Title

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Journal

Psychology of Violence, 6(3)

ISSN

2152-0828

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Publication Date

2016-07-01

DOI

10.1037/vio0000037

Peer reviewed

Psychology of Violence
2016, Vol. 6, No. 3, 442–451

2152-0828/16/$12.00 http://dx.doi.org/10.1037/vio0000037

Ethical Challenges of Randomized Violence Intervention Trials: Examining the SHARE Intervention in Rakai, Uganda

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Objective: We identify complexities encountered, including unanticipated crossover between trial arms and inadequate "standard of care" violence services, during a cluster randomized trial (CRT) of a community-level intimate partner violence (IPV) and HIV prevention intervention in Uganda. ***Method:*** Concepts in public health ethics—beneficence, social value of research, fairness, standard of care, and researcher responsibilities for posttrial benefits—are used to critically reflect on lessons learned and guide discussion on practical and ethical challenges of violence intervention CRTs. ***Results:*** Existing ethical guidelines provide incomplete guidance for responding to unexpected crossover in CRTs providing IPV services. We struggled to balance duty of care with upholding trial integrity, and identifying and providing appropriate standard of care. While we ultimately offered short-term IPV services to controls, we faced additional challenges related to sustaining services beyond the "short-term" and posttrial. ***Conclusion:*** Studies evaluating community-level violence interventions, including those combined with HIV reduction strategies, are limited yet critical for developing evidence-based approaches for effectively preventing IPV. Although CRTs are a promising design, further guidance is needed to implement trials that avoid introducing tensions between validity of findings, researchers' responsibilities to protect participants, and equitable distribution of CRT benefits.

Keywords: intimate partner violence, cluster randomized trial, research ethics, HIV, Rakai, Uganda

Intimate partner violence (IPV), one of the most common forms of violence against women (VAW), is defined as "any behavior within an intimate relationship that causes physical, psychological, or sexual harm to those in the relationship" (Krug, Dahlberg, Mercy, Zwi, & Lozano, 2002). A 2010 meta-analysis using data from 81 countries found 30.0% of women aged 15 years and above have experienced physical and/or sexual IPV in their lifetime. The settings with the highest IPV prevalence were in sub-Saharan Africa (Devries et al., 2013), the region most affected by HIV/AIDS (UNAIDS/World Health Organization, 2013) and where significant associations have been found between IPV and HIV infection (Kouyoumdjian et al., 2013a; UNAIDS/World Health Organization, 2013). It is now widely accepted that IPV is both a precursor to and sequelae of HIV infection (Campbell et al., 2008; Maman, Campbell, Sweat, & Gielen, 2000; UNAIDS/World Health Organization, 2013). In response, a growing number of combination IPV and HIV prevention interventions has been implemented and systematically evaluated through randomized trials, primarily in sub-Saharan Africa. The purpose of this article is to discuss some of the practical, ethical, and safety challenges introduced by randomized violence intervention trials. We examine field-based experiences of and lessons learned by the researchers who conducted and evaluated the Safe Homes And Respect for Everyone (SHARE) Project in rural Uganda between 2005 and 2009.

A Call for Rigorous Evaluation of IPV Interventions

Given the high global prevalence of IPV and the negative health and social consequences associated with its occurrence (Campbell, 2002; Campbell & Soeken, 1999; Ellsberg et al., 2008), a range of different prevention approaches has been designed and implemented in multiple countries and development contexts. Some of these interventions have combined strategies to address the bidirectional relationship between IPV and HIV infection, particularly in sub-Saharan Africa (Anderson, Campbell, & Farley, 2013). Nonetheless, research to evaluate the feasibility and effectiveness of these programmatic efforts is limited, particularly in low and middle income countries. As a result, urgent investment has been

This article was published Online First January 25, 2016.

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called for to increase the evidence base on effective partner violence prevention interventions (Ellsberg et al., 2014; Heise, 2011), including approaches that address gender inequality and violence as part of a combination HIV response (Watts & Seeley, 2014). Evaluating the impact of primary prevention approaches conducted in low and middle income countries has emerged as a high research priority (Ellsberg et al., 2014; Heise, 2011). In areas of high IPV and HIV prevalence, such as sub-Saharan Africa, community-level work has been identified as an important strategy for sustained change at the population level (Michau, Horn, Bank, Dutt, & Zimmerman, 2014). In order to inform policy and support effective and efficient approaches to violence prevention, it is necessary to evaluate the impact of primary prevention interventions in a scientifically valid and rigorous way (Ellsberg et al., 2014; Heise, 2011).

