Intervention Overview

AGENCY IN RELATIONSHIPS & SAFER MICROBICIDE ADHERENCE

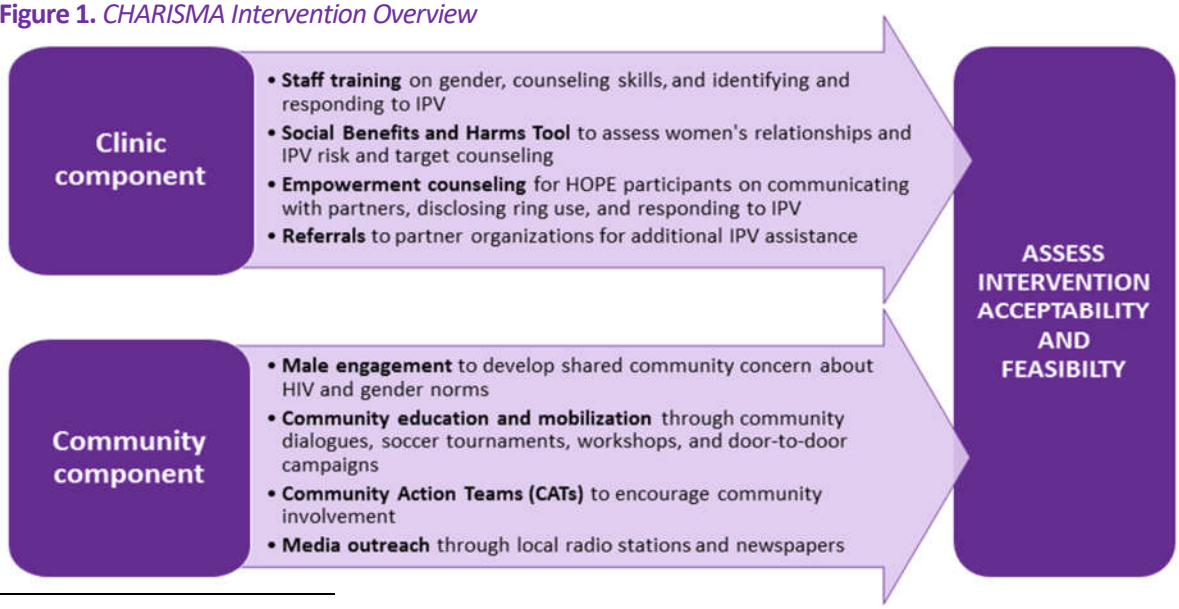
CHARISMA

BACKGROUND. CHARISMA (Community Health Clinic Model for Agency in Relationships and Safer Microbicide Adherence) is a pilot intervention to increase women's agency to safely use ARV-based HIV prevention, engage male partners in HIV prevention, overcome harmful gender norms, and reduce intimate partner violence (IPV).

Microbicides were designed to give women an HIV prevention tool they could use without a male partner's involvement. However, research suggests that the approval or support of male partners is often desired, or even required, to enable women to use microbicides. Secondary data (both qualitative and quantitative) from the ASPIRE, VOICE, CAPRISA 008, and other trials, as well as a review of primary and secondary analyses of data from six qualitative studies implemented in conjunction with microbicide trials in South Africa, Kenya, and Tanzania, showed that for some women, microbicide use improved communication with partners, reinforcing product adherence.[1] However, it increased partner conflicts and the risk of IPV for others.

THE INTERVENTION. The CHARISMA intervention is being pilot tested among approximately 100 participants in the HIV Open-label Prevention Extension (HOPE) study at the Wits Reproductive Health and HIV Institute site in Hillbrow, Johannesburg, South Africa. HOPE is a follow-on study to the ASPIRE trial, which found that the dapivirine vaginal ring was safe and helped protect women against HIV. Women who participated in the ASPIRE trial are being invited to enroll in HOPE, which is further assessing the safety of the ring and study participants' adherence. Embedded within the HOPE trial, the CHARISMA intervention consists of a clinic and a community component, implemented simultaneously (see **Figure 1**).

