balancing benefits and risks of harm in an intimate partner violence and HIV prevention trial: An ethical case study from rural Uganda

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Outline

- Background of Project
- Introduction to Rakai Case Study
- Context of Public Health and Research Ethics
- Ethical Trade-offs in Rakai
- Open Discussion
The relationship between IPV and HIV

- Intimate partner violence (IPV) increases women’s risk for HIV infection
- HIV-infection increases women’s risk for IPV
- Definition of IPV

Any behavior by a man or a woman within an intimate relationship that causes physical, sexual or psychological harm to those in the relationship. (World Health Organization, [www.who.int](http://www.who.int))
Framework

The relationship between IPV and HIV

Intimate partner violence
- Physical IPV
- Sexual IPV*
- Threats of physical or sexual IPV
- Emotional IPV
*includes marital rape

Risky sex practices
- Multiple lifetime partners
- Concurrent sex partners
- Sex with drugs/alcohol
- Early sexual debut

Compromised self-protection
- No/low condom use
- Lack of choice about sex (frequency/type)
- Unable to communicate openly with sex partner(s)

More risky sex partners
- More likely to have HIV/STIs
- More sexual risk taking – including multiple partners
- More controlling/violent

HIV infection

1-way solid arrow denotes direct link between IPV and HIV
2-way dotted arrow denotes indirect link between IPV and HIV

HIV testing & treatment
- Requesting HIV test
- Getting HIV test
- Disclosing results
- Accessing treatment

Unequal gender norms • Patriarchy • Women’s unequal access to land & other resources • Lack of education opportunities for girls • Divorce restrictions for women • Lack of women’s solidarity or work groups • Low political power for women • Low/no law protecting women from IPV

Contextual Variables
The process of investigating and “treating” people experiencing IPV and/or HIV involves risks that often exceed those inherent to other types of human subjects research.

Focusing here on ethical challenges of violence research/practice
Ethical Challenges in IPV Research

- **Methodological constraints**
  - Under-reporting of abuse
  - Question format does not correctly measure IPV

- **Safety planning difficult due to:**
  - No existing violence related resources
  - Culturally inappropriate to seek help for “private matter”

- **Resource-poor settings and reduced capacity**
  - Unable to pay for needed services
  - Resources not available to train health/research personnel to ask about violence
PUTTING WOMEN FIRST:
Ethical and Safety Recommendations for Research on Domestic Violence Against Women

Accessed from:
Recommendations (1)

1. The safety of respondents and the research team is paramount.
2. Prevalence studies need to be methodologically sound and build upon current research to minimize under-reporting of violence.
3. Protecting confidentiality is essential to ensure both women’s safety and data quality.
4. All researchers should be carefully selected and receive specialized training and ongoing support.
Recommendations (2)

5. Study design must include actions to reduce any possible distress caused to the participants by the research.

6. Fieldworkers should be trained to refer women to available local services. Where few resources exist, the study should create short-term support mechanisms.

7. Findings should be properly interpreted and used to advance policy and intervention development.

8. Violence questions should only be incorporated into surveys designed for other purposes when ethical and methodological requirements can be met.
ETHICAL CASE STUDY

Setting: Rakai District, Uganda
Background: IPV and HIV in Rakai

- **Intimate partner violence**
  
<table>
<thead>
<tr>
<th>IPV type</th>
<th>Lifetime</th>
<th>Past year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical</td>
<td>30%</td>
<td>20%</td>
</tr>
<tr>
<td>Sexual</td>
<td>24%</td>
<td>14.5%</td>
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</tbody>
</table>

- **HIV prevalence**
  
  - 16% in women; 12% in men

- **Links between IPV and HIV**
  
  - Women whose 1st sex involved force were more likely to acquire HIV ($aIRR = 1.59, 95\% CI: 1.06-2.36$)
  
  - HIV prevalence higher found in women who reported sexual violence and alcohol use ($aOR = 1.79, 95\% CI: 1.25-2.56$)
Combination IPV and HIV prevention intervention trial, Rakai, Uganda

2005 – 2009

The Safe Homes and Respect for Everyone (SHARE) Violence Prevention Project was integrated into Rakai Health Sciences Program, a reproductive health and HIV/AIDS research and service provision collaborative, rural Uganda.
Intervention Trial Design

- RCT to assess impact of combination prevention intervention on IPV, sexual risk behaviors and HIV incidence
- Rakai Community Cohort Survey (RCCS)
  - Conducted in 47-50 communities organized in 11 clusters
  - All consenting adults aged 15-49 years
  - Annual surveys and biological samples
- Randomization scheme for IPV/HIV trial
  - 4 intervention regions
  - 7 control regions
Exposure

- Intervention areas
  - IPV prevention
  - Routine HIV services
  - Enhanced HIV service
- Control areas
  - Routine HIV services
## Intended Outcomes and Impact of Intervention to Reduce HIV and IPV in Rakai