Randomized controlled trials (RCT) have come to be regarded as the "gold standard" for evaluating the effectiveness of public health interventions and the strengths of this study design are widely recognized. RCTs allow for simultaneous comparison of intervention and control groups. Further, if randomization is done correctly, it can enhance investigators' ability to ensure participants in both arms are comparable on all characteristics apart from the intervention conditions under study (Hayes & Moulton, 2009). For some health interventions, it is more appropriate to randomize groups of individuals (vs. individual participants) to the different treatment arms. This design is known as a cluster randomized trial (CRT). CRTs are ideal when the intervention will be applied to entire communities (or other groupings of individuals), such as community mobilization activities recommended for IPV prevention (Michau et al., 2014). Other reasons for the CRT design are when contamination between individuals in the same community is likely if they are randomized to different treatment arms; and when a main research goal is to measure population-level effects of the intervention (Hayes & Moulton, 2009).

Ethical Challenges of Randomized IPV Intervention Trials

International guidelines have been established for the ethical conduct of biomedical research involving human subjects (Council for International Organizations of Medical Sciences, 2002; World Medical Association, 2013). However, despite the widespread use of internationally and locally accepted ethical guidelines, the subject of VAW and the method of CRTs each have practical aspects that are not easily resolved with these standard guidelines. For instance, research focused on VAW can raise questions on how to maintain participant confidentiality when conducting research in settings with mandatory reporting laws, and how to mitigate underreporting of abuse so as to prevent biased information about the magnitude of the problem (Ellsberg & Heise, 2002; Wagman, Francisco, Glass, Sharps, & Campbell, 2008; World Health Organization, 2001). CRTs are more complex than the traditional RCT design and introduce ambiguity with respect to defining the research subject, how and from whom to obtain consent, and how to balance risks and benefits across both individuals and groups that are involved in CRTs (Hayes & Moulton, 2009; Weijer et al., 2012). In response to these and many other issues, two sets of targeted guidelines have been developed: The World Health Organization developed recommendations for conducting safe and ethical population-based survey research on domestic VAW (World Health Organization, 2001). They were written for researchers, donors, research ethics committees (RECs), and others initiating or reviewing research on VAW. Eight recommendations were put forth to address safety of respondents and the research team; ensuring domestic violence studies are methodologically sound; protection of confidentiality; careful selection and training of researchers; reducing participant distress; training fieldworkers to make referrals; dissemination of findings; and only including violence questions in surveys designed for other purposes when ethical and methodological requirements can be met. More recently, the Ottawa Statement on the Ethical Design and Conduct of Cluster Randomized Trials set out 15 recommendations for the ethical design, conduct, and review of CRTs. The 15 recommendations were written to provide guidance to researchers and RECs on seven ethical issues: justification of a cluster randomized design, the need for REC review, the identification of research participants, obtaining informed consent, the role of gatekeepers in protecting group interests, the assessment of benefits and harms, and the protection of vulnerable participants (Weijer et al., 2012).

Although these additional violence and CRT guidelines were a step forward, randomized trials to evaluate IPV prevention interventions—including those aimed at both individuals and groups of individuals—face practical challenges in responding to common research ethics and safety considerations. For example, what should be offered to control communities in a trial investigating the optimal delivery approach of an intervention likely to be effective in a setting with no standard of care? How should researchers balance obligations to provide care for at-risk individuals while upholding the validity of a randomized cluster design? What responsibilities do researchers have for the sustainability of effective, community-level intervention approaches? Although some of these issues have been addressed in recent recommendations for VAW intervention research (Hartmann & Krishnan, 2014), practical experiences and lessons learned are essential for moving the field toward the development of refined guidelines for the safe and ethical conduct of randomized IPV intervention trials.

This paper describes the practical and ethical challenges researchers experienced when unanticipated crossover occurred during a CRT to evaluate a community-based, primary IPV prevention intervention (the SHARE Project) that was integrated into an existing HIV organization in rural Uganda (the Rakai Health Sciences Program). We briefly describe the IPV intervention, and the unexpected crossover that occurred during the intervention trial's implementation, discuss the practical and ethical challenges that followed, summarize lessons learned, and raise questions for further consideration.

The SHARE Intervention Setting

Rakai District, Uganda

The SHARE intervention was conducted between 2005 and 2009 in the southwest Ugandan district of Rakai, where the first HIV/AIDS cases were identified in the country in 1982 (Serwadda et al., 1985). The district has a generalized HIV epidemic and HIV prevalence (12%) remains among the highest in the country, exceeding the national average of 7.2% (UNAIDS/World Health Organization, 2013). IPV against women is highly prevalent in

Rakai. Half (49.8%) of all women (aged 15–49 years) report having experienced some form of IPV (emotional, physical, and/or sexual) in their lifetime; approximately one third (29.0%) report any IPV in the past year. Two thirds (66.0%) of abused women in Rakai reported that they experienced more than one form of violence concurrently (Kouyoumdjian et al., 2013b). Partner violence's role in increasing women's risk for HIV infection has been evidenced in Rakai. Research found women who had ever experienced IPV were significantly more likely to acquire HIV compared with women who had never experienced abuse (aIRR = 1.55, 95% CI: 1.25–1.94; Kouyoumdjian et al., 2013a).

