Ethical and safety recommendations for intervention research on violence against women

Building on lessons from the WHO publication
Putting women first: ethical and safety recommendations for research on domestic violence against women

World Health Organization

RTI INTERNATIONAL

Ethical and safety recommendations for intervention research on violence against women

Building on lessons from the WHO publication
Putting women first: ethical and safety recommendations for research on domestic violence against women

World Health Organization

RTI INTERNATIONAL

Acknowledgements

Contents

Acronyms and Abbreviations

ACASI	Audio computer-assisted self-interviewing
CIOMS	Council for International Organizations of Medical Sciences
CP MERG	Child Protection Monitoring and Evaluation Reference Group
DSMB	Data safety and monitoring board
IPV	Intimate partner violence
PI	Principal investigator
SVRI Forum	Sexual Violence Research Initiative Forum, Bangkok, 2013
VAW	Violence against women
VCT	Voluntary HIV counselling and testing
WHO	World Health Organization

Introduction

The Need for Intervention Research Guidelines

The publication of the World Health Organization (WHO) recommendations *Putting women first: ethical and safety recommendations for research on domestic violence against women* provided researchers with a set of concrete actions and best practices for conducting survey research on violence against women (VAW) in a manner that was both ethical and safe *(1)*. These recommendations have spawned additional publications highlighting ethical concerns in different aspects of research on VAW. Most recently, additional guidelines have been released focusing on general recommendations for conducting research on VAW *(2)*, on primary prevention initiatives *(3)*, on sexual violence in emergency settings *(4)*, with perpetrators of sexual violence *(5)*, and on violence against children *(6)*. The recommendations and guidance have been useful for researchers and practitioners in the context of cross-sectional descriptive research.

As the evidence base on the magnitude, context and consequences of VAW has grown, research efforts and attention have begun to focus on decreasing the knowledge gap on effective responses through intervention research. Demonstrating this focus, in November 2012 the WHO Department of Reproductive Health and Research convened a group of experts to discuss health sector-based research to respond to violence against women. This global network of researchers, scientists and practitioners was brought together to enhance existing research efforts and to advocate for greater funding for research on interventions to address VAW and policies and programmes related to it.

With the increased interest in and attention of the global community of researchers, practitioners and policy-makers regarding rigorous intervention research for preventing and responding to VAW, a discussion of the ethical considerations specific to this type of research is warranted.

As highlighted by WHO over a decade ago and by many others since, the sensitive nature of research on VAW requires special ethical and safety considerations *(1, 5, 7, 10)*. Although the broad considerations remain the same in intervention research, such as the need to protect the safety of the participant and the researcher, the implementation of intervention research also raises additional ethical and safety questions. For example, how can researchers safely approach selection, recruitment and follow-up of participants in a study to evaluate the outcomes and impacts of an intervention to prevent violence? How do researchers address randomization of participants into control or intervention arms? How do researchers monitor and manage risk of violence from participation in the intervention? And what additional protections should be put in place when the research involves populations requiring special considerations, such as pregnant women?

Intent and Content of These Guidelines

These recommendations have been developed to help answer questions specific to conducting research on health-based interventions to prevent and respond to VAW. Research on strategies that use health or health care as an entry point (regardless of the implementation setting, such as a clinic or community) is the focus. However, the discussion may be relevant to research on other kinds of VAW interventions.

The target audience for these guidelines includes stakeholders engaged in research on health-based interventions to address VAW. Such research may be conducted by multidisciplinary and cross-national or regional teams composed of researchers, programme implementers, evaluators, activists, advocates and care providers. Thus, in this document, the terms research team and researcher represent a range of stakeholders engaged in studying VAW interventions. These recommendations do not address ethical challenges and dilemmas that may arise in the context of collaborations to study VAW interventions. For example, issues related to respect and equity within research teams and across global North–South partnerships *(11, 13)* are not discussed, although we provide a few references on this and related topics where possible.

The focus of this document is on ethical and safety considerations for various stages and types of research on health-based interventions to address VAW, from design and development of interventions to evaluation of outcomes and impacts, and finally to obligations upon study completion. We focus specifically on ethical and safety issues associated with conducting longitudinal research (quantitative and/or qualitative) on VAW interventions, including randomized controlled trials, quasi-experimental studies and prospective programme evaluations. The recommendations are intended to support research teams to design ethical and safe studies and discuss these issues with research ethics review boards, and ultimately to protect the safety of those implementing and participating in such research.

Importantly, these recommendations are not designed to replace existing research ethics and safety guidelines nor are they designed to replace WHO's *Putting women first: ethical and safety recommendations for research on domestic violence against women (1)*; rather, they act as a companion piece. Existing guidelines address a broad range of issues relevant to developing and testing VAW prevention interventions, including informed consent, privacy and confidentiality, and staff recruitment and training. This publication begins by highlighting additional considerations related to several recommendations in *Putting women first*, followed by a presentation of issues specific to research on health-based interventions to address VAW.

There are a few related issues that are not discussed in these guidelines. We do not address ethical and safety issues involved in working with children or adolescents in the context of VAW intervention research, and offer alternative resources on this issue. This document does not address additional protections that may be needed when working with individuals living with HIV infection. Also, it does not comprehensively consider issues that may arise in VAW interventions outside the health sector.

Finally, given the evidence suggesting that pregnancy may be an optimal time for intervention, we have included a section on ethical and safety considerations when working in the context of antenatal care to address the lack of guidance on conducting VAW research among this population. Resources related to other relevant populations, such as children or HIV-positive individuals, are highlighted where available.

Putting women first: Recommendations

h — Violence questions should only be incorporated into surveys designed for other purposes when ethical and methodological requirements can be met.

a — The safety of respondents and the research team is paramount and should guide all project decisions.

g — Researchers and donors have an ethical obligation to help ensure that their fndings are properly interpreted and used to advance policy and intervention development.

b — Prevalence studies need to be methodologically sound and to build upon current research experience about how to minimize the under-reporting of violence.

f — Fieldworkers should be trained to refer women requesting assistance to available local services and sources of support. Where few resources exist, it may be necessary for the study to create short-term support mechanisms.

c — Protecting confidentiality is essential to ensure both women's safety and data quality.

e — The study design must include actions aimed at reducing any possible distress caused to the participants by the research.

d — All research team members should be carefully selected and receive specialized training and ongoing support.

Intervention Research Recommendations: Additional Considerations

This section outlines additional ethical and safety considerations for VAW intervention research. The graphic "*Putting women first recommendations*" provides an overview of the recommendations in the original WHO publication *Putting women first: ethical and safety recommendations for research on domestic violence against women (1)*. It is highly recommended that researchers closely review that document. Only the five recommendations outlined in black in the graphic, with additional considerations for intervention research, are presented below. Their original order and labels (a, c, d, f, g) are retained for ease of reference to the original content.

a — The safety of respondents and the research team is paramount and should guide all project decisions.

The overall principle underlying this recommendation applies to intervention research. However, there are several additional issues—particularly related to confidentiality of the research topic and the consent process—to consider in the context of intervention research.

Confidentiality of the research topic when involving couples, families or communities and during longitudinal research

Both the focus and length of intervention research may result in or necessitate disclosure of the research topic at the household and/or community level. This may be particularly true for intervention research focused on prevention, which may choose to reach more than one member of a social network or group, and which may involve longer and more frequent presence of the research team in the community. In these instances it may not be possible to completely conceal from household members or the group/community that the research addresses VAW. However, health promotion, and/or the promotion of relationship health more broadly, can offer a safe way to frame the research that relates to violence, especially for studies conducted in the health-care setting. The contextualization of violence as one factor with an impact on the health of women, children and communities allows researchers, and participants, to explain the inclusion of violence in the study in a less controversial manner. For example, a study may be referred to publicly as a study on women's health. This approach has been successfully used by numerous researchers *(5, 14)*. See the Appendix for examples of language.

Considering All Stakeholders

Prior to study implementation, it is recommended that researchers undertake formative research, including a stakeholder analysis. An analysis of this type allows researchers not only to understand who the various stakeholders are, both formal and informal, but also to identify the most effective messages for each audience. Increased understanding of the level and type of information needed by each stakeholder to support the project, while maintaining confidentiality about the topic, can help researchers to craft culturally appropriate, stakeholder-specific language to be incorporated into study scripts.

Studies that have successfully involved other household or community members in VAW intervention research while maintaining the confidentiality of the study's primary focus on violence indicate that the following actions can assist in this effort.

- Give careful consideration to the **title of the study** or intervention and **how it is described** to other team members, the public, participating agencies and potential participants.

- Pay attention to the **questions asked of each type of participant**. For example, when engaging both victims and perpetrators of violence in interventions where violence is being indirectly assessed (i.e. the focus on violence has not been disclosed to the perpetrators of violence), it is advisable to avoid focusing on the perpetrators; questions about both perpetration and experience of violence should be posed to both groups.

- Develop **standardized scripts** that both staff and participants can use comfortably to answer questions about the study posed by uninvolved family and community members, that avoid disclosing violence as the primary focus. Use standardized scripts during community-based data collection or participant follow-up when research teams may interact with, or be interrupted by, uninvolved family and community members.

- Actively **monitor how the research is discussed within the community**, which may include monitoring of rumours by community advisors, or interviews with community members to assess their awareness of the study's focus on violence *(15, 16)*.

Ongoing Participant Consent

The often longitudinal nature of intervention research requires that participants' consent be monitored to ensure ongoing, voluntary, informed participation and continued safety. *Putting women first (1)* underscores the importance of ensuring that women have an opportunity to consider the sensitivity of the research topic and are fully informed about the kinds of questions that will be posed in the interview[1]. This becomes even more important if a period of time elapses between initial consent and follow-up interviews. Evidence from clinical trials demonstrates that although participants may be well informed at enrolment, they may not retain critical information regarding the study or remain informed throughout the entire trial period. Understanding the risks and benefits of study participation, having rights to discontinue participation, and having opportunities to ask questions have been highlighted as areas requiring more regular follow-up *(17)*. The sensitive nature of VAW intervention research, including the potential for increased physical and social risks if others become aware of participation, further emphasizes the need for ongoing consent in this context.