Figure 1. *CHARISMA Intervention Overview*



[1] Doggett, E. G., Lanham, M., Wilcher, R., Gafos, M., Karim, Q. A., & Heise, L. (2015). Optimizing HIV prevention for women: a review of evidence from microbicide studies and considerations for gender-sensitive microbicide introduction. *Journal of the International AIDS Society*, *18*(1).

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The CHARISMA intervention aims to:

1) Promote women's ability to decide if, when, and how to involve male partners in microbicide use.
2) Improve women's ability to communicate and negotiate with their male partners about microbicides and HIV prevention.
3) Screen for IPV and support women at risk of, or experiencing, violence in their relationships.
4) Increase men's awareness, acceptance, and support for women's use of microbicides.

If the CHARISMA intervention is found to be feasible and acceptable at the Hillbrow site, it may be adapted and implemented at additional sites in South Africa.

Clinic-based component

Lay counselors delivering the CHARISMA intervention received training to understand the relationship between gender, HIV prevention, and microbicides, and to improve their counseling skills, and identify and respond to IPV. HOPE staff participated in a shorter training session to learn about the effects of gender biases on HIV prevention.

During HOPE screening/enrollment, counselors use the Social Benefits and Harms Tool (SBHT), developed specifically for CHARISMA, to assess each woman's relationships and IPV risk. Guided by each woman's responses to the SBHT and selected measures from HOPE case report forms, they provide counseling tailored to meet each woman's needs. Counseling aims to empower women with skills to 1) decide whether and how to disclose ring use to male partners; 2) communicate and negotiate conflict with partners; and 3) respond to experiences of IPV.

BOX 1. *EVIDENCE-BASED DESIGN*

The CHARISMA intervention is adapted primarily from two evidence-based interventions (see **Box 2**) and informed by:

- A ***landscape analysis*** of gender and violence in South Africa and best practices for engaging men in women's health.
- ***Secondary data analysis*** of social harms during microbicide trials and male partner involvement in product use.
- ***Primary data collection,*** including in-depth interviews with former ASPIRE trial participants and their male partners; focus group discussions with healthcare providers; and cognitive interviews and surveys with former ASPIRE trial participants and women in the community.
- ***Input from key stakeholders***, including members of community advisory boards in Hillbrow and a multinational scientific advisory group of experts on gender, IPV, microbicides, HIV prevention, and public health programs.

Counseling occurs during a participant's study enrollment visit with a follow-up visit at month one. Any woman who discloses (during her quarterly visits or at any other time) that she has changed partners or experienced violence will be offered additional counseling. CHARISMA staff refer women to partner organizations for IPV care or assistance as needed and track referral uptake. Staff also provide partner referrals for women who would like their partners to come to the clinic for additional information about the ring or for HIV counseling and testing.

Foundational to the clinic-based component is an emphasis on counselors treating women as experts in their own lives and relationships. This means that counselors value and support women's decisions about disclosure of ring use to their male partners, as well as women's relationship needs and their readiness to respond to any violence they may experience.

Community component

Sonke Gender Justice (Sonke), a CHARISMA partner, leads the community component of the CHARISMA intervention, engaging men, community leaders, and communities to cultivate a shared concern about HIV and gender norms. Community mobilizers from Sonke implement community education and mobilization activities specifically designed for CHARISMA, emphasizing the following messages:

- A man should respect his partner's right to control her own sexual health and be supportive of her choice to use HIV prevention methods, including oral pre-exposure prophylaxis (PrEP) and vaginal microbicides such as the ring.

- HIV prevention is not solely a woman's responsibility. Every man should also take responsibility for his own health, including regular HIV testing and taking steps to prevent HIV or initiating and adhering to antiretroviral (ARV) treatment after an HIV diagnosis.