Rakai Health Sciences Program and Rakai Community Cohort Study

The SHARE IPV prevention intervention and evaluation trial were conducted by the Rakai Health Sciences Program (RHSP), which has conducted research on and provided services for HIV/AIDS and reproductive health in rural Uganda since 1988. Since 1994, RHSP has followed an open, community-based cohort of approximately 12,000 participants aged 15–49 years who reside in 50 communities that are aggregated into 11 study clusters. This longitudinal study is called the Rakai Community Cohort Study (RCCS), and it has been described in detail elsewhere (Wawer et al., 1998; Wawer et al., 1999). RCCS is the main study conducted by RHSP but serves as an offshoot to many smaller quantitative and qualitative investigations. All RHSP study participants are offered general health services including routine medical care, family planning, health education, and community mobilization. They are also provided standard of care HIV-related services including voluntary HIV testing and counseling (HCT), HIV prevention education, condom distribution, prevention of mother-to-child HIV transmission, provision of antiretroviral therapy (ART), and pre-ART care and provision of a basic HIV care package.

The SHARE Violence Prevention Intervention Trial

The SHARE Intervention

In June 2005, RHSP initiated the multicomponent SHARE IPV prevention intervention, which has been described previously (Wagman et al., 2012). In this paper, we focus on ethical issues related to the primary component of the SHARE intervention, which was a community mobilization approach that aimed to reduce physical and sexual IPV by changing social norms that support violence. SHARE was uniquely positioned to also address the links between IPV and HIV infection since the intervention was integrated into RHSP's existing HIV programming (Wagman, King et al., 2015). As such, SHARE also implemented an HCT-based screening and brief intervention (SBI) program. The goals of the SBI were to increase rates of nonviolent HIV disclosure among women testing HIV positive for the first time and improve women's capacity to negotiate consensual and HIV risk-free sex (e.g., by using condoms) with violent spouses/partners (Wagman, Gray, et al., 2015; Wagman, King, et al., 2015).

SHARE's community mobilization approach was an adaption of Raising Voices' *Resource Guide* for preventing domestic violence, which was specifically developed for use in East and Southern Africa (Michau & Naker, 2003). Its methods were previously found to reduce partner-level violence and attitudes condoning its acceptance in urban Uganda (Raising Voices and Center for Domestic Violence Prevention, 2003). Its approach is based on the Transtheoretical Model of behavior change, the central construct of which is the Stages of Change Theory (Prochaska & DiClemente, 1983; Prochaska & Velicer, 1997). This theoretical approach was chosen by Raising Voices based on their extensive practical experience, during which they found it to be appropriate and acceptable in many different cultures and countries, including Uganda (Michau & Naker, 2003). The *Resource Guide* has been successfully implemented in 22 African countries including 8 in East and Southern Africa (Ruff, 2005).

As recommended (Michau & Naker, 2003), we scaled up the Stages of Change Theory for delivery at the community level because societal transformation requires moving beyond individuals, and it was posited that communities, like individuals, go through multiple stages of change before any given value system or final behavior change is fully adopted. Following the suggested process, we organized SHARE in five consecutive phases for affecting social change. These five phases, based on the stages of individual behavior change but amplified to work at a broader community level, were spread out over the life of the intervention (ending in December 2009). SHARE also adapted methods from Stepping Stones to address gender roles and promote equitable relationships among adolescents. We chose the Stepping Stones approach because it was originally developed for use in Uganda (and deemed culturally appropriate), has been used in more than 40 countries, including many East and Southern African countries (Welbourn, 1995) and found to reduce male perpetration of IPV in South Africa (Jewkes et al., 2008).

The SHARE Evaluation Trial

SHARE was conducted as part of an intervention trial to assess whether it would reduce IPV and HIV incidence in individuals enrolled in RCCS. We chose a cluster randomized design, with four intervention group and seven control group clusters, because SHARE was primarily delivered to entire communities, a main goal was to measure population-level effects of the intervention, and we expected some contamination between arms (Hayes & Moulton, 2009).

The SHARE intervention study built on a prior CRT (1999–2003) conducted to assess the impact of enhanced family planning outreach in Rakai. The family planning CRT randomized five RCCS clusters to the control arm and six to the intervention arm (Lutalo et al., 2010). We built on this design and randomly chose (via a computer-generated randomization program) four SHARE intervention clusters from the original six family planning intervention clusters. More intervention clusters were not chosen for the SHARE trial due to funding limitations. The seven control clusters in our study consisted of the five control clusters from the original family planning CRT plus the remaining two family planning intervention clusters (Wagman, Gray, et al., 2015). Figure 1 shows a map of the Rakai district and highlights the location of the four intervention and seven control clusters for the SHARE trial.

