Social Harms and Use of the Dapivirine Vaginal Ring

CHARISMA

INTRODUCTION

The MTN-020/ASPIRE trial and IPM 027/The Ring Study found that use of a monthly vaginal ring containing the antiretroviral drug dapivirine offers women some protection against HIV if they use it as directed.[1,2] The ring and other woman-initiated HIV prevention methods are designed to enable women to have more control over their sexual health and risk of HIV exposure, but research has revealed that women's male partners often influence their ability to use these methods.

Male partners may support women's adoption and continued use of woman-initiated methods. However, negative influences such as discord in relationships and intimate partner violence (IPV) have been linked to low adherence to both antiretroviral treatment and oral pre-exposure prophylaxis (PrEP) for HIV prevention.[3-7] Whether experiencing social harms reduces adherence to other HIV prevention methods is unclear. An analysis of ASPIRE trial data was the first to assess whether exposure to social harms affected women's adherence to the dapivirine ring.[8]

METHODS

During quarterly study visits for the ASPIRE trial, 2,629 participants at the 15 clinical trial sites in Malawi, South Africa, Uganda, and Zimbabwe were systematically asked about whether they had experienced social harms. They could also report social harms spontaneously during any study visit.

Social harms were defined as nonmedical adverse consequences of dapivirine ring use or trial participation and did not include other negative or violent experiences unrelated to being in the trial. Blood samples were also collected and tested for the presence of dapivirine as an objective measure of adherence.

THE ANALYSIS ASSESSED WHETHER EXPOSURE TO SOCIAL HARMS AFFECTED WOMEN'S ADHERENCE TO THE DAPIVIRINE RING.

RESULTS

Social harms were uncommon and were primarily related to male partners.

Almost all (93 percent) of the 94 social harms reported during ASPIRE were associated with male partners. Of the 2,629 women who participated in in the study, 85 reported a total of 87 social harms related to

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male partners over an average follow-up period of 1.6 years.

Social harms were often prompted by discovery of the ring during sex or foreplay; suspicion that the ring was associated with witchcraft, promiscuity, or ill health; or partner notification of a sexually transmitted infection requiring treatment.

Many partner-related social harms were reported to have minimal effects on the quality of life, but almost 29 percent resulted in physical harm.

Women reported that almost 59 percent (51 of 87) of the social harms had minimal impact on their quality of life. They classified 31 percent (n=27) of the social harms as a moderate disturbance and 10 percent (n=9) as a major disturbance with significant impact (see **Figure 1**).

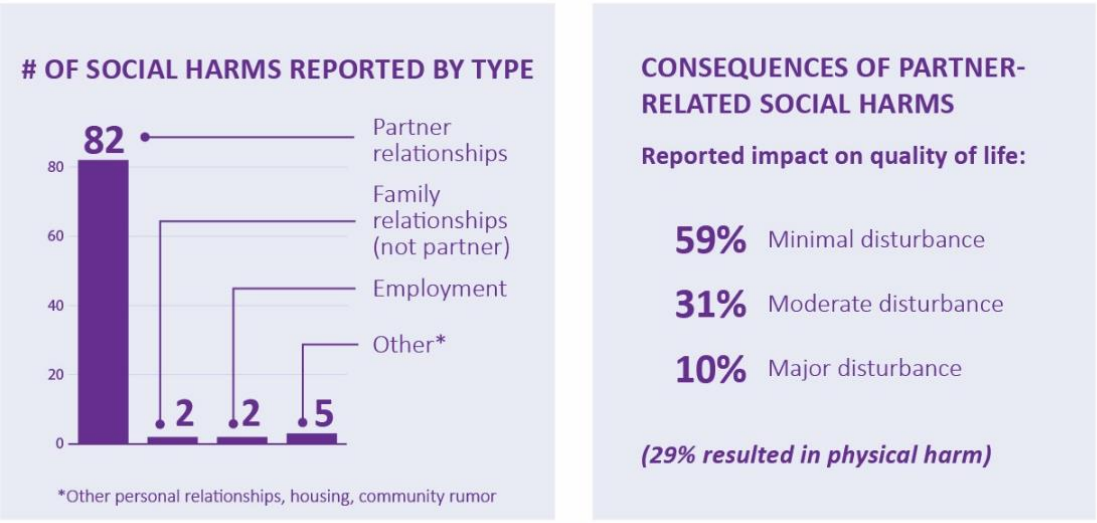
The most common consequences of a social harm were removal or destruction of the ring by a partner, physical and verbal violence, and termination of a relationship. Twenty-six of the social harms resulted in physical harm to a study participant.

Women ages 18 to 26 were more than three times as likely as women in older age groups to experience a social harm.

When researchers controlled for other factors that might affect risk, age was the only demographic characteristic associated with social harm. The likelihood of experiencing a social harm decreased with age.

Younger age was associated with poor adherence to the dapivirine ring as well as social harms. The ASPIRE trial found that the dapivirine ring did not provide protection against HIV among women ages 18 to 21, though it reduced risk for women ages 22 to

Figure 1. *Context of Social Harms*



45 by 56 percent—a difference that was associated with levels of adherence.

Recent experience of a social harm was associated with lower adherence to dapivirine ring use.

Women were 2.5 times more likely to have low adherence at visits when they reported having experienced a social harm during the past month compared to visits where no social harm was reported. In analyses that controlled for age, study site, and time in the study, no differences in adherence were seen when women reported experiencing a social harm more than one month before a visit, suggesting an acute, short-term effect.

Women who had experienced a recent social harm were far less likely to return their rings.

Women who reported a social harm in the past month were 25 times more likely not to return a ring at their next study visit. They were also more likely to decline a new ring, though such refusals occurred at only 0.2 percent of all visits in the trial.

PROGRAM IMPLICATIONS

Reported social harms were low (<5% of trial participants); however, the results suggest that future programs should:

- Integrate IPV detection and response to address violence as both a risk factor for HIV and a barrier to adherence to HIV prevention methods.
- Screen clients who decline to use the ring or do not return the ring for experiences of partner violence or other social harms.
- Evaluate strategies to help women navigate challenges to their relationships that may arise from ring use and to support women who have experienced partner-related social harm.

ASPIRE was conducted by the National Institutes of Health-funded Microbicide Trials Network. The International Partnership for Microbicides developed the study product and supplied the rings for the trial.

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.

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