Relevant to this discussion are recommendations made by Fontes in her article on ethics in research on VAW *(8)*. In the context of a cross-sectional interview, Fontes suggests using multiple decision points over the course of an interview where women are offered opportunities to either continue or stop participation. Applying this principle to longitudinal intervention research, women's willingness to continue their participation can and should be reassessed on a regular basis. The interval at which this reassessment occurs, as well as the method of reassessment, should be determined by the research team and may depend on factors such as the length and complexity of the study and the resources available.

---

[1] Here the term interview refers to either a qualitative or quantitative interview.

An informed consent comprehension checklist (see the Appendix for an example), similar to those used in a clinical trial context, is a useful tool to guide and document this discussion. A checklist can also be used as part of check-in at each study visit to enquire how women feel about continuing in the study. This should be conducted by research staff who are not involved in implementing the intervention, so that participants do not feel pressured to continue their participation for the sake of the researchers. As an added measure of assurance, principal investigators (PIs) may choose to confirm ongoing consent with a subsample of participants.

Consent of partners, family or other community members

Related to the above discussion on confidentiality, research involving members of a woman's social network as part of the strategy to address violence also brings up unique issues of consent. In these instances women who are experiencing, or are at risk of, violence should have the opportunity to make an informed decision about the recruitment of another individual in her network. Recognizing that social networks can be complex and extensive in many settings, this recommendation specifically pertains to cases where members of a social network (e.g. a mother-in-law or partner) are recruited as part of the strategy to address violence experienced by the primary female participant, as opposed to studies that may include members of a social network as primary research participants themselves (e.g. friends, neighbours, cousins). See box.

In a study conducted in Bangalore, India that targeted women experiencing violence along with their mothers-in-law, the daughters-in-law were first asked for their consent to recruit the mother-in-law. If, and only if, the daughter-in-law consented was the mother-in-law approached for possible enrolment. If both daughter-in-law and mother-in-law consented, the dyad was enrolled in the study. Each individual was informed of her right to discontinue participation at any time, independently of the other.

Ensuring voluntariness of consent in the context of an intervention study

Like all researchers, those conducting intervention research on VAW have an ethical obligation to ensure participants are able to choose to participate in a study, free of coercion or other factors that may impede their ability to weigh the possible risks and benefits accurately. In the context of VAW intervention research, this includes addressing therapeutic misconception and minimizing the effects of power hierarchies.

Addressing therapeutic misconception

A critical responsibility of VAW researchers is to ensure individuals understand that the intervention being studied has not been proven effective, and that their circumstances may not improve as a result of participation. The belief that participation will mitigate violence and/or improve their circumstances may be especially likely in contexts where the perpetration of violence is often left unaddressed. Thus the vulnerability of women in these settings, including added vulnerabilities such as HIV infection or migrant or disability status, should be considered in relation to what the study offers, or is perceived to offer, participants. Researchers can minimize the therapeutic misconception by ensuring the benefits and risks of participation are clearly explained during informed consent and by verifying potential participants' comprehension. See the Appendix for sample language.

Minimizing power hierarchies

In addition to not overstating the therapeutic benefit of the study, researchers should be sensitive to the potential influence of social hierarchies on voluntary informed participation. For example, in many settings health-care providers are treated with respect and deference, and individuals, particularly those who are experiencing violence, may be disinclined to refuse their requests. Research study staff obtaining informed consent should be trained to minimize these power hierarchies. This may be through standards of behaviour or appearance, such as dress, jewellery or mode of transportation, that can reduce social differences. Another strategy that may mitigate these power hierarchies is to recruit staff of a similar sociodemographic background to the study population.

In addition to the previously mentioned strategies, PIs/research managers involved in overseeing the research should take the following actions.

- Monitor enrolment and retention among participants or subgroups of participants unusually high enrolment may suggest problems with the informed consent process, including undue inducement.
- Observe interactions between staff involved in obtaining informed consent and potential participants to ensure that interactions are respectful and adhere to approved protocols.

It is important to keep in mind that coercion can take on more nuanced forms than direct pressure or force. Subtleties in the way that staff interact with participants during procedures such as informed consent may create a sense of pressure among a population already vulnerable to psychological coercion.

A shared process of safe, informed consent

Although participants should ultimately be properly informed and empowered to make their own determination as to whether it is safe to consent to study participation, this process may be shared with the research team. As an added measure to ensure a participant's ability to consent voluntarily and safely, some research teams have used tools or additional staff to assess the safety of individual participants' circumstances.

For example, a Population Council study involving routine intimate partner violence (IPV) screening and referral protocols used a hospital-based psychologist to assess consenting respondents' psychological readiness to be interviewed. The underlying idea was that respondents who had a more distant IPV encounter would demonstrate a different level of psychological readiness than those who had a more recent encounter.

A University of Melbourne study developed a risk-assessment tool that accounted for a participant's individual risk factors and other contextual circumstances (e.g., housing, legal, mental/physical health, support system) to categorize women into high, medium and low risk. Although not required, tools such as these may be used to further discuss possible risk with potential participants, such that they too can make a more informed decision *(18)*.

<div style="background:#4bbfc4;color:white;padding:10px">

c **Protecting confidentiality is essential to ensure both women's safety and data quality.**

</div>

In addition to maintaining the confidentiality of the research topic (section a, above), studies on health-based interventions to address VAW bring additional challenges and considerations related to protecting the participant's confidentiality.

Protecting participant confidentiality when involving couples, families or communities

Protecting participant confidentiality involves issues similar to those discussed above on maintaining confidentiality of the research topic (see section a). In addition to the recommendations outlined above, partners, family and/or community members should be asked to respect the confidentiality of all research participants. This may be especially important in group-based interventions or when using focus group discussions as part of data collection. In such cases, intervention research participants may be requested to avoid sharing details regarding other participants. Such confidentiality requests are often made in the context of qualitative research using focus group discussions. The need for confidentiality should be reaffirmed on an ongoing basis and participants should be asked to acknowledge their responsibility to respect the confidentiality of others.

Researchers should be cognizant of the limitations on their ability to protect participants' confidentiality, and should explain these limitations to potential participants during the informed consent process. Researchers may be legally required to report certain types of violence to relevant authorities, even though this reporting may conflict with the ethical obligation to protect participants' confidentiality and respect their autonomy (see "Special considerations related to mandatory reporting requirements", below). It is essential that researchers understand and plan appropriately for situations in which mandatory reporting requirements may apply, recognizing that different standards apply across countries. They will need to explain the limits of confidentiality to research participants. In addition, it may be ethically appropriate to screen participants for immediate safety concerns and to refer them directly to additional support services for their own and their children's safety and well-being.

> Researchers in South Africa faced an ethical and legal dilemma when an interviewee voluntarily disclosed incriminating details of child murder. South African law obliges adult citizens, including researchers, to report cases of child maltreatment to the authorities, and the interviewee's second, surviving child remained at potential risk. In this case it became necessary for researchers to breach participant confidentiality to fulfil their legal duty and minimize greater harm to society *(19)*.

Protecting participant confidentiality during follow-up and retention activities

Intervention studies typically involve following up on individuals and multiple interactions, leading to an increased risk of breaches in confidentiality. Researchers should take into account the risks associated with each study-related interaction, keeping such interactions to the necessary minimum and taking precautions to minimize potential breaches in confidentiality. Recommendations for protecting participants' safety during follow-up and retention activities are discussed in detail below, but broadly include:

- establishing safe methods and times to receive follow-up contact or messages
- identifying alternative trusted contacts in cases where participants are unreachable
- using an agreed script and code words (such as a security question or a phrase that not many people would know) for messages and/or home visits, if acceptable *(15, 16, 20, 21)*.

All the above strategies should be discussed with participants upon enrolment and reassessed at regular intervals (in line with ongoing consent). Strategies may differ depending on the context in which follow-up occurs.

Establishing safe methods and times for contact

Participant follow-up may occur over the phone, via mail or in person, depending on the circumstances and the needs of the research team. Regardless of study method, participants should be consulted about the safety of each option and informed about whether these points of contact can be used safely. For example, although the proliferation of mobile phones in low- and middle-income countries has facilitated the follow-up of research participants, it has also introduced new risks. When considering follow-up by phone, study staff should confirm a woman's level of phone access and use; possible monitoring of her phone by a partner; and whether the phone is shared with anyone else and if so, with whom, to minimize the potential for breaches in confidentiality *(22)*. In addition, staff should discuss whether specific times of day are safer than others for these contacts (e.g. while partner is at work) and should maintain flexibility in their own work schedules to accommodate these needs.

Identifying and using safe contacts

Over the course of an intervention study, research teams may encounter situations in which a participant is unreachable. In VAW intervention research, this may be because of specific constraints faced by women experiencing violence (such as the need to change residence during the course of the study because of violence; because partner is controlling access), or other reasons. Regardless of the reason, VAW researchers must take special care to identify safe contacts and use these in an ethical and safe manner.

A review of retention among longitudinal survey studies with abused women conducted in the USA recommends obtaining six safe contacts and suggests that close relatives are best, followed by neighbours, friends and colleagues *(23)*. However, the cultural context and physical environment should be carefully considered when requesting such information, as the number and type of contacts viewed as trusted may differ by setting.

Regardless of the level of trust a participant has in a contact, participants should be made aware that external contacts will be used only in rare instances when study staff have made repeated unsuccessful attempts to locate the participant. In these instances staff should avoid sharing information about the research and the participant with any of the contacts *(15, 23)*. See the Appendix for sample language regarding obtaining and using these contacts.