Participants in the four intervention clusters were provided RHSP's standard of care health and HIV services, and were also exposed to SHARE's community-level mobilization intervention

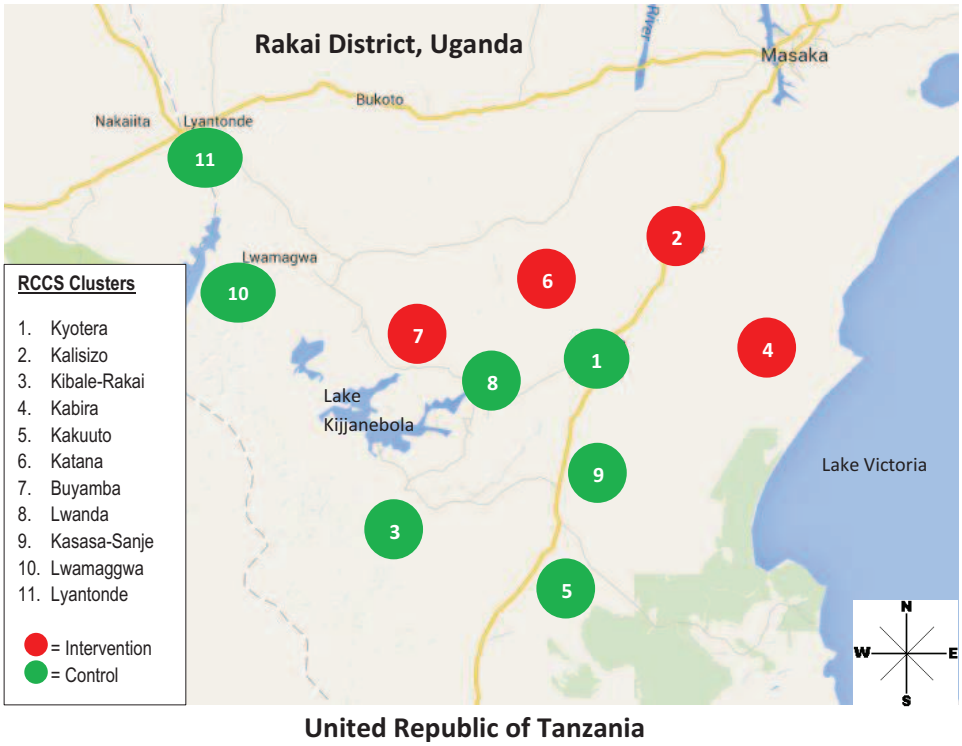

Figure 1. Map of SHARE intervention and control clusters in Rakai District, Uganda.

as well as the HCT-based SBI. The seven control group clusters received only standard of care health and HIV services from RHSP. The impact of SHARE was evaluated by analyzing RCCS data from three time points. A baseline survey (February 2006–June 2006) was conducted prior to the initiation of SHARE intervention activities. Two follow-up surveys were conducted between August 2006 and April 2008, and June 2008 and December 2009. The primary endpoints for our study were self-reported experience (women) and perpetration (men) of past year IPV (emotional, physical, and sexual) and laboratory-based diagnosis of HIV incidence in the study population (Wagman, Gray, et al., 2015). Thus, the SHARE trial included an evaluation both of the effectiveness of the community-level mobilization to reduce IPV in the Rakai society, as well as the effectiveness of the implementation approach of integrating IPV prevention within the existing HIV service delivery infrastructure of RHSP.

Practical and Ethical Challenges

SHARE's community mobilization approach used five main IPV prevention strategies: advocacy, capacity building, community activism, learning materials, and special events. The advocacy and capacity building activities were primarily organized with targeted groups of participants in designated, controlled locations, and thus had minimal public exposure. In contrast, most of the activism, learning materials and special events were designed for community-based implementation and to maximize public exposure, and were thus conducted in open spaces. Table 1 outlines the five SHARE strategies, lists main activities conducted under each, and indicates the level of public exposure per strategy.

Unanticipated Crossover of Participants Between Trial Arms

Crossover during community events. Given the nature of and activities involved in the SHARE strategies, all individuals present in the intervention arm clusters were offered full exposure to the community-level forms of "intervention" (e.g., community activism, learning materials, and special events). As demonstrated in Figure 1, some of the RHSP/SHARE trial's intervention and control regions were adjacent or close to one another. Movement between different communities and regions is not uncommon. Concerns emerged when SHARE staff members realized that some intervention activities were attended by control region individuals who were present in intervention areas (to visit friends/relatives, go shopping, passing through, etc.) at the time of the event.

