Measuring Social Harms in Research and Programs on Women-Initiated HIV Prevention Methods

Few published studies have systematically measured and reported social harms experienced during HIV prevention trials. Under the USAID- and PEPFAR-funded CHARISMA project, researchers analyzed data on social harms from five studies of women-initiated HIV prevention products in sub-Saharan Africa. They also reviewed the study protocols, procedural manuals, and data collection forms to identify how social harms were defined, measured, referred for follow-up care, and reported.

The aim was to understand how recent (since 2009) multisite trials of microbicide candidates and related studies among cisgender women defined and measured social harms; assess the frequency of such harms; and identify best practices for monitoring and addressing social harms in future research and programs.[1]

How are social harms measured?

Social harms were defined and measured in different ways in the five studies, as summarized in **Table 1**. As a follow-up to initial questions about social harm, all the studies asked about the relationship in which a social harm occurred, usually by presenting a participant with a list of people that included an open-ended "other" response.

The authors noted challenges with social harm assessment, including classification, under-reporting, and overly "scientific" terminology. For example, it is unknown how well, or how consistently, participants understood the meaning of "social harm." Using a general term such as "problems," as the Microbicide Trials Network (MTN) did in several studies, may be an effective screening question for identifying potential social harms but could result in *over*-reporting or other classification errors.

Three of the studies limited the definition of social harms to events that occurred as a result of study participation. The definitions of social harms used in the other two studies — the International Partnership for Microbicides'

What are social harms?

In HIV prevention research, safety monitoring has been expanded beyond medical issues to include "social harms," which are generally defined as **negative social, emotional, physical, or economic consequences of study participation or use of a study product.**

Why are they important?

Recent studies suggest experiences of social harm, including intimate partner violence (IPV), may inhibit some women's ability to consistently use HIV prevention products.[2–3] Documenting experiences of social harm is critical for women's safety and successful use of HIV prevention.

(IPM's) Ring Study and the MTN–015 trial — included experiences of harm and violence that were not related to study participation. However, it may be difficult to determine whether an event is study related, particularly in abusive or controlling relationships. Some women may consider a social harm an everyday life experience.

Table 1. How Trials Defined and Measured Social Harms

Study	Definition	Measurement*
The Ring Study (IPM 027) *2012–2016* Phase III randomized controlled trial (RCT) of a vaginal ring containing the antiretroviral (ARV) drug dapivirine	An untoward event that causes physical, emotional, or financial harm to a trial participant; included experiences of harm and violence that were not related to study participation	Counselors assessed experiences of social harm during every HIV counseling visit but did not use a standardized questionnaire. They recorded type of social harm, whether it was study-related, and whether it was resolved.
VOICE (MTN–003) *2009–2012* Phase IIb RCT of daily use of an ARV tablet (tenofovir or TDF/FTC) or a vaginal gel containing tenofovir	Non-medical adverse consequences experienced as a result of participation in a study	Study staff used a structured questionnaire, asking participants at every visit if they had experienced any "problems" since the last visit as a result of being in study. If yes, they were asked whether the problem(s) resulted in specific types of harm.
ASPIRE (MTN-020) *2012–2015* Phase III RCT of a vaginal ring containing the ARV dapivirine	Same as VOICE (MTN–003) definition	At every visit, study staff asked participants a standardized question about whether they had experienced a social harm related to study participation and recorded whether it involved physical harm and its impact on quality of life.
MTN–015 *2009–2016* Prospective, observational cohort study of women after HIV-1 seroconversion during trials of ARV-based HIV prevention products	Definition of study-related problems used in VOICE (MTN–003) expanded to include others' reactions to participant's recent HIV diagnosis	Same as in VOICE (MTN–003), except social harms were categorized as "definitely" or "possibly" study-related.
EMBRACE (MTN–016) *2010–2015* Prospective observational cohort study of women who became pregnant during trials of ARV-based HIV prevention products, and their infants	Same as VOICE (MTN–003) definition	Study staff asked about experiences of social harm at all visits and recorded the type, including whether it affected the woman, her child, or both. No questionnaire was used; inquiring about social harms was an item on the provider's checklist.

* Participants could also spontaneously report experiences of social harm.

How frequent are social harms?

The incidence of social harms recorded in the five studies was low, ranging from 1.3 to 3.6 percent per year. Most social harms were associated with male partners rather than, for example, experiences of stigma in the community. Many partner-related social harms were acts of IPV — mainly emotional violence, but also physical violence. When women were asked about impact, they reported that most of the social harms had a minimal impact on their quality of life.

The rates of total social harms reported differed by study product, with lower incidence among women in the dapivirine ring trials. These reported differences were likely a result of the different approaches to measuring social harms described in Table 1.

How can measurement and documentation of social harms be improved?

The researchers recommend the following ways to enhance measurement of social harms in trials and programs:

- **Communicate with community members** — including women and their male partners — before and during a study or program, to build trust and improve understanding of the study or program and to give staff a better understanding of community perceptions.
- **Adopt a hybrid measurement approach:** enquire about problems with various types of people (such as family members, friends, partners, health care providers, and immigration officials) at every visit, then probe about, and document, social harms through counseling discussions and the use of structured questionnaires.
- **Capture data about the disturbance caused** by each social harm reported and its impact on quality of life.
- **Consider documenting all social harms and quantifying** how related a social harm was to the research or intervention.
- **Collect data on the social benefits,** as well as the social harms, of study participation and product use. Such benefits may include counseling support and enhanced confidence.
- **Develop short, validated tools** for measuring social harms in trials or public health programs. Self-administered or electronic-based tools may help address human resource constraints and reduce under-reporting of social harms.
- **Follow up with participants** after they have completed a study to address continuing or new social harms and improve understanding of the effects of product use as well as trial participation.

Limitations of social harms measurement

Participants may have under-reported social harms. Some may have feared that they would have to leave the study if they reported experiencing social harms, even though they were assured that would not happen in most cases.

The low incidence of reported social harms may also signal that women who participate in trials have different experiences from those who do not. For example, some of the women who are most at risk of social harm may be unwilling or unable to join HIV prevention trials.

References

1. Montgomery ET, Roberts ST, Nel A, Malherbe M, Torjesen K, Bunge K, et al. Social harms in female-initiated HIV prevention method research: state of the evidence. AIDS 2019;33(14): 2237-44.
2. Palanee-Philips T, Roberts ST, Reddy K, Govender V, Naidoo L, Siva S, et al. Impact of partner-related social harms on women's adherence to the dapivirine vaginal ring during a Phase III trial. J Acquir Immune Defic Syndr. 2018;79(5): 580-89.
3. Roberts ST, Haberer J, Celum C, Mugo N, Ware NC, Cohen CR, et al. Intimate partner violence and adherence to HIV pre-exposure prophylaxis (PrEP) in African women in HIV serodiscordant relationships: a prospective cohort study. J Acquir Immune Defic Syndr. 2016;73(3): 313-22.

This analysis was conducted under the CHARISMA project, which aims to increase women's agency to safely and consistently use oral PrEP and microbicides, constructively engage male partners in HIV prevention, overcome harmful gender norms, and reduce IPV.

The CHARISMA project is currently testing an intervention with women using PrEP that assesses their relationships and IPV risk and provides tailored counseling and referrals.

For more information, contact:
info@charismaproject.org

CHARISMA