Using scripts and code words

Even in the absence of disclosing research details, in certain settings contacting neighbours or others in a woman's community may spark rumours that could result in a breach of confidentiality or cause harm. Thus, regardless of the chosen location or method of follow-up (phone, mail or in person), researchers must take additional precautions to reduce the risks involved in each contact. Developing and role-playing scripts (as described in section a) to be used during interactions with both the participant and other contacts may help staff feel at ease with these approaches and avoid mistakes leading to disclosure of participation *(15)*. In addition, when using the phone as a point of contact, pre-established codes or security questions should be used to determine whether the correct individual has been identified and is able to safely talk over the phone, and in instances where a phone call has been interrupted *(22)*.

Additional strategies when conducting follow-up in the community

Although the need for in-person follow-up is becoming less likely as more women have access to mobile phones, there may still be instances when it is required. In these instances researchers should take additional precautions to avoid risks of disclosure, such as conducting community meetings in advance of the study to introduce the staff and the broader purpose of the study (e.g. to promote women's or families' health). One strategy is to recruit staff who are from or familiar with the study community, which may reduce rumours resulting from their activities in the community. However, this approach should be balanced with other confidentiality concerns, such as discomfort among participants about sharing their experiences of violence with a known member of their community. In these cases staff may require additional training and supervision on confidentiality protection because of their relationships and familiarity with the study community. Requiring staff to take an oath of confidentiality can increase the weight of, and adherence to, confidentiality protection protocols.

An alternative and perhaps preferable solution to hiring staff from the research community is to hire staff from similar nearby communities. This may allow for increased familiarity with the community setting without raising ethical concerns associated with staff who live in the same community as participants.

Confidentiality in health-care settings

Studies conducted in a health-care setting offer several advantages in terms of confidentiality protection. Researchers may be able to use health centre telephones and/or staff to follow up with participants in the apparent context of a routine health-care follow-up, reducing the chance that the phone number or individual making the contact is viewed suspiciously by participants' partners or others in their social network *(16, 23, 24)*. Women may have the opportunity to visit a health centre with little scrutiny from others. However, other risks remain that should be addressed. The health centre staff may be known to the woman in her personal life (e.g. friends, family members, neighbours), which can raise issues of confidentiality. Staff should be prepared ahead of time as to how to handle these circumstances (e.g. with the use of scripts and code words). It should not be assumed that a woman's visits to a health-care provider will go unquestioned, especially if she is required to attend at greater frequency than usual. For example, a recent study assessing the experience of IPV among female participants in an HIV-prevention trial suggested that receiving calls from a health centre, or visiting the centre without approval of their male partner, resulted in threats and actual occurrence of violence *(25)*. Women should always be prepared by the study team to respond to questions from family members or others regarding where they are going and why they are going with a certain frequency, and should be consulted regarding safe practices for contact (as described above).

All research team members should be carefully selected and receive specialized training and ongoing support.

The provision of an intervention changes the nature of the relationship between researchers and participants and increases researchers' obligations to participants. As a result, new considerations for training and supporting study staff arise in the context of intervention research. These considerations are highlighted below. Researchers are also encouraged to review chapter 10, "Building your research team", in the WHO document *Researching violence against women: a practical guide for researchers and activists (2)*. The chapter provides detailed guidance regarding staff selection, training and support that is applicable to intervention research settings.

Division of counselling and research roles

Although the separation of counselling and research roles is often considered a methodological issue, in that separating these roles reduces a potential source of bias, it also poses ethical issues. As *Putting women first (1)* highlights, researchers are obligated to collect the most valid data possible, which includes an obligation to reduce bias. Furthermore, blinding staff who are providing counselling or other intervention components may be necessary to protect women's confidentiality and to improve the reliability of the data. In Kotch's longitudinal survey study on maltreatment *(26)*, social workers who were employed as project staff were blinded to information on abuse that they would be legally required to report. The key motivation for blinding was respect for participants' confidentiality (other reasons are detailed in the section "Special considerations related to mandatory reporting requirements", below). Blinding was accomplished by placing the most sensitive interview questions at the end of the face-to-face interview questionnaire booklet. At the end of the face-to-face interview, staff were instructed to give the booklet to the participants, who would circle their answers after staff read out the questions. The booklet was then sealed with tape and was opened only at the project's central office by staff other than the social workers/interviewers. These data were separated from any identifying information and entered by a different group of staff. Increased confidentiality around the issue of abuse allowed data collectors, despite being social workers, to maintain a greater distinction between their roles as researchers and service providers. In this case data collection was quantitative, participants were literate (although visuals/symbols could be used for illiterate populations), and the study did not involve testing an intervention in response to maltreatment so the social workers were not called upon as part of the research design to provide counselling to participants.

In studies testing or evaluating an intervention, particularly those in which the intervention being tested includes a counselling component, the separation of these roles becomes more challenging. The study size and budget may not allow for hiring additional staff for data collection. In addition, it may not be feasible to separate these roles in studies that test the effectiveness of interventions delivered by health-care providers. For example, studies that evaluate different screening or case-identification protocols in health-care settings typically involve health-care providers implementing the protocols, recording information on the outcomes of interest (e.g. numbers of women who disclose experiencing violence), and engaging in appropriate responses. Nevertheless, thoughtful mechanisms that create divisions between counselling and research roles in intervention-based research should be considered, including the use of audio computer-assisted self-interviewing (ACASI) for the violence-specific sections (used similarly to the booklets in the above example). Close monitoring is also necessary throughout the study to ensure that staff adhere to protocols.

Jack's suggested guidelines for nurse-researchers reflecting on this conflict of roles when conducting qualitative research provide several thoughtful considerations that are useful in this context *(27)*. They include:

- establishing **appropriate boundaries** with participants (e.g. around self-disclosure or sharing of personal values, beliefs or opinions)
- being thoughtful about how the **role of researcher** is described to the participant, taking into consideration participants' beliefs about certain clinical roles
- predefining when it is **appropriate to intervene** within the research context.

As the final point suggests, the need for separation should never prevent researchers from ensuring that participants receive counselling and other support services when needed. Establishing a protocol to respond to a participant's distress or risks (e.g. of suicide) can aid in clearly defining, in advance, when an intervention is appropriate, and describing to participants the separation of this response from the research.

<div style="background-color:#b6dcd6; padding:1em;">

Distress and disclosure protocols

The SARAH Project, a study conducted at the University of Melbourne with children of women experiencing domestic violence, includes the following steps to guide researcher responses in cases of distress *(18)*.

1. When distress is detected, inform the participant that the research process has been suspended and that the researcher will use her professional skills as a counsellor to provide brief counselling support to alleviate any distress.

2. Provide and/or refer the participant for support.

3. Discuss the appropriateness of continuing the research process on that or on another occasion, or to opt out of the project altogether.

4. If continuing with the research, inform the participant that the researcher is resuming her research role, and that the process can be interrupted again if the woman or child becomes distressed again or does not want to continue for any reason.

</div>

<div style="border:1px solid #e8a33d; padding:1em;">

SUMMARY OF TRAINING NEEDS

Timing: At study start-up and according to a well defined schedule of refresher training (some researchers do this as often as every 6 to 8 weeks).

Topics:
- Maintaining confidentiality through extensive role-playing of scenarios and scripts.
- Conducting ongoing consent.
- Minimizing power dynamics between staff and participants.
- Maintaining separation of research and intervention roles.
- Managing social network relationships.
- Managing repeated acts of violence.
- Preparing for closure of the research relationship with participants.

</div>

One consideration is the background training of potential research team members. In Kotch's study *(26)*, social workers were hired to serve as data collectors. However, there may be instances when hiring individuals with extensive experience in violence-related service provision to fill a research role creates challenges for rigorous implementation of intervention studies. As with therapeutic misconception on the part of participants, staff who are used to providing services and view them as therapeutic may find it difficult to follow a research protocol that limits the extent of intervention in terms of individuals (intervention versus control group) or services. Special efforts may be needed to ensure these staff understand and are comfortable with maintaining a distinction between research and service provision roles during the study, and with implementing all aspects of the research protocol. This is particularly important to avoid falsely conveying to participants that the intervention is intended to be therapeutic rather than under evaluation, and also has implications for data quality and implementation rigour. If the protocol requires aspects such as randomization, which these individuals may feel uncomfortable implementing, they should not be considered for a research role. Although staff should always be empathetic to women's experiences and be trained to help women access support, maintaining a distinction between research and intervention roles is important to ensure researchers' ethical obligation to collect rigorous evidence is met.

Additional areas of training

Given that research team members may spend a significant period of time with participants, dealing with very intimate details of their lives, they may require additional skills to cope with and manage their professional roles and relationships. Study training and implementation protocols should address strategies to maintain a professional relationship with participants and handle situations that might arise if a research team member leaves the study. McFarlane and Wiist describe how the termination of the relationship between research team member and participant, whether because of staff leaving the study early or at the natural end of the study, may be particularly challenging and require special training and support *(28)*. In the context of their advocacy-focused intervention study, which included multiple interactions including home visits between participants and their "mentor mothers", they found it necessary to incorporate issues of closure in staff training. In addition, the research coordinator offered each mentor mother personal assistance in this process as the study drew to a close.

Studies involving couples, families or other members of a participant's social network also require training specific to handling relationship dynamics, including how to deal with group dynamics in such a way that confidentiality is promoted and protected *(15)*. Role-playing during training, using a variety of scenarios that may arise in group settings, can also strengthen staff's ability to respond to these dynamics.

Over the course of a study, researchers may encounter new or continued reports of incidents of violence. They should be trained in how to respond and process such repeated acts of violence *(29)* as laid out in safety protocol procedures (see section 5 under "New recommendations," below). Depending on the length of the study, refresher training will also be important to re-emphasize safety, ethical and confidentiality procedures, among others.