As part of the community activism strategy, SHARE appointed 40 community volunteers (CVs)—10 per each SHARE cluster—to help, on an ongoing basis, facilitate project activities and events (Wagman et al., 2012). Because CVs were resident members of their cluster, they were able to recognize familiar and unfamiliar intervention participants. Crossover for community events was most commonly reported by CVs in the Katana (#6) and Buyamba (#7) intervention clusters, which were adjacent to the Kyotera (#1) and Lwanda (#8) control clusters, respectively. Such "unintended exposure" was concerning to SHARE staff who realized that unanticipated behavior change might occur among control participants and ultimately bias study results. While we expected some contamination between treatment arms and planned to employ an "intention to treat" statistical analysis (anticipating some unavoidable "crossover effects" in our findings), the unintended exposure

Table 1
Level of Community Exposure, Activities, and Target Population of Each SHARE IPV Prevention Strategy

Strategy	Level of community exposure	Activities conducted	Target population
Advocacy	High exposure among target group only Low exposure in general community	• Workplace dialogues • Targeted local group seminars • Focused dialogues with opinion and local leaders • Professional network for service providers	Local and religious leaders, local organizations and government, teachers, health care workers.
Capacity building	High exposure among target group only	• Staff development workshops • Training of resource persons and volunteers	Police, probation and social welfare officers, health care providers, teachers, local and religious leaders, SHARE staff and volunteers, and RHSP counselors and staff.
	Low exposure in general community	• Seminars • Targeted workshops and trainings on IPV, human and women's rights.	
Community activism	High exposure in general community (target population = community)	• Collaborative work with community volunteers • Public booklet clubs • IPV prevention action groups • Door-to-door awareness activities	Women and men, youth and children within the community.
Learning materials	High exposure in general community (target population = community)	Development, adaptation, and distribution of: • Booklets and brochures • Posters • Story cards • Other educational materials	General public, community members, local organizations, health care providers, and social service officers.
Special events	High exposure in general community (target population = community)	• Local fairs • Public marches • Public campaigns • Open poster exhibitions • Community drama shows • Outdoor films and music events	Community members, leaders, the general public, and local institutions.

contributed to a more difficult challenge that we had not planned for, namely responding to requests for services for the additional crossover population.

Unanticipated crossover related to requests for service and individual support. The crossover led to additional requests for services and individual support from abused women residing in control clusters. Some women from control areas heard about the SHARE Project (through diffusion of information, including word of mouth from SHARE volunteers), sought out intervention staff and disclosed personal experiences of IPV, and/or requested access or referral to focused IPV-related support, care, and health services. As mentioned, we trained RHSP's resident HCT counselors in SHARE clusters (one per cluster) to screen for IPV and help women develop safe HIV disclosure plans, offer facilitated disclosure of HIV results, and practice risk reduction strategies for avoiding violence in intimate relationships (Wagman, Gray, et al., 2015). We also appointed and trained 12 community counseling aides, three per intervention cluster, to offer basic support to community members experiencing violence and liaise with and refer to RHSP's professional counselors (Wagman et al., 2012). Although each of the control clusters also had a resident HIV counselor from RHSP, focused IPV counseling and support was not available from these providers. Further, community counseling aides were not appointed in control clusters. Thus, some violence victims in control areas heard indirectly about the availability of specialized IPV-related services in neighboring regions and traveled to seek personal assistance for their own situational needs.

The ethical issues surrounding our response to unanticipated crossover. This unanticipated crossover created a tension between the integrity of the trial and maintaining appropriate comparison groups, and a duty of care to protect participants from harms and ensure that any risks of harm are justified by the benefits of the research. Our goal of evaluating a violence intervention that was integrated into an existing HIV program in Rakai was rooted in the social value of the research, and our aim to find effective strategies to reduce behaviors that increased risk for IPV in the population. Randomizing some clusters to receive no intervention is ethically justified when it can be argued that there is equipoise, meaning genuine uncertainty regarding the relative efficacy of one treatment condition over another (Hayes & Moulton, 2009). In studies that address specific delivery methods, such as the integrated IPV/HIV delivery approach used in SHARE, it has been argued that the concept of equipoise should apply to the uncertainty of the delivery approach and how an intervention ought to be delivered, rather than the uncertainty surrounding the effectiveness of the intervention itself (Hyder, Pratt, Ali, Kass, & Sewankambo, 2014; Kukla, 2007). However, in this case, there were different levels of uncertainty associated with the effectiveness of the IPV intervention and the integrated approach within the HIV service infrastructure. Although SHARE *did* adapt "proven successful" IPV prevention strategies from Raising Voices (Michau & Naker, 2003; Raising Voices and Center for Domestic

Violence Prevention, 2003) and Stepping Stones (Jewkes et al., 2008; Welbourn, 1995), there remained some level of uncertainty about its effectiveness in the Rakai context, although it may have been presumed more likely to be effective than not. There was much greater uncertainty around the effectiveness of the approach of integrating IPV within existing HIV services infrastructure, as no prior IPV evaluation was shown effective in lowering HIV incidence (Wagman, Gray, et al., 2015). Thus, it could be justifiable to randomize clusters to the SHARE IPV intervention given the uncertainty regarding the outcomes of the integrated delivery approach, yet at the same time, ethically objectionable to deny an individual from the control group access to the IPV intervention shown to be effective in other settings.

