



# CHARISMA

## **Toolkit Guide to Implementation and Adaptation**

Empowerment counseling  
to improve women's ability to  
use PrEP safely and effectively



# Acknowledgments

**The toolkit guide was developed by Michele Lanham (FHI 360), Clare Schroder, and Neeraja Bhavaraju (FSG) with technical input from:**

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## **RTI International**

Elizabeth Montgomery, Miriam Hartmann, Danielle Wagner, and Sarah Roberts

## **Wits RHI**

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## **USAID**

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This work is licensed under a Creative Commons Attribution-Noncommercial 4.0 International License. This work was made possible by the generous support of the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and the American people through the United States Agency for International Development (USAID). The contents are the responsibility of the CHARISMA project and do not necessarily reflect the views of USAID, PEPFAR, or the United States Government. CHARISMA is led by RTI International with core partners FHI 360, Wits RHI, and the University of Washington.

Suggested Citation: FHI 360, RTI International, Wits RHI. CHARISMA toolkit guide: empowering counseling to improve women's ability to use PrEP safely and effectively. Durham (NC): FHI 360; 2020.

*The CHARISMA Toolkit is dedicated to the memory of Portia Duma, a lay counselor, colleague, and friend at Wits RHI. Her commitment to helping her colleagues and women in the CHARISMA study inspired us all.*

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# I. Introduction

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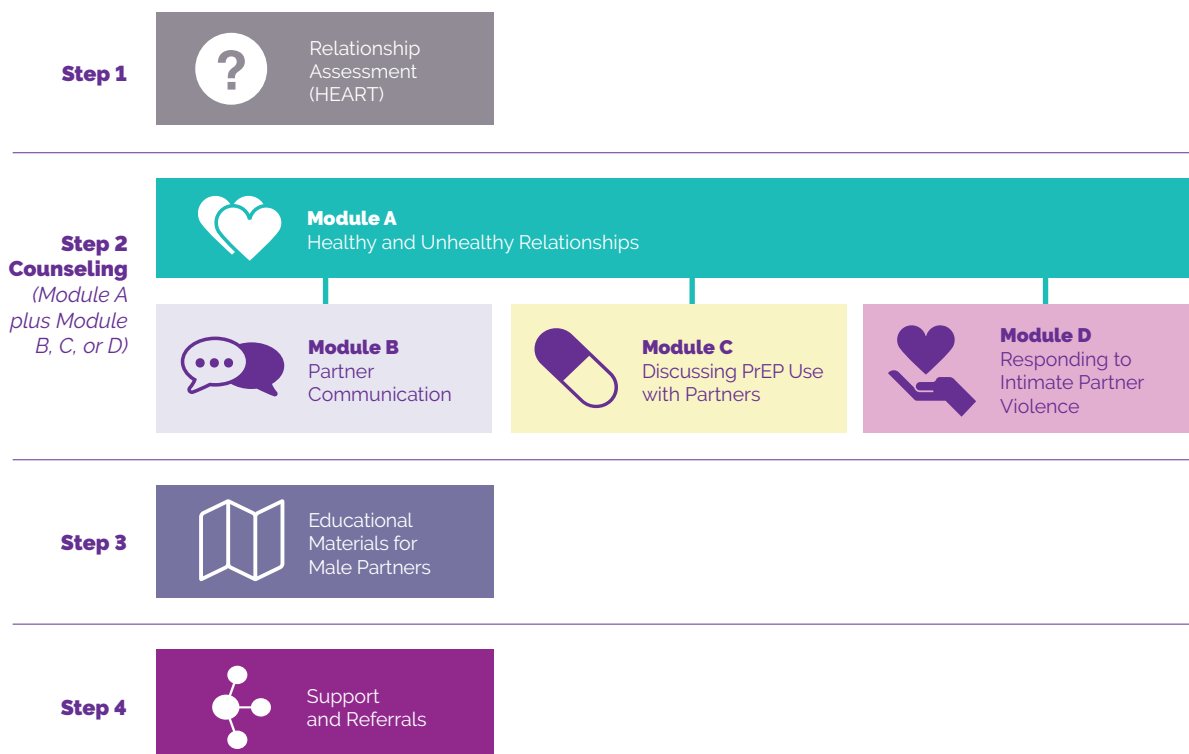
## ABOUT CHARISMA

The CHARISMA<sup>a,b</sup> intervention was developed to address some of women's greatest challenges to effective use of antiretroviral (ARV)-based HIV prevention technologies (referred to as "PrEP" throughout this toolkit): harmful relationship dynamics with male partners and exposure to intimate partner violence (IPV).