Assessing and addressing need for staff support

As *Putting women first* highlighted *(1)*, staff involved in research on VAW are not immune to experiences of violence, which may occur in their personal life regardless of their employment with the study, and/or may occur as a result of their employment. If this issue is left unaddressed, research projects may experience high rates of staff attrition which, given the intense training needs and the need to build trust with participants, can have a negative impact on the continuity of the research team and thus the quality and safety of VAW intervention research.

Recommendations include offering opportunities for staff to come to terms with and address their experiences of violence. In some cases, staff may need to be reassigned to different job duties; for example, staff who are responsible for intervention implementation may find it emotionally challenging when dealing with their own experiences of violence. PIs will need to assess the scale and source of the problem to respond adequately, and to consider the confidentiality of the staff member. For example, if conflict with a partner occurs as a result of a staff member's earnings, appropriate solutions may include helping the staff member set up a separate bank account where wages can be provided in a more discreet manner. Ideally, staff should have opportunities to discuss personal issues with the study's PI or research manager and should have access to external support services. The provision of external services is especially important as staff may not always feel comfortable discussing personal issues with their colleagues or supervisor. Moreover, PIs may not always be readily accessible (in the same location as the staff), and supervisors may not always have the skills or resources to fully address staff needs in this area.

In addition to staff experiences of violence within their own family, they may be at risk of violence from individuals perpetrating violence against study participants. *Putting women first* recommends logistical planning to increase interviewer safety, including travelling in pairs, carrying mobile phones, using a designated means of transport, and keeping supervisors abreast of their whereabouts *(1)*. Researchers should put in place an immediate plan of action and sources of support in the event that violence occurs. In addition to using community-based services identified as referral sources for participants (see section f, below), developing a community advisory board that can identify potential challenges and mobilize to support staff in cases of danger is one way to address this concern proactively. When considering the composition of the board, researchers should look for women and men who are respected in the local community and individuals who could step in to mediate issues of staff safety. Expectations around board members' role in mediating issues of safety should be discussed in advance. Finally, research experience suggests that VAW research team members may experience trauma, either physical or emotional, simply as a result of being exposed to participants' experiences of violence. Described as vicarious trauma, the risk of this form of trauma among research team members may be increased by the number and level of interactions with participants in intervention research; or decreased through the opportunity to offer women an intervention that may mitigate their experience of violence. PIs/research managers should prepare their staff for the possibility of experiencing this form of trauma and put in place measures to mitigate its occurrence. This should include acknowledging the issue during training, preparing team members to identify early warning signs, developing and using self-care strategies, and engaging with additional support systems and services, such as debriefing opportunities and access to counselling provided through the study. The SVRI's documents on researcher trauma and vicarious trauma offer additional suggestions on responding to this issue, including forms of self-care and how to structure debriefing opportunities *(30, 31)*.

f **Fieldworkers should be trained to refer women requesting assistance to available local services and sources of support. Where few resources exist, it may be necessary for the study to create short-term support mechanisms.**

Because of the potentially longitudinal nature of intervention research, the responsibility of the research team, as well as the opportunity, to refer women to additional services and sources of support may be increased. Depending on the length of the study, this increased responsibility and opportunity may necessitate additional actions to keep the research team's knowledge of resources and relationships with referral service providers up to date. Refresher visits and contacts with service providers by the research team are recommended on a regular basis (e.g. quarterly). If no referral services exist, researchers have an ethical obligation to ensure the research team has the capacity to handle crisis situations, including crisis counselling and safety planning. In addition, because seeking support can be difficult for women experiencing violence, researchers may find that providing a list of referral services is insufficient and that offering assisted or escorted referrals is beneficial. The need to provide escorted referrals may be compounded in settings where access to transport is a challenge *(15, 28)*, or where on-site care for violence exists but may be challenging for women to locate on their own *(24)*. Researchers will need to weigh their ethical obligation to offer support to women experiencing violence against their ethical obligation to maintain confidentiality and to ensure they are able to evaluate whether the proposed intervention is efficacious. Taking thoughtful precautions to avoid disclosure of a woman's participation in a research study during escorted referrals may be warranted.

g Researchers and donors have an ethical obligation to help ensure that their findings are properly interpreted and used to advance policy and intervention development.

Putting women first (1) emphasizes the ethical obligation of VAW researchers to share results and ensure they are properly interpreted and used for the advancement of intervention and policy development. As noted in that document, dissemination of results to participants, researchers, service providers and the general public should avoid stigmatizing or exacerbating risks faced by participants and the vulnerable populations they represent.

The ethical obligation to advocate for the availability of an intervention, should it be proven effective, is unique to intervention research. In line with ethical guidance in the Helsinki Declaration *(32)* and the Council for International Organizations of Medical Sciences (CIOMS) International ethical guidelines *(33)*, VAW intervention researchers need to consider what constitutes reasonable availability of an effective intervention to the study population and/or the broader community or country upon completion of the research.

Because ethical obligations are likely to be context-specific and have not been extensively discussed within the research literature on VAW interventions, or on social and behavioural interventions more broadly, our specific recommendations focus on the processes for determining post-study obligations, rather than suggesting what should be provided. Based on discussions in the biomedical research context, the following are suggested.

- Consult with local stakeholders at the study outset to discuss the health, social and economic circumstances that may influence expectations and the future provision of interventions.
- Discuss sustainability/scale-up of effective interventions with study sponsors prior to study launch. Issues include the strength of evidence and what additional data may be needed to determine decisions regarding the availability of effective interventions to the study population or the broader community (city, state, country).
- Clarify actions needed to advance adoption and implementation of efficacious interventions such as establishing links with advocacy groups, strengthening human resources or providing training.
- Maintain transparency with all consultations and resulting decisions, taking care to minimize any unequal power hierarchies between the research team, community members and participants *(34–36)*.

Researchers' level of responsibility to undertake these processes will depend in part on the intent of the research. If the intent is to investigate the effectiveness of an intervention, as opposed to earlier phases of intervention research (e.g. feasibility or efficacy testing), then the obligation to undertake these steps will be increased.

HELSINKI DECLARATION

Medical research with a vulnerable group is justified only if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research.

CIOMS INTERNATIONAL ETHICAL GUIDELINES

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 priorities of the population or community in which it is to be carried out
- any intervention or product developed, or knowledge generated, will be made reasonably available for the benefit of that population or community.

New recommendations for intervention research

1. Intervention studies need to be methodologically sound and build upon the current evidence base of interventions and intervention research experience.

5. Measuring and monitoring harm related to the research should be incorporated into safety protocols.

2. Processes and criteria for participant recruitment should be carefully considered to avoid excluding women who may not initially disclose experience of violence.

4. The provision of services to comparison arm participants should maintain a minimum standard of care.

3. Participant randomization should be transparent and described in a way that can be easily understood by those involved in the research.

<div style="background:teal">

New Recommendations

</div>

Along with the considerations discussed, conducting intervention research on VAW entails several new ethical considerations.

---

1 | Intervention studies need to be methodologically sound and build on the current evidence base of interventions and intervention research experience.

Following the guidance in *Putting women first* (section b, above), intervention studies should be methodologically sound and build on the existing evidence base. Intervention research also has the responsibility of drawing from both research and programmatic experience to avoid repeating ineffective and potentially harmful interventions. In addition to considering whether interventions have been tested previously, intervention research teams must ensure that a particular strategy is tested in a methodologically sound manner. This includes maintaining fidelity to key intervention components (if previously evaluated), with appropriate, well documented adaptations to the specific context in which it is being tested. A badly implemented intervention study is a lost opportunity to build the evidence base around effective interventions to prevent VAW, and a waste of scarce resources. Moreover, it may put participants in direct harm. In particular, this may be a concern when replicating evidence-based strategies to address VAW from high-income countries in lower-income settings without taking into account contextual differences, including the availability, or lack of support services *(3)*.

Considering the current lack of evidence around what works to prevent VAW, research teams may need to build evidence incrementally to support larger-scale testing of promising approaches. In doing so, researchers should use a phased approach to designing their studies, including when adapting existing interventions to new settings. The Medical Research Council of the United Kingdom and the South African Medical Research Council have published guidance on these phases of research as they relate to developing and evaluating complex interventions. Phases include:

- thoughtfully developing the intervention, making explicit the theory of change behind it
- conducting pilot, feasibility, acceptability and/or safety testing
- evaluating the intervention for efficacy and/or effectiveness.

Approaching research on innovative interventions in this phased manner allows researchers and interventionists to consider carefully and identify issues of safety and unintended consequences on a smaller scale before exposing large numbers of women to a yet untested approach *(37)*. Once researchers reach the efficacy or effectiveness evaluation stage, a variety of study designs may be considered, including randomized controlled trials and alternative randomized design approaches, such as stepped wedge and wait list designs that retain critical elements of methodological rigour *(38)*. Research teams should choose a design that is feasible as well as ethically appropriate, keeping in mind their responsibility to generate rigorous evidence. Designs that allow for delayed provision of the intervention to control-arm participants may help overcome resistance among stakeholders and/or research ethics committee review boards to testing an intervention that is widely perceived as beneficial, even if not yet proven as such.

<div style="border:1px solid orange">

FACTORS TO CONSIDER IN RECRUITMENT STRATEGIES

Focus of intervention study: Eligibility criteria for study recruitment will vary depending on whether the intervention being tested aims to prevent the first occurrence of VAW or to mitigate VAW and its adverse health consequences. For studies that aim to test an intervention's effectiveness in preventing the initial occurrence of violence, recruiting women who experience violence may not be necessary or appropriate.

Location of study: In certain settings, physicians routinely ask women about experience of domestic violence. In these cases, researchers may contact physicians to ask for their help in recruitment. Although it would be unethical for researchers themselves to approach potential participants, initial contact could be made by the physician or nurse who has access to the relevant information.