We were also confronted with a limitation in our ability to minimize harms to participants given our limited resources. Although SHARE had the capacity to do public prevention activities for as many individuals as wished to participate, specialized services, such as counseling, were only set up to serve the needs of those in the intervention regions. No such systems had been put in place to offer specialized IPV-related services in control regions. Extending these services to control participants who crossed over to intervention regions would have had negative consequences for the providers, who lacked resources to serve so many people, as well as to the intervention participants, who would not receive adequate attention. Thus, even if there were no concerns for the integrity of the trial, and we sought to provide services to all women identified with IPV risk, resource constraints presented obstacles to referring control region residents to the services provided in the intervention arm.

This pushed us to consider our responsibilities more carefully. How far did our responsibility as care-givers to "prevent or remove harm" extend? What did we, as researchers, owe to those allocated to the control arm of the trial? We recognized that withholding support services (e.g., psychosocial counseling) and referral (e.g., links to social welfare) might be life-threatening, fail to prevent the preventable (future violence) or cause serious physical, sexual, or emotional harm. At the same time, we recognized the importance of generating evidence for these kinds of interventions for future policy impact, which may have much broader social benefit, and were aware that the standard of care in Uganda did not offer IPV services in any form. We thus had to reconcile a duty of care to participants with our responsibilities as researchers for the social value of the investigation.

To establish our course of action, we consulted several individuals and groups with capacity to make decisions to effectively balance benefits and harms to the research population in Rakai. We discussed all issues with RHSP senior investigators, and sought feedback from the local institutional review board. We also convened a meeting with members of RHSP's Community Advisory Board, which provides local knowledge input on new and ongoing studies, liaises with communities, and is involved with the review and approval of all RHSP studies and projects.

Together, we identified three options. First, we could allow control region individuals to freely participate in SHARE violence prevention and treatment activities and note this as a limitation in our research. Second, we could allow control region individuals to participate in SHARE violence prevention activities but not access IPV-related services. Third, we could exclude control area individuals from all SHARE activities and instead refer those seeking violence prevention services elsewhere in Rakai.

Ultimately, we felt our duty to protect women at risk of violence from harm, irrespective of where they resided, outweighed concerns for the integrity of the trial design. We made a preliminary decision to allow control region individuals to participate in SHARE violence prevention activities (since it was too difficult to limit exposure) but exclude them from accessing specific IPV-related services (such as psychosocial support, risk reduction counseling) offered through SHARE and instead refer them to available services in their respective communities. This, however, led to a new challenge, namely the lack of adequate, existing "standard of care" IPV-related services.

When There Is No Standard of IPV Care

As is common in many resource poor settings, violence-related support services were basically nonexistent in the SHARE and non-SHARE regions of Rakai. As part of the intervention, we *did* establish a prevention and referral network among local agencies and professionals in Rakai. Network members included Rakai District Police, probation and social welfare officers, and government representatives from the Offices of Health, Education, and Gender. Police and social welfare officers were offered a one-time training on IPV and all members were invited to participate in biannual information sessions, and a system of referral was established to help women seek legal and civil assistance and counseling where possible (Wagman et al., 2012). Despite these activities, however, network members were not specifically attached to any of the RCCS clusters, and most were not trained to ask about or offer meaningful services related to cases of IPV. As a result, referring women from control cluster to violence-related services in their own communities may not have been successful in minimizing harms.

The ethical issues surrounding inadequate standard of care and our course of action. Concerns about appropriate standard of care provided to RCT and CRT participants in settings where local health services may not be adequate are common (Hayes & Moulton, 2009). In the SHARE example, we followed the WHO's guidelines for ethical and safe research on domestic violence (World Health Organization, 2001) by creating short-term support mechanisms for responding to cases of violence that we did not have the capacity to serve immediately via the SHARE Project. SHARE staff members were trained to screen individuals who disclosed violence and assess the severity of their situation and potential for danger. All violence victims were offered immediate support in the form of private and confidential (short-session) counseling and a discussion about risk reduction techniques. All women were also provided contact information (verbally, so as to prevent a paper trail that could be discovered by an abuser) about the SHARE Project and how to contact us for further assistance in the case of an emergency. All women were also triaged. Those experiencing less severe and threatening forms of abuse were referred to a welfare officer, as well as a RHSP counselor in her own community for monitoring and follow-up. Although these individuals (welfare officers and counselors) had not been working as closely with SHARE as those in the intervention regions, they had connections with the overarching RHSP/SHARE infrastructure and