<table>
<thead>
<tr>
<th>Intermediate Outcomes</th>
<th>Long-term Impact</th>
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<tbody>
<tr>
<td><strong>Risky sex practices</strong></td>
<td></td>
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<tr>
<td>1. Reduce the number of non-marital sexual partners</td>
<td></td>
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<tr>
<td>2. Reduce alcohol use with sex</td>
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<tr>
<td>3. Delay sexual debut</td>
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<tr>
<td><strong>Self-protection</strong></td>
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<tr>
<td>4. Increase the rate of consistent condom use</td>
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<tr>
<td>5. Increase couple communication about HIV</td>
<td></td>
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<tr>
<td><strong>HIV prevention, testing and treatment</strong></td>
<td></td>
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<tr>
<td>6. Raise awareness about the link between HIV and IPV</td>
<td></td>
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<tr>
<td>7. Appoint and train SHARE community counselors</td>
<td></td>
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<tr>
<td>8. Train HIV counselors to screen for, handle and refer IPV cases</td>
<td></td>
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<tr>
<td>9. Integrate IPV screening and prevention into RHSP’s treatment</td>
<td></td>
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<tr>
<td><strong>Contextual variables</strong></td>
<td></td>
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<tr>
<td>10. Change attitudes about the acceptability of IPV</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1. Reduce physical IPV</td>
</tr>
<tr>
<td></td>
<td>2. Reduce sexual IPV</td>
</tr>
<tr>
<td></td>
<td>3. Reduce HIV Incidence</td>
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# Community-based IPV prevention

<table>
<thead>
<tr>
<th>STRATEGY</th>
<th>ACTIVITIES</th>
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<tbody>
<tr>
<td><strong>Advocacy</strong></td>
<td>Workplace dialogues, local group seminars, dialogues with opinion and local leaders.</td>
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<tr>
<td><strong>Capacity building</strong></td>
<td>Staff development workshops, training of resource persons and volunteers, seminars, community based workshops on IPV, human rights and women’s rights.</td>
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<tr>
<td><strong>Community activism</strong></td>
<td>Work with community volunteers and drama groups, booklet clubs, IPV prevention action groups, door-to-door awareness activities, films.</td>
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<tr>
<td><strong>Learning materials</strong></td>
<td>Development and adaptation of booklets, brochures, posters, story cards, and other educational materials.</td>
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<tr>
<td><strong>Special events</strong></td>
<td>Local fairs, public marches and campaigns, poster exhibitions, seminars and collaboration meetings.</td>
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Targeted IPV prevention

- **Adolescents**
  - 15-19 y.o. at increased risk for IPV and HIV infection
  - Stepping Stones package to foster improved communication skills and gender-equitable relationships

- **Men and boys**
  - Uganda is culturally and socially patriarchal and men are main perpetrators of IPV
  - We partnered with male role models from community and engaged traditional male counselors/activists in the implementation of project. All male facilitators received training on (1) Understanding IPV and its link with HIV; (2) Human rights awareness; (3) Advocating for women’s rights
Counseling Tools to Address HIV and IPV with Female Clients

- Following WHO recommendations we pilot tested two tools for addressing IPV as a barrier to women’s access of HIV testing and counseling and to help women safely disclose and reduce risk.

  - **Tool 1:** To assess clients’ fear of violence, safety of HIV disclosure and to help develop (safe) disclosure plans.

  - **Tool 2:** Risk reduction counseling for women at heightened vulnerability for IPV.
Building Capacity of VCT Counselors to Address IPV

- Resident counselors in each region were trained to:
  - Screen for IPV and offer short-term support to victims
  - Encourage couple communication about HIV, couples VCT, mediated disclosure and or safety planning
- Community counseling aides were appointed in 4 intervention regions and trained to offer basic counseling support and referral
- A referral network established involving SHARE, RHSP’s HIV counselors, district level social welfare officers and district police
Enhanced HIV treatment and support services

- ARV counselors trained to screen for violence, handle cases disclosed by clients, and offer referral

- Support groups established and led by HIV-infected women
Ethical safeguards put in place

- **Training and support**
  - All new study staff were carefully selected. All staff received specialized training and on-going support.

- **Referrals**
  - Intervention regions = fieldworkers were trained to refer women to SHARE staff.
  - Control regions = short-term support mechanisms established and referrals made to available local services.

- **Study design**
  - Confidentiality protected.
  - Voluntary nature of research emphasized.
  - Privacy ensured
Ethical challenges emerged (1)

- ISSUE #1: Control region participants sought involvement in violence prevention/treatment (due to migration and closeness of regions)
  - Some “cross over” expected in community participation
  - More concerning was disclosure of violence experience and indication of risk for future abuse

- CHALLENGE/CONCERNS
  - Having control residents participate threatened to bias data
  - Systems had not been put in place to offer similar IPV-related prevention and treatment services in control regions (due to implicit nature of trial)
  - Services providers in intervention arm were not equipped to take on increased workloads

- QUESTION
  - How do we balance research duties to ‘reduce risk’ and also ‘benefit’ participants?
  - How should we, as public health researchers & service providers, respond to a conflict between our desires to conduct scientifically valid research and also do what was in the best interest of the population?
Ethical challenges emerged (2)

- **ISSUE #2**: Although temporary/short term mechanisms of support were established in control regions, adequate violence related services were not available.