</div>

2 Processes and criteria for participant recruitment should be carefully considered to avoid excluding women who may not initially disclose experience of violence.

As research experience has indicated, given the sensitive nature of violence, many individuals may not immediately disclose their experiences of violence. Depending on the nature of the intervention and the context in which it is to be tested, this has implications for how researchers recruit women. Research teams have an obligation to ensure intervention research reaches those most in need. However, it may be difficult to identify these individuals in settings where there may be underreporting of VAW.

This challenge may be especially acute when recruitment activities occur outside settings where women seek support for, or are routinely asked about, violence (such as health-care settings in the United States). Researchers must consider how, when, and what measures should be used to determine risk or exposure, if required to recruit only women who report having experienced violence. Drawing from lessons outlined in *Putting women first* (section b, above), researchers should avoid loaded terms when asking about violence; carefully consider the context of recruitment, including who is present; and consider the sex, skills and attitudes of those hired to recruit participants.

Researchers conducting intervention studies may have the opportunity to develop a multi-step identification process, such that violence is not mentioned or used as an eligibility criterion at initial contact, but rather at a later point in time. This may offer staff and potential participants an opportunity to establish rapport and increase women's willingness to disclose. In contexts where disclosure of violence is more common, or if a multistep identification process is not feasible, researchers should, as a minimum, ask questions about violence further into the identification (screening) questionnaire. Other strategies to increase disclosure include:

- asking questions in **multiple ways** (e.g. both directly and indirectly)
- asking questions **multiple times** during the screening questionnaire.

For standard examples of how to ask about violence in a way that maximizes disclosure, researchers are encouraged to consult the *WHO multi-country study on women's health and domestic violence against women: initial results on prevalence, health outcomes, and women's responses (39)*.

Alternatively, if evidence exists demonstrating a sufficiently high incidence of VAW in a given population or setting, researchers may consider not using disclosure of violence as a criterion for eligibility *(15, 40)*.

WEAVE, an Australian study designed to enhance general practitioners' ability to respond to domestic violence, used a two-stage process to recruit participants. The first stage involved a questionnaire mailed to participants. Numerous questions were asked regarding health topics, from alcohol use to smoking to depression, with questions on violence buried among these other topics. The second stage involved a call from a research team member who again emphasized the contextualization of the issue of violence within broader emotional health *(41)*.

3 Participant randomization should be transparent and described in a way that can be easily understood by those involved in the research.

The strongest research designs include a comparison (control) group to clearly understand and measure changes that occur as a result of an intervention. Although deemed necessary to understand intervention efficacy more conclusively, randomizing participants to a control group may raise ethical concerns, particularly when all participants are identified as needing intervention of some sort. This dilemma is not exclusive to the case of VAW intervention research, although many of the issues described above, including the particular vulnerability of this population and the possible expectations of participants in these circumstances, make this issue worthy of extra consideration. Attending to this issue may include considering alternative randomized study designs, such as the stepped wedge or wait list designs that incorporate provision of the intervention to control participants at a later point *(42, 43)*. Regardless of study design, the informed consent should provide clear information to potential participants about what level of access to the intervention they may expect after the duration of the study, if this is shown to be effective (as discussed in section g on post-study obligations). The randomization rationale and process should also be transparent and described in a way that can be easily understood by everyone involved in the research, from the study staff to the participants. A common approach is to describe randomization as a lottery where the opportunity to receive the study intervention is decided by chance *(44-46)*.

4 The provision of services to comparison-arm participants should maintain a minimum standard of care.

If the benefits of an intervention are not yet established, and the intervention can be provided safely through a randomized controlled design, then researchers must ensure the usual standard of care is provided to participants in a control group. It might also be appropriate, and preferable from an ethical perspective, to provide an enhanced standard of care to a control group. This depends greatly on the context and may be considered, keeping in mind that offering an enhanced control condition can reduce the strength of findings relative to the intervention group. In some settings a referral list may be an appropriate enhanced control condition, whereas in others referrals may not be a viable option.

As recently outlined in ethical guidance on the conduct of cluster randomized trials, the delayed provision to control-arm participants of an intervention being tested does not justify the lack of provision of services known to be effective to all participants *(47)*.

In addition, women whose lives are at risk or whose children's lives are at risk should be ineligible to participate in the research. Research teams should be prepared to ensure a direct referral to immediate services for such women (which may include crisis counselling, police, shelter) *(48)*. In settings where referral services are unavailable, local capacity to provide crisis counselling should be developed and these services should be made available to all potential participants as well as to those who may need them during the course of the research study.

Researchers have an ethical obligation to monitor and measure harms, or threats of harm, that may occur during the conduct of a study and to determine what, if any, experiences result from research participation. Drawing on clinical research experience and guidelines on tracking adverse events and social harms, VAW intervention research teams need to determine up front what and how they will measure and report, and they will respond to these issues. Although any potential harm that comes to researchers' attention should be documented, a case-by-case approach will be necessary to determine whether the incident is study-related and what, if any, follow-up actions are needed. Complicating researchers' ability to determine which events are study-related is the fact that the study population is, or is likely to be, at risk of violence even in the absence of the research. Thus it becomes particularly important that researchers anticipate and define a process for documenting, investigating and responding to safety issues and incidents (see the Appendix for an example of a documentation form). Level of severity should also be taken into consideration. For example, while general mental distress may not warrant further investigation because of the baseline levels of distress experienced by the study population, serious threats of suicidal intention or attempts are situations to which research teams should be prepared to respond. Asking women periodically whether they feel more, less, or the same level of threat in terms of their personal safety may be another way to assess the safety of the intervention. Finally, researchers should build in regular, formal reviews of data through the use of a data safety and monitoring board (DSMB) that can help assess differences in the severity and frequency of violence between control- and intervention-arm participants, or over time if no control group is used.

Special considerations for research in antenatal care settings

Research on interventions to address VAW has focused, and is likely to continue to focus, on antenatal care for several reasons. First, there is considerable evidence from around the world indicating that violence is common during pregnancy *(49)*, and that violence has severe consequences for the health of women and children *(50-55)*. Second, concerted efforts to improve maternal and child health globally have resulted in high utilization of antenatal care services; these services offer a window of opportunity to prevent, identify and respond to violence. Health-care settings can provide a safe and confidential environment for violence interventions as part of health promotion. However, interventions with pregnant women also involve unique ethical considerations. In this setting, researchers must be prepared to address the potential for increased risk of preterm birth and pregnancy loss and have mechanisms in place to determine whether the event is IPV-related and/or study-related (see section on monitoring adverse outcomes). For studies where recruitment of pregnant women occurs outside the antenatal care setting, researchers should ensure women are aware of antenatal care recommendations, and where and how to access these and other relevant services. For example, the research team should be prepared to offer referrals to services such as HIV testing, voluntary HIV counselling and testing (VCT), and other related referrals, given the high overlap between these issues and VAW *(56, 57)*.

Finally, although it is not within the scope of this document to review detailed considerations regarding the ethics and safety of child participants, these may also be important when VAW intervention research conducted with pregnant women extends beyond the perinatal period and/or includes data collection on the infant/child. In these situations it is recommended that researchers consult additional resources, such as the report published by the global Child Protection Monitoring and Evaluation Reference Group (CP MERG), *Ethical principles, dilemmas, and risks in collecting data on violence against children (6)*.

Recruiting during antenatal care

Although antenatal care offers a unique window of opportunity to recruit women who may be experiencing violence, researchers should also be aware of potential safety challenges. Male partners, sometimes potential perpetrators, may accompany their female partner to the clinic. In South Africa, for example, this is especially the case for migrants who may have language barriers. In these cases, the male partner may attend specifically to serve as an interpreter. Being cognizant of the potential presence of perpetrators, researchers should avoid conducting any activities related to recruitment, screening or other study activities in the waiting rooms or in any areas that may be accessed by others. Where translators are used, they should be known to the researchers and unrelated to the participant.

Special considerations related to mandatory reporting requirements

In the course of VAW intervention research, staff may become aware of certain types of safety risks or violence that they may be legally mandated to report to relevant authorities. For example, a participant may disclose an intention to engage in self-harm or harm to others, or an experience of sexual assault. Given the co-occurrence of intimate partner violence and child maltreatment (58), information pertaining to the safety and well-being of participants' children (e.g. incidents of child physical or sexual abuse) may come to light during the course of the research. Researchers' legal obligations to report this information may conflict with their ethical obligations to protect participants' confidentiality, respect their decision-making autonomy, and ensure additional protections for vulnerable groups such as children.

Researchers should anticipate and be prepared to address these situations. They should:

- Ensure an **appropriate and timely response,** such as referrals to, or the provision of, crisis counselling, safety planning or childcare services.

- Be aware of relevant **local reporting laws and procedures** as well as the likely implications and outcomes of reporting, and make limitations to confidentiality explicit in the informed consent.

- Develop a plan to handle issues related to **mandatory reporting requirements,** including strategies to minimize the possibility of collecting certain kinds of information. For example, researchers may need to make it clear in the informed consent that if child maltreatment is disclosed they will be obliged to report it. (Where researchers feel the reporting may actually lead to a more harmful scenario for the child, this may require special consideration and discussion with the ethics review board.) In some settings it is possible to obtain a waiver of mandatory reporting in the context of research, and this option should be explored by PIs.

- **Explain to potential participants** during the informed consent process about the researchers' obligation to report certain incidents (see the Appendix for sample language).

In some cases, researchers may feel that reporting could lead to increased risks to the woman and/or child. For example, reporting may increase a woman's risk of violence, or may lead to children being placed in an institution where they are even more vulnerable to abuse or neglect. In such situations, researchers should ensure that their actions are in the best interest of the individual concerned, and that they base their actions on the principle of non-maleficence.