could access additional support if needed. Further, a SHARE staff member contacted each of these individuals to let them know they should expect the new client and to follow up on each case. Women who disclosed more severe and urgent forms of abuse were immediately referred to a SHARE-trained HCT counselor for follow-up and support either with the woman individually or together with her abusive partner (when appropriate and safe). With the abused woman's consent, she was also connected with one of the SHARE CVs for ongoing support, and she was referred to a social welfare officer in the SHARE region as well as her own. All cases of severe abuse were followed up on regularly by SHARE staff, CVs, and community counselors.

Discussion and Lessons Learned

Our practical and ethical experiences conducting the SHARE study via an existing cluster randomized trial offer several informative lessons for future randomized IPV intervention evaluations, particularly in resource-poor settings. We discuss three lessons below.

Lesson 1: There Is Ongoing Need to Formally Evaluate Interventions That Address Multiple and Overlapping Vulnerabilities of Individuals Experiencing IPV and At Risk for or Living with HIV

When we began this trial, it was only the third combination IPV/HIV prevention intervention to be evaluated via CRT. Two prior trials had been conducted in South Africa (Jewkes et al., 2008; Pronyk et al., 2006), and neither had shown effective outcomes for both IPV and HIV. The dearth of existing literature on combined IPV/HIV prevention interventions represents a need for further efforts to identify the most effective ways to address overlapping risks. This is particularly important in low resource settings where combined approaches may be a particularly efficient use of limited resources, and in settings like sub-Saharan Africa where resources are usually more readily available for HIV than IPV research and service provision.

Lesson 2: Cluster-Randomized Trials Are a Promising Approach for Intervention Evaluation but Introduce Numerous Challenges with Practical and Ethical Implications (Hayes & Moulton, 2009; Weijer et al., 2012)

The CRT design contributed to two larger considerations for violence intervention research: (1) What did we owe to control communities?, and (2) What were our responsibilities for sustaining benefits after the trial?

What should be offered to control communities? CRTs investigating the effectiveness of IPV interventions or combined approaches, such as HIV/IPV reduction efforts, raise complex issues about what ought to be offered to control communities. Despite that control community participants in the SHARE study received general health services and standard of care HIV-related services, they were not exposed to the multicomponent IPV prevention activities. Cluster selection in the SHARE trial was done by building on a prior family planning outreach CRT in order to take advantage of the existing infrastructure for community health workers (Wagman, Gray, et al., 2015), yet this approach resulted in having some "control" and "intervention" communities in geographically adjacent regions and contributed to the unanticipated crossover.

Recent ethical and safety recommendations for intervention research on VAW suggest "the availability of services to comparison arm participants should maintain an ethically sound standard of care" (Hartmann & Krishnan, 2014). The Ottawa Statement on the Ethical Design of Cluster Randomized Trials states that control communities must not be deprived of effective care or programs to which they would have access, were there no trial (Weijer et al., 2012). Thus, although our design was justified given that control communities would not otherwise have access to violence related services, the intervention nevertheless set up an inequity in access to an intervention that seemed likely to be effective.

Hartmann and Krishnan (2014) encourage violence intervention researchers to consider alternative randomized design approaches, such as stepped wedge and wait list designs, after the efficacy or effectiveness evaluation stage. The stepped wedge design seems particularly appropriate given its approach of involving random and sequential crossover of clusters from control to intervention. This design is increasingly employed for evaluation of service delivery interventions because it allows participants in all clusters to be exposed eventually, resulting in a more justifiable distribution of benefits than traditional randomized designs (Hemming, Haines, Chilton, Girling, & Lilford, 2015). However, step-wedge designs are not appropriate for all contexts. In areas with small or homogenous clusters, the design may not be scientifically valid (Hemming et al., 2015). Although RCCS clusters were large, they were relatively homogenous (Todd et al., 2003), so this would not have been an ideal design for the SHARE trial.

Other researchers have assigned intervention clusters *en bloc* in order to minimize potential crossover and the ethical tensions it raises (Bandewar & John, 2011). Although this approach may have limited crossover and thus the extent to which service providers experienced distress about how to respond to requests for services, it would not have addressed the underlying ethical concern that women in control clusters, regardless of location, lacked access to needed services that RHSP could potentially provide. Thus, additional guidance may be needed to assist researchers in providing an equitable distribution of benefits while maintaining a valid approach that protects the scientific integrity of CRT results. Further, while we followed WHO guidelines and set up short-term response mechanisms for those in need in control communities, this approach also introduced questions about the extent of researcher's responsibilities to ensure continued access to beneficial interventions beyond the short-term and after the conclusion of the trial.