- **CHALLENGE/CONCERNS**:  
  - We could not meet the needs of some individuals who specifically sought our assistance.

- **QUESTIONS**:  
  - How far did our ethical duty to “prevent or remove harm” (nonmaleficence) extend within the populations we allocated to the separate arms of the trial?
What concerns do you have?

- Safety of participants
- Scientific Validity
- Benefits owed to participants
- Quality of Evidence
Bioethics vs. Public Health Ethics

**INDIVIDUALS**
- Respect for Persons
- Beneficence
- Non-maleficence
- Justice

**POPULATIONS**
- Respect for Individual liberties
- Produce benefits
- Reduce harms
- Distributive justice
Additional Considerations of Population Level Ethics

- Social justice – protection of vulnerable
- Reciprocity and relationships
- Effectiveness
- Stewardship of scarce resources
- Procedural Ethics
  - Transparency
  - Participation
  - Accountability
Public Health and Research Ethics

- Does the research meet the needs of the community?
- Are the participants protected from individual and group harms?
- Are the findings of the research likely to be translated?
- Will the participants in this research be able to benefit from the findings? Will their communities?
- What standard of evidence / care is appropriate?
Guidelines

- Council for International Organizations of Medical Sciences (CIOMS)
- Ottawa Statement on the Ethical Design and Conduct of Cluster Randomized Trials
- Ethical and Safety Recommendations for Research on Domestic Violence Against Women (WHO)
CIOMS – International Ethics Guidelines for Biomedical Research

- Ethical justification and scientific validity of research
- Ethical Review Committees
- Informed consent
- Inducements to participate
- Risk/benefits for participants
- Research in communities with limited resources
- Choice of clinical trial/control group
- Equitable distribution of burdens and benefits
- Vulnerable populations
- Confidentiality
- Rights of injured participants
- Ethics review capacity
- Obligation of sponsors to provide health-care services
Ottowa Statement

- Addresses special concerns of research where unit of interest is a group, population, or community rather than individual subjects
  - Consent
  - Gatekeepers
  - Assessing benefits and harms
  - Protecting vulnerable populations

  http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.1001346
WHO Guidelines for Research on Domestic Violence Against Women

- Safety
- Methodologically sound
- Confidentiality protections
- Specially trained research team
- Design to reduce distress of participants
- Field workers trained to referral to local services
  - Where few resources exist, it may be necessary for the study to create short-term support mechanisms
- Researchers and donors have ethical obligation to ensure findings are interpreted and advance policy and practices
- Violence questions only included when ethical and methodological requirements met
Ethical Tension in Rakai

- Beneficence towards women in control communities
  - Reduce risk of IPV
  - Protect from harms of participation

- Validity of study findings
  - Implications for policy influence
  - Well-being of future populations
  - Reciprocity for participants taking on risks

- Feasibility Considerations
Options to reconcile tension

- How strong is the justification for a control group?
- How much will “cross-over” affect results?
- How much harm will result from not providing the “control” subjects with assistance?
- How much harm will result from compromising rigor of study?

- What options are realistically available to you?
Resolution?
Chosen course of action in Rakai

- Decided to provide support to everyone at risk of harm from violence.
- Control region individuals allowed to participate in community-based violence prevention but not specific IPV-related services (e.g. psychosocial support, risk reduction counseling) unless severe in nature and needs could not be met by existing services.
- Else, referred to local providers in control regions.
Questions for Discussion

- Should women in IPV research be considered vulnerable populations?

- What minimum level of capacity, if any, should be in place when conducting community level research on IPV?

- What does “temporary support” mean?

- How long should researchers be responsible for sustaining temporary support?
Thank you!
Vulnerable Populations

- Introduced in Nuremberg Code (1949)
- Declaration of Helsinki (1964)
- Belmont Report (1979)
- 45 CFR 46
  - Pregnant women and fetuses
  - Prisoners
  - Children
  - Additional protection for economically, educationally, decisionally impaired
Vulnerability

“Vulnerability” refers to a substantial incapacity to protect one’s own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group.” -- CIOMS
The ethical justification of biomedical research involving human subjects is the prospect of discovering new ways of benefiting people’s health.

Such research can be ethically justifiable only if it is carried out in ways that respect and protect, and are fair to, the subjects of that research and are morally acceptable within the communities in which the research is carried out.

Moreover, because scientifically invalid research is unethical in that it exposes research subjects to risks without possible benefit, investigators and sponsors must ensure that proposed studies involving human subjects conform to generally accepted scientific principles and are based on adequate knowledge of the pertinent scientific literature.
Research in populations and communities with limited resources

Before undertaking research in a population or community with limited resources, the sponsor and the investigator must make every effort to ensure that:

- the research is responsive to the health needs and the priorities of the population or community in which it is to be carried out; and

- any intervention or product developed, or knowledge generated, will be made reasonably available for the benefit of that population or community
Resources for Public Health Ethics

- Frameworks
  - Childress et al. (2002)
  - Baum et al. (2007)
  - Lee (2012)
  - Nuffield Council on Bioethics
    - Stewardship model:
      http://www.nuffieldbioethics.org/public-health/public-health-ethical-framework