The decisions made by researchers conducting a longitudinal survey study of maltreatment of women and children in the United States are illustrative of this issue *(26)*. The study team realized that the majority of reported cases of maltreatment are ultimately not substantiated by the legal system; that reporting may put the child at risk by angering the accused family members; and that even if successfully proven, interventions themselves may have negative long-term consequences. Thus they limited data collectors' chances of identifying cases that would require mandatory reporting by minimizing their access to sensitive data and training interviewers to adhere strictly to structured questions.

Conclusion

In light of global statistics on the prevalence of VAW and the large body of evidence demonstrating the myriad adverse impacts of violence on the health and well-being of women and children *(39, 49, 59, 60)*, it is imperative that attention and resources be focused on the identification of effective approaches to prevent and mitigate violence. Investments in generating evidence on what works to prevent and respond to violence are increasing *(61-63)*, and health-based interventions comprise an important and growing category of work in this area. As noted in the WHO's *Putting women first* guidance *(1)*, ensuring that research on VAW is conducted in an ethical and safe manner is of the utmost importance. *Putting women first* provides a comprehensive description of issues that VAW research teams should consider in designing and implementing their studies. However, additional ethical and safety challenges arise in the context of research on interventions to address VAW because such research is often longitudinal, raises specific kinds of expectations among participants and communities, and may go beyond involving women to engage with members of their family, social network and community. The focus of intervention research is likely to be on women who are at higher risk of experiencing violence, so monitoring safety can be especially difficult because of the need to untangle baseline and study-related risks of violence. Existing ethical and safety guidelines do not address these challenges specific to conducting research on interventions to prevent and mitigate VAW.

Using the existing literature and consultations with experts in the field, we have summarized additional ethical and safety challenges associated with research on health-based interventions to prevent and mitigate VAW, and offer recommendations to research teams on how to address these challenges. The recommendations fall into two broad categories: additional considerations related to recommendations provided within *Putting women first (1)*; and new recommendations associated with challenges that can arise specifically in the context of VAW intervention research (Table 1). As with all recommendations, research teams will need to interpret the information provided here in the context of their own research questions and settings. Finally, given the relatively new focus on intervention research, we recognize that these recommendations will need to be updated as additional experience is gained. We hope this will be a growing resource for future research teams.

If you would like to contribute your experiences to future editions of this document, please send your suggested contributions to reproductivehealth@who.int.

Table 1: Summary of recommendations for VAW intervention research

Recommendations from *Putting women first:* additional considerations
a. The safety of respondents and the research team is paramount and should guide all project decisions.

Confidentiality of research topic

- Consider research/intervention title and description so that it avoids the word violence.
- Pay attention to questions each type of participant is asked to avoid disclosure of topic.
- Develop standardized scripts for staff and participants to respond to questions about the study.
- Monitor community responses to research, particularly awareness of violence as research focus.

Participant consent

- Institute regular process of ongoing consent.
- Use staff not conducting the intervention to confirm consent.
- Have PI confirm ongoing consent with subsample (optional).
- When research involves members of a woman's social network as part of the strategy to address violence, offer women experiencing violence an opportunity to make informed decisions about their recruitment.
- Ensure risks/benefits are fully explained and verify participant comprehension to minimize therapeutic misconception.
- Minimize power hierarchies by setting standards of dress/behaviour, and/or by hiring staff of similar socioeconomic background.
- Monitor enrolment rates among study participants or subgroups of them.
- Observe interactions between staff obtaining informed consent and participants.

c. Protecting confidentiality is essential to ensure both women's safety and data quality

Confidentiality of participants

- Continually reaffirm need for confidentiality.
- Ask participants to acknowledge their responsibility to respect confidentiality of others.
- Communicate limits of researchers' ability to respect confidentiality of participants (e.g. mandatory reporting requirements or in focus group context).
- Identify safe methods and times for participant follow-up and assess on an ongoing basis:
  - confirm privacy levels of mobile phones
  - identify trusted contacts
  - prearranged script and code words to ensure safety in case of interruption.

Table 1: Summary of recommendations for VAW intervention research *(continued)*

d. All research team members should be carefully selected and receive specialized training and ongoing support

Division of roles

- Establish appropriate boundaries and explain staff roles to participants.
- Predefine when and what type of intervention is necessary and acceptable through a protocol for responding to participant distress:

    -explain clearly to participant when acting as researcher versus counsellor

    -emphasize to staff distinction between research and service roles.
- Consider background training of staff hired into research roles.

Additional staff training

- Offer strategies for maintaining professional relationships with participants.
- Train staff on handling relationship/group dynamics.
- Train staff to respond to and process repeated acts of violence.
- Conduct refresher trainings on safety, ethics and confidentiality procedures, among others.

Support services for staff

- Offer opportunities for staff to come to terms with and address their experiences of violence and, if necessary, change person to other roles.
- Offer opportunities for staff to discuss personal issues with PI/research manager.
- Offer access to external support services.
- Make logistical plans to ensure interviewer safety (e.g. travel in pairs, carry mobile phones, designate means of travel).
- Develop community advisory board to mediate potential issues of staff safety.

f. Fieldworkers should be trained to refer women requesting assistance to available local services and sources of support. Where few resources exist, it may be necessary for the study to create short-term support mechanisms.

Support services for participants

- Maintain staff knowledge of referral service providers through regular (e.g. quarterly) visits and contacts.
- Build capacity to handle crises as needed while maintaining confidentiality (e.g. train local providers, offer escorted referrals if transport is difficult).

g. Researchers and donors have an ethical obligation to help ensure that their findings are properly interpreted and used to advance policy and intervention development.

Determine what constitutes reasonable availability of intervention, if proven effective

- Consult local stakeholders to assess contexts that may affect intervention provision.
- Agree with study sponsors and other decision-makers on evidence needed to make effective interventions more widely available.
- Clarify actions needed for intervention adoption.

Table 1: Summary of recommendations for VAW intervention research *(continued)*

New recommendations for intervention research
1. **Intervention studies need to be methodologically sound and build on the current evidence base of interventions and intervention research experience.**

- Draw from research and programmatic experience.
- Maintain fidelity to key components and methodology of original study when replicating.
- Use a phased approach to build evidence:
    - -initial development/concept (with related theory of change)
    - -pilot, feasibility, acceptability and/or safety testing.

2. **Processes and criteria for participant recruitment should be carefully considered to avoid excluding women who may not initially disclose experience of violence.**

- Be mindful of recruitment context, people present, and the sex, skill and attitude of recruiters.
- Leverage existing networks (e.g. physician-patient relationships).
- Use multistep identification ("screening") process.
- Ask questions multiple times and in multiple ways during identification process.
- In areas of high incidence of VAW, consider foregoing disclosure of violence as a criterion.

3. **Participant randomization should be transparent and described in a way that can be easily understood by those involved in the research.**

- Consider alternative randomized study designs (e.g. stepped wedge).
- Describe methodology in accessible terms (e.g. analogy of lottery to explain randomization).

4. **The provision of services to control participants should maintain a minimum standard of care.**

- Be prepared to address crisis situations through counselling, safety planning and/or contact information for referral services.
- Build local capacity of services if none are available.

5. **Measuring and monitoring harm related to the research should be incorporated into safety protocol procedures.**

- Define process for documenting, investigating and responding to safety issues and incidents.
- Conduct regular, formal reviews of data to assess fluctuations in severity and frequency of violence.

Annex: Sample language

The following examples are included to provide research teams with a general idea of how to operationalize some of the guidance provided within these recommendations. They are not meant to be used verbatim and should be modified to fit the specific context and population of the research.

To describe the project as part of a larger health study

"[Project name] is a project that is interested in understanding women's experiences of the health care they receive from their primary provider, particularly in relation to relationship issues and emotional health (such as being afraid of their partner, domestic violence, and so on)."

"[Project name] is a family health research project that is going to be conducted by a group of researchers, doctors and counsellors working in the field of health research for more than [x] years. Our research is a collaboration between [names of collaborators]. We have been working to understand and improve women's health issues such as menstruation, sexually transmitted infections (fill in with other conditions as appropriate to your study), and relationships between women and men. The research we undertake is to help improve health services for women, families and the community. We are now planning to conduct programmes and research to help improve family health based on health challenges experienced by older women, younger women and infants."

Standardized phone script for follow-up

Staff instructions: Contact with participants will be made by the designated staff member, by phone, after obtaining agreement from the woman at the initial interview that it is safe for her to be called . If possible, try to establish with the woman when it is a good time to call her (e.g. when she will be alone). If necessary, a code may be established with the woman to indicate that she is not alone when the research assistant calls.

If the participant is there:
"Hi [Her first name], my name is [Your first name]. I'm calling you to [purpose of call, such as follow-up]. Is this a good time to talk? It will take [estimate of time for call]."

If not a good time to talk:
"When would be a good time for me to call back?" [participant offers another time] "Great, I'll call you back at [repeat the time back to her]. Very good. I'm looking forward to talking with you, [Participant's first name]."

If OK to talk now:
"I'd like to [purpose of call, such as follow-up]."

On completion of the follow-up call:
"Would it be OK if I call you on [date and time] for the next call?] I'd like to give you a phone number that you can call if you need to leave me a message. You can call our hotline number at any time at [provide number]."

If participant is not home and someone else has answered the phone:
"Hi. May I speak to [Potential participant's name]? [she's not there] Okay. Do you know when would be a better time to call her back? [wait for reply]. Thank you." [If the person wants to know more about what you are calling about, use a culturally specific pre-prepared explanation that is agreed to be safe (e.g. calling from a health centre about a service).]

Informed consent comprehension checklist for ongoing consent

See Table 2.