What responsibilities do researchers have to ensure continuation and uptake of effective interventions after the conclusion of the trial? Although setting up a short-term response mechanism allowed us to minimize the immediate harms experienced by women in the control arm, we then had to make decisions about how long to continue services for those in control areas, but eventually for those in the intervention communities as well. The question of posttrial access to effective interventions, or study benefits more broadly, has been raised extensively in the context of posttrial access to—HIV/AIDS drugs in particular (Doval, Shirali,

& Sinha, 2015; Sugarman, Rose, & Metzger, 2014; Usharani, & Naqvi, 2013)—and continues to present challenges with respect to what interventions ought to be continued, for how long, and by whom. Intervention evaluations similarly raise questions about responsibility for sustainability of effective interventions and expansion to nontrial communities. In this low resource setting, it was apparent that health systems' constraints in terms of facilities and human resources with expertise in IPV counseling were limited, and expansion would not be feasible without additional investment beyond what had been budgeted for in the evaluation.

Instead, the SHARE intervention aimed to engage community members in all aspects of the project, including both participation and implementation, and promote "community ownership" of positive change. For example, we trained CVs and counseling aides to work as resident local SHARE ambassadors who would remain in the study setting after the trial concluded. We took these steps to increase local investment during the implementation of the intervention and to increase its likelihood of sustainability after the research and program funding ended. The last two years of the intervention (Phase 5: 2008–2009) involved activities to transition SHARE staff members away from routine work in the intervention clusters and help community members assume the day-to-day tasks of the project. Our objective was to help the community develop long-term action plans and local bylaws that continued prevention efforts, and ensured that they could sustain the reduced levels of IPV and HIV transmission. Nonetheless, while SHARE was associated with lower levels of IPV and HIV incidence during the intervention period, multiple challenges including staff turnover and limited resources at local institutions hindered efforts to sustain intervention activities in the community, and the reduction in HIV transmission was not maintained after SHARE ended. Thus, continued exposure to the full intervention might be needed to achieve a sustained effect (Wagman, Gray, et al., 2015).

Lesson 3: Given Widespread Underreporting of IPV, Evaluation of Violence Interventions May Have Particularly High Levels of Unanticipated Demand

IPV is frequently underreported (Ellsberg & Heise, 2002; Wagman et al., 2008; World Health Organization, 2001), which may exacerbate potential for complexities like those experienced in the SHARE trial. At the same time, investing in evaluations of intervention delivery methods, integration with existing programming, and cost-effectiveness studies, is critically important for the broader social value of preventing IPV and addressing underlying risks for HIV infection and other adverse health outcomes. However, given the potentially high unmet need, crossover during CRTs may be significant; "intention to treat" analyses will not be sufficient to determine true intervention effects, nor will they prepare researchers to respond to the ethical challenges of responding to unmet need. Thus, there is a need for additional guidance to help researchers develop study designs that better address the scientific and ethical challenges of evaluating IPV intervention delivery approaches in low resource settings. In particular, additional guidance for developing short-term response and how to eventually end such support will be needed for IPV intervention research to progress in an ethical and effective way.

Conclusion

Given the global magnitude of IPV and its significant associations with a range of adverse outcomes, investments are needed to find effective interventions for preventing IPV alone and in combination with other outcomes, such as HIV transmission. The practical and ethical complexities of conducting violence intervention research, particularly when using a randomized trial design, require further examination and discussion by researchers, practitioners, interventionists, and those participating in the studies.

In their new guidelines, Hartmann and Krishnan (2014) set out five recommendations regarding the safe and ethical conduct of intervention research on VAW, two of which are particularly relevant to the current paper: "Participant randomization should be transparent and described in a way that can be easily understood by those involved in the research" and "The provision of services to comparison arm participants should maintain an ethically sound standard of care." Although these are important recommendations, our experience indicates it will be necessary for researchers to interpret them with respect to their own research setting and the context in which the work is being conducted. Since specific actions are often context-dependent, it may not be possible to refine existing guidelines in a way that provides global standards for conducting safe and ethical randomized IPV intervention trials. However, with more empirical and normative work, we believe a framework of relevant considerations could be developed to guide violence intervention researchers through what are potentially common challenges of randomized IPV research in low resource settings. Such a framework could prompt researchers to systematically consider factors that may give rise to ethics concerns and design their research in a way that better prepares them to respond to unmet need in low resource settings and more fully develop plans for transitioning short-term response activities to locally sustainable practices. Sharing field lessons like those from the SHARE intervention trial will be essential for developing this type of framework, as well as revising and improving guidelines for the ethical conduct of IPV intervention research in sub-Saharan Africa and other settings.

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Received May 1, 2015
Revision received December 4, 2015
Accepted December 9, 2015 ■