The intervention goes beyond current global guidance on IPV enquiry and response in healthcare settings by offering a comprehensive model to integrate counseling on a broader range of relevant topics, including counseling on understanding relationship dynamics with male partners, partner communication, disclosure of HIV prevention use, and IPV.

The intervention is comprised of four steps administered by counselors as part of PrEP service delivery: (1) a relationship assessment, (2) tailored empowerment counseling, (3) information materials for male partners, and (4) referrals to community-based services (see Figure 1).

**Figure 1: CHARISMA Intervention**



<sup>a</sup> CHARISMA is an acronym for "Community Health Clinic Model for Agency in Relationships and Safer Microbicide Adherence." We refer to it only as CHARISMA because the community component was dropped after the pilot study and the term "microbicides" is not being used in PrEP programs.

<sup>b</sup> The CHARISMA intervention was designed and tested through the USAID-funded CHARISMA project. The project sought to establish improved approaches for addressing harmful gender norms and challenges to PrEP use for women. The project consisted of primary and secondary data analysis to inform intervention development; pilot testing of the intervention with 98 women using the dapivirine vaginal ring in Johannesburg, South Africa, from 2016–2018; and a randomized controlled trial conducted in Johannesburg, South Africa, from 2018 to 2020 among women using or interested in using oral PrEP. RTI International led the project with the Wits Reproductive Health Institute, FHI 360, Sonke Gender Justice, and the University of Washington.

CHARISMA was developed and tested in a research clinic setting in Johannesburg, South Africa, among cisgender women ages 18 to 45 who reported having male sexual partners. The intervention was first assessed in a pilot study among women in the MTN-025/HOPE open-label extension study of the dapivirine vaginal ring, and then, after modification, in a randomized controlled trial (RCT) among 400 women who used oral PrEP.

Results from both studies show that CHARISMA was highly acceptable to the participants who received the intervention; however, the RCT found **no measurable impact on adherence to PrEP or experience of IPV**. Disclosure of PrEP use to partners was higher in the group of women who received the CHARISMA counseling intervention (92%) at month 6 compared to the group receiving the standard screening, support, and referrals for IPV (82%); no other evidence of a statistically significant impact on relationship dynamics was found.

Additional analyses of the RCT results suggest that the CHARISMA intervention might have a greater impact on women who have a specific relationship issue that the intervention is designed to address, including IPV, a partner's controlling behavior, PrEP nondisclosure, or partner opposition to PrEP use. Further analysis and evaluation are needed to determine who might benefit most from CHARISMA, the optimal duration of the intervention, and whether it leads to more accurate reporting of IPV, which may have masked the effects of the intervention on IPV. (See the [Appendix](#) for more information about the RCT results.)

Although the RCT did not demonstrate a measurable impact on adherence to PrEP or experience of IPV, the CHARISMA intervention tools are being shared because few existing resources address the critical issues of IPV and relationship dynamics as barriers to effective PrEP use. **The hope is that the content and approach can be further adapted by toolkit users and evaluated for impact.**








The intervention was tested among cisgender women ages 18 to 45 but has the potential to be adapted to other populations and settings and for other prevention or treatment methods. (See Section IV of this toolkit, "[Guidance on Adaptations](#).")

## ABOUT THE TOOLKIT

The CHARISMA Toolkit, available at <https://www.prepwatch.org/charisma/>, provides a comprehensive set of tools to support integration of the CHARISMA intervention into PrEP programs. Three audiences may find this toolkit useful:

- **PrEP program implementers** looking to