Table 2: Informed consent comprehension checklist for ongoing consent

Open-ended question/ statement	Required points of comprehension	✓	Comments
1. Please tell me your understanding of the purpose of the study	[insert key purpose of study] Should demonstrate understanding that intervention is not known to produce therapeutic benefits		
2. What are the possible risks for continuing in the study?	[insert key risks, e.g. may increase conflict in the home]		
3. What will happen if a woman decides to leave the study?	Free to make her own decision about leaving the study		
	No change to her access to health care whether she stays in the study or not		
4. How will information about participants in the study be protected?	Information about participants is confidential, private, and locked away		
	Only people working on the study have access to her information		
5. What are the possible benefits for participants in the study?	[insert benefits, e.g. opportunity to discuss experiences]		
6. What should participants do if they have questions or concerns about their health or about what is happening in the study?	Must state how to contact study staff		

Outcome

❑ Demonstrated comprehension of all required points, decided to continue to participate.

❑ Demonstrated comprehension of all required points, decided NOT to continue participation in study.

❑ Did not demonstrate comprehension of all required points (yet), needs more time/discussion.

❑ Other (specify): _____

Staff signature: _____

For addressing therapeutic misconception

"First let me tell you a little bit about the study. We're trying to find the best ways to help women who have been abused by their partners. We're looking at what can be done to help abused women to manage their health better. So this study may or may not help to stop the abuse, but what we find out from doing this study will help other women to manage their health better in the future."

For obtaining safe contacts

"Sometimes we can find it difficult to make contact with people again at later dates for a variety of reasons, such as [relevant reasons e.g. moving, visiting relatives]. Would you mind providing the contact details, just first name and best phone number, of [x] people who will always know how to contact you (such as a parent or close friend)? We wouldn't call them unless we had tried to contact you unsuccessfully on four occasions, and we would state we were calling about [contextually safe reason e.g. health care]. We would not state anything about the study topic."

Documenting adverse events/social harms

See Table 3.

Explaining mandatory reporting requirements around child abuse to participants

[Prior to disclosure, if the participant seems to be moving toward a disclosure of current abuse]: "It sounds like you might want to talk about current issues of violence that are occurring. Before you tell me more about these issues, I want to remind you that if you disclose current child abuse, I may have to inform someone outside this research process."

[If, following this, the participant does disclose current abuse or imminent risk of harm]: "Thank you for sharing that with me. As I said, I may need to inform [relevant people/groups that need to be informed]. Is this the first time you've told someone about this? Your child's safety is my greatest concern here, which is why I need to report this."

Table 3: Form to document adverse events/social harms

Adverse events social harms report
This form is to be completed for any participant who reports an adverse event or social harm. Staff member completes form based on investigation

1. Describe the adverse event/social harm:

   ☐ Participant declined to describe

---

2. Date of event onset | `D` `D` `M` `M` `Y` `Y` `Y` `Y`

---

3. What type of harm is this event? (mark all that apply)
   - ☐ Physical
   - ☐ Emotional
   - ☐ Financial
   - ☐ Other, specify

---

4. Did this event include unwanted disclosure of study participation?
   - ☐ Yes, specify to who _____
   - ☐ No
   - ☐ Unknown/information

---

5. What impact did this situation have on the participant's quality of life?
   - ☐ No disturbance
   - ☐ A minimal disturbance that had no significant impact
   - ☐ A moderately upsetting disturbance, but no significant impact
   - ☐ Other, specify: _____
   - ☐ Unknown/information not provided

---

6. Based on your discussion with the participant and other relevant individuals, was this situation related to study participation?
   - ☐ Yes
   - ☐ No

---

7. Based on your discussion with the participant and other relevant individuals, do you think this situation is resolved?
   - ☐ Yes
   - ☐ No
   - ☐ Other, specify _____

---

8. What action, recommendation or suggestion was provided to the participant to help resolve this situation? | Describe:

---

9. Referrals made (mark all that apply)
   - ☐ Counsellor on site
   - ☐ Other, specify: _____
   - ☐ No referrals needed

   Additional comments:

Glossary of relevant terms

Confidentiality: An explicit or implicit guarantee by the researcher to the participant that the information disclosed by the participant will be disseminated only in ways consistent with their original understanding. Confidentiality requires researchers to be mindful that only authorized access to information occurs and that the privacy of participants is respected.

Formative research: Research carried out prior to intervention development to gather empirical data about potential users and implementers of a proposed program such that interventions are appropriately designed for the target audience.

Informed consent: The communication process by which a potential study or intervention participant receives information relevant to their role and is able to make a voluntary choice to participate with full information of benefits and potential risks. Informed consent often involves discussing the research or intervention itself; stating the potential risks, benefits and uncertainties of participation; and assessing participants' understanding.

Intervention research: Assesses the impacts of interventions, with the goal of improving existing initiatives and helping design new ones. Research can span different phases of the intervention from its initial development to its feasibility, acceptability and safety upon implementation, and to its overall efficacy and effectiveness.

Intimate partner violence (IPV): Threatened, attempted or completed physical, sexual or psychological harm by a current or former partner or spouse. This includes physical violence, sexual violence, threats of physical or sexual violence, and psychological or emotional violence. IPV can occur among partners of any sexual orientation and does not require sexual intimacy.

Longitudinal research: Refers to observational studies that gather data on the same subjects or variables across extended periods of time.

Non-maleficence: The principle that we should act in ways that do not cause harm to others. In particular, we should not cause avoidable or intentional harm. This includes avoiding even the risk of harm.

Prevention of VAW: Prevention is a sustained process of intervention that seeks to end violence against women by targeting it before it occurs, mitigating harm and responding after the event, and working with survivors and perpetrators over the long term. Possible measures can take the form of women's economic and psychological empowerment, education campaigns, campaigns to reduce availability of alcohol, safe housing and health services, or support groups.

Privacy: Participants being able to control the extent, timing and circumstances under which they share their experiences, thoughts, beliefs, etc. with the researcher.

Therapeutic misconception: An ethical problem in which research participants confuse the procedures and outcomes of clinical research with those of ordinary treatment, inaccurately believing the research process to produce established, and often positive, results.

Undue influence: Factors exert undue influence when they manipulate an individual's independent judgement and affect their ability to act according to free will. In the context of social science research, this may take the form of incentive systems that induce conflicts of interest within the research participant.

Vicarious trauma: This refers to a negative transformation in researchers' thoughts, perceptions and interpretations as a result of empathetic or sustained engagement with traumatic materials and experiences during research. Vicarious trauma can have an impact on perceptions of safety, ability to trust, self-esteem and esteem of others, feelings of control, and attitudes toward intimacy.

Violence against women (VAW): As defined by the United Nations, violence against women refers to "any act of gender-based violence that results in, or is likely to result in, physical, sexual, or mental harm or suffering to women, including threats of such acts, coercion, or arbitrary deprivation of liberty, whether occurring in public or private life". This broad definition includes, but is not limited to, violence occurring in the family, violence within the general community, trafficking and forced prostitution, and violence perpetrated or condoned by the state.

---

[1] Krug EG, Dahlberg LL, Mercy JA, Zwi AB, Lozano R, eds. World report on violence and health. Geneva: World Health Organization; 2002.
[2] General Assembly resolution 48/104, Declaration on the elimination of violence against women, A/RES/48/104 (20 December 1993), http://www.un-documents.net/a48r104.htm (accessed 21 December 2015).

References

1. Putting women first: ethical and safety recommendations for research on domestic violence against women. Geneva: World Health Organization; 2001.

2. Ellsberg M, Heise L. Researching violence against women: a practical guide for researchers and activists. Washington (DC): World Health Organization, PATH; 2005.

3. WHO, London School of Hygiene and Tropical Medicine. Preventing intimate partner and sexual violence against women: taking action and generating evidence. Geneva: World Health Organization; 2010.

4. WHO. WHO ethical and safety recommendations for researching, documenting, and monitoring sexual violence in emergencies. Geneva: World Health Organization; 2007.

5. Jewkes R, Dartnall E, Sikweyiya Y. Ethical and safety recommendations for research on perpetration of sexual violence. Pretoria: Sexual Violence Research Initiative, South African Medical Research Council; 2012.

6. Child Protection Monitoring and Evaluation Reference Group, Technical Working Group on Data Collection of Violence against Children. Ethical principles, dilemmas, and risks in collecting data on violence against children: a review of available literature. New York: Statistics and Monitoring Section/Division of Policy and Strategy, United Nations Children's Fund; 2012.

7. Ellsberg M, Heise L. Bearing witness: ethics in domestic violence research. Lancet. 2002;359(9317):1599604.

8. Fontes LA. Ethics in violence against women research: the sensitive, the dangerous, and the overlooked. Ethics Behav. 2004;14(2):14174.

9. Jewkes R, Watts C, Abrahams N, Penn-Kekana L, García-Moreno C. Ethical and methodological issues in conducting research on gender-based violence in Southern Africa. Reprod Health Matters. 2000;8(15):93103.

10. Leach F. Researching gender violence in schools: methodological and ethical considerations. World Dev. 2006;34(6):112947.

11. Costello A, Zumla A. Moving to research partnerships in developing countries. BMJ. 2000;321(7264):827.

12. Edejer TT-T. Northsouth research partnerships: the ethics of carrying out research in developing countries. BMJ. 1999; 319(7207):438.

13. Lansang MA, Dennis R. Building capacity in health research in the developing world. Bull World Health Org. 2004;82(10):76470.

14. Krishnan S, Subbiah K, Khanum S, Chandra PS, Padian NS. An intergenerational women's empowerment intervention to mitigate domestic violence: results of a pilot study in Bengaluru, India. Violence Against Women. 2012;18(3):34670.

15. Krishnan S, Subbiah K, Chandra P, Srinivasan K. Minimizing risks and monitoring safety of an antenatal care intervention to mitigate   domestic violence among young Indian women: the Dil Mil Trial. BMC Public Health. 2012;12(1):943.