The community component includes two-day workshops and focused outreach in taverns and other meeting places, as well as soccer tournaments, community murals, and door-to-door outreach. This outreach focuses primarily on men and male community leaders, but also engages women. Community Action Teams (CATs) of workshop participants who express a commitment to continue activism and community mobilization for social and gender justice support the Sonke staff in community outreach activities. To expand the reach of the community campaign and encourage a supportive environment, Sonke also disseminates messages through radio shows and local newspapers.

BOX 2. *INTERVENTION MODELS*

The CHARISMA intervention is adapted primarily from the following evidence-based models:

- ***Safe + Sound:*** Implemented by the Wits Reproductive Health and HIV Institute in antenatal clinics in Johannesburg, South Africa, this IPV intervention includes empowerment counseling by nurses and enhanced linkages to referral services. Based on the Conceptual Model of Help Attainment,[2] Safe + Sound positions women's actions within a broader socio-ecological context, acknowledging that responses to IPV depend not only on personal desire to seek help, but also on the usefulness of community resources, a woman's "social location" (e.g., socioeconomic status, race/ethnicity), her social environment, and key structural factors.

- ***One Man Can Campaign:*** Sonke Gender Justice's gender-transformative intervention employs community education and community mobilization, including workshops and public awareness activities, to encourage men and women to become actively involved in advocating for gender equality, preventing gender-based violence (GBV), and responding to HIV. The One Man Can model has been implemented in several South African provinces and in other African countries through the MenEngage Africa Network.

[2] Kennedy AC, Adams A, Bybee D, Campbell R, Kubiak SP, Sullivan C. A model of sexually and physically victimized women's process of attaining effective formal help over time: the role of social location, context, and intervention. Am J Community Psych. 2012;50(1-2):217-28.

Evidence supporting the intervention design

- The Social Benefits and Harms Tool developed for CHARISMA enables counselors to assess where women's relationships fall on a continuum of potential partner support or harm so that counseling meets women's individual needs. The use of the continuum is based on data from ASPIRE, VOICE, CAPRISA 008, and other trials showing that male partners' roles in women's microbicide use ranged from opposition (including conflict and violence due to mistrust, jealousy, or loss of control within the relationship) to agreement to active support.
- More intensive male engagement activities supplement the HOPE trial's efforts to involve men through information sessions and counseling for male partners and couples. These CHARISMA male engagement activities are focused in the community rather than the clinic, based on the low clinic attendance of male partners during ASPIRE, VOICE, and CAPRISA 008 and interview data from CAPRISA 008. Those data indicate that getting male partners to come to clinics is challenging because of multiple factors including men's work schedules, dislike of clinics, and fear of HIV testing.
- Areas of focus in the training for CHARISMA counselors were informed by data from the landscape analysis and secondary data analyses about the importance of providers understanding the concepts of gender, IPV, and links with HIV; recognizing and avoiding bias in counseling; and respecting women as the authorities on their relationships.
- Counseling is delivered by lay counselors rather than nurses based on feedback from former ASPIRE trial participants that nurses might be too busy to deliver quality counseling; stakeholders and health care workers confirmed during focus group discussions that nurses are already overburdened. Former ASPIRE trial participants also said they felt more at ease with lay counselors, who seemed more approachable. Landscape analysis findings indicate that using lay health workers to screen for IPV and deliver counseling on gender equality in relationships is acceptable, and stakeholders said this approach may be more sustainable because lay counselors are paid less than nurses.
- CHARISMA provides counseling at any follow-up visit when a woman reports having a new sexual partner, based on evidence from ASPIRE that having a new primary partner within the past three months was associated with a higher likelihood of social harms.
- The focus of the community component was informed by findings from the landscape analysis and secondary data analyses indicating that it would be important to: 1) address the acceptability of IPV among men and women in South Africa; 2) raise awareness about the relationship between IPV and HIV; and 3) increase knowledge of microbicides, including their safety, side effects, and efficacy.
- Community workshops with men address men's belief that they should have control in a relationship—including whether their partners use microbicides—a concern that was voiced by trial participants and in the pilot testing of the community workshop.

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