16. Tiwari A, Leung WC, Leung TW, Humphreys J, Parker B, Ho PC. A randomised controlled trial of empowerment training for Chinese abused pregnant women in Hong Kong. BJOG. 2005;112(9):124956.

17. Smith W, Grady C, Krohmal B, Lazovski J, Wendler D. Empirical evaluation of the need for 'on-going consent' in clinical research. AIDS. 2011; 25(1):107 14.

18. Morris A, Hegarty K, Humphreys C. Ethical and safe research with children about domestic violence. Res Ethics. 2012;8(2):12539.

19. Sikweyiya YM, Jewkes R. Disclosure of child murder: a case study of ethical dilemmas in research. S Afr Med J. 2011;101(3):1649.

20. Klevens J, Kee R, Trick W. Effect of screening for partner violence on women's quality of life: a randomized controlled trial. JAMA. 2012;308(7): 6819.

21. Zink T, Putnam F. Intimate partner violence research in the health care setting: what are appropriate and feasible methodological standards? J Interpers Violence. 2005;20(4):36572.

22. Tiwari A, Fong DYT, Yuen KH, Yuk H, Pang P, Humphreys J et al. Effect of an advocacy intervention on mental health in Chinese women survivors of intimate partner violence. JAMA. 2010;304(5):53643.

23. McFarlane J. Strategies for successful recruitment and retention of abused women for longitudinal studies. Issues Ment Health Nurs. 2007;28(8):88397.

24. Undie C, Maternowska MC, Mak'anyengo M, Askew, I. Is routine screening for intimate partner violence feasible in public health care settings in Kenya? J Interpers Violence. 2016;31(2):282-301.

25. Stadler J, Delany-Moretlwe S, Palanee T, Rees H. Hidden harms: women's narratives of intimate partner violence in a microbicide trial, South Africa. Soc Sci Med. 2014;110:4955.

26. Kotch JB. Ethical issues in longitudinal child maltreatment research. J Interpers Violence. 2000;15(7):696709.

27. Jack S. Guidelines to support nurse-researchers reflect on role conflict in qualitative interviewing. Open Nurs J. 2008;2:5862.

28. McFarlane J, Wiist W. Preventing abuse to pregnant women: implementation of a 'mentor mother' advocacy model. J Community Health Nurs. 1997;14(4):237-49.

29. McFarlane JM, Groff JY, O'Brien JA, Watson K. Secondary prevention of intimate partner violence: A randomized controlled trial. Nurs Res. 2006;55(1):52-61.

30. Sexual Violence Research Initiative. Researcher trauma, safety, and sexual violence research. Pretoria: South African Medical Research Council; 2015 (http://www.svri.org/trauma.htm, accessed 21 December 2015).

31. Sexual Violence Research Initiative. Vicarious trauma: understanding and managing the impact of doing research on sensitive topics. Pretoria: South African Medical Research Council; undated. (http://www.svri.org/researcherhandout.pdf, accessed 21 December 2015).

32. World Medical Association. World Medical Association declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA. 2013;310(20):2191.

33. International ethical guidelines for biomedical research involving human subjects. Geneva: Council for International Organizations of Medical Sciences; 2002.

34. El Setouhy M, Agbenyega T, Anto F, Clerk CA, Koram KA, English M et al. Moral standards for research in developing countries from "reasonable availability" to "fair benefits." Hastings Cent Rep. 2004;34(3):1727.

35. Lairumbi GM, Parker M, Fitzpatrick R, English MC. Forms of benefit sharing in global health research undertaken in resource poor settings: a qualitative study of stakeholders' views in Kenya. Philos Ethics Humanit Med. 2012;7(7):7.

36. London AJ, Zollman KJ. Research at the auction block. Hastings Cent Rep. 2010;40(4):3445.

37. Developing and evaluating complex interventions: new guidance. Cape Town: South African Medical Research Council; 2008.

38. Handley MA, Schillinger D, Shiboski S. Quasi- experimental designs in practice-based research settings: design and implementation considerations. J Am Board Fam Med. 2011;24(5):58996.

39. García-Moreno C, Jansen H, Ellsberg M, Heise L, Watts C. WHO multi-country study on women's health and domestic violence against women: initial results on prevalence, health outcomes, and women's responses. Geneva: World Health Organization; 2005.

40. Kiely M, El-Mohandes AAE, El-Khorazaty MN, Gantz MG. An integrated intervention to reduce intimate partner violence in pregnancy: a randomized trial. Obstet Gynecol. 2010;115:273.

41. Hegarty K, O'Doherty L, Chondros P, Taft A, Brown S, Valpied J, Feder G, Taket A, Gold L, Astbury J, Gunn J. Effect of screening and brief counselling for abused women on quality of life, safety planning, and mental health: a primary care cluster randomised controlled trial (WEAVE). Lancet. 2013;382(9888):24958.

42. Langhinrichsen-Rohling J, Turner L. The efficacy of an intimate partner violence prevention program with high-risk adolescent girls: a preliminary test. Prev Sci. 2011:111.

43. Pronyk PM, Hargreaves JR, Kim JC, Morison LA, Phetla G, Watts C et al. Effect of a structural intervention for the prevention of intimate-partner violence and HIV in rural South Africa: a cluster randomised trial. Lancet. 2006;368(9551):197383.

44. Abramsky T, Devries K, Kiss L, Francisco L, Nakuti J, Musuya T et al. A community mobilisation intervention to prevent violence against women and reduce HIV/AIDS risk in Kampala, Uganda (the SASA! Study): study protocol for a cluster randomised controlled trial. Trials. 2012;13:96.

45. Hirani SS, Karmaliani R, McFarlane J, Asad N, Madhani F, Shehzad S. Testing a community derived intervention to promote women's health: preliminary results of a 3-arm randomized controlled trial in Karachi, Pakistan. South Online J Nurs Res. 2010;10(3) (http://www.resourcenter.net/images/snrs/files/sojnr_articles2/Vol10Num03Art06.html, accessed 21 December 2015).

46. Karmaliani R, McFarlane J, Asad N, Madhani F, Hirani S, Shehzad S et al. Applying community-based participatory research methods to improve maternal and child health in Karachi, Pakistan. Nurs Outlook. 2009;57(4):2049.

47. Weijer C, Grimshaw JM, Eccles MP, McRae AD, White A, Brehaut JC et al. The Ottawa Statement on the ethical design and conduct of cluster randomized trials. PLoS Med. 2012;9(11):e1001346.

(http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001346, accessed 21 December 2015).

48. Saftlas AF, Harland KK, Wallis AB, Cavanaugh J, Dickey P, Peek-Asa C. Motivational interviewing and intimate partner violence: a randomized trial. Ann Epidemiol. 2014;24(2):14450.

49. García-Moreno C, Jansen HA, Ellsberg M, Heise L, Watts CH. Prevalence of intimate partner violence: findings from the WHO multi-country study on women's health and domestic violence. Lancet. 2006;368(9543):1260.

50. Altarac M, Strobino D. Abuse during pregnancy and stress because of abuse during pregnancy and birthweight. J Am Med Womens Assoc. 2002;57(4):20814.

51. Bullock LF, McFarlane J. The birth-weight/battering connection. Am J Nurs. 1989;89(9):11537.

52. Janssen PA, Holt VL, Sugg NK, Emanuel I, Critchlow CM, Henderson AD. Intimate partner violence and adverse pregnancy outcomes: a population-based study. Am J Obstet Gynecol. 2003;188(5):13417.

53. Valladares E, Ellsberg M, Peña R, Högberg U, Persson LÅ. Physical partner abuse during pregnancy: a risk factor for low birth weight in Nicaragua. Obstet Gynecol. 2002;100(4):7005.

54. Jejeebhoy SJ. Associations between wife-beating and fetal and infant death: impressions from a survey in rural India. Stud Fam Plann.1998:3008.

55. McFarlane J, Campbell JC, Sharps P, Watson K. Abuse during pregnancy and femicide: urgent implications for women's health. Obstet Gynecol. 2002;100(1):2736.

56. Dunkle KL, Jewkes RK, Brown HC, Gray GE, McIntryre JA, Harlow SD. Gender-based violence, relationship power, and risk of HIV infection in women attending antenatal clinics in South Africa. Lancet. 2004;363(9419):141521.

57. Maman S, Mbwambo JK, Hogan NM, Kilonzo GP, Campbell JC, Weiss E et al. HIV-positive women report more lifetime partner violence: findings from a voluntary counseling and testing clinic in Dar es Salaam, Tanzania. Am J Public Health. 2002;92(8):13317.

58. Schechter S, Edleson J. Effective intervention in woman battering & child maltreatment cases: guidelines for policy and practice. Reno (NV): National Council of Juvenile and Family Court Judges, 1999. (https://www.childwelfare.gov/pubPDFs/ncjfcj.pdf, accessed 21 December 2015).

59. Abrahams N, Devries K, Watts C, Pallitto C, Petzold M, Shamu S et al. Worldwide prevalence of non- partner sexual violence: a systematic review. Lancet. 2014;383(9929):164854

60. Global and regional estimates of violence against women: prevalence and health effects of intimate partner violence and non-partner sexual violence. Geneva: World Health Organization, 2013.

61. Executive order preventing and responding to violence against women and girls globally. Washington (DC): White House, Office of the Press Secretary; 2012 (http://www.whitehouse.gov/the-press-office/2012/08/10/executive-order-preventing-and-responding-violence-against-women-and-gir, accessed 21 December 2015).

62. United States strategy to prevent and respond to gender-based violence globally. Washington (DC): United States Department of State and USAID; 2012.

63. A call to end violence against women and girls: Action Plan 2013. London: Her Majesty's Government; 2013.

Notes

Ethical and safety recommendations for intervention research on violence against women

9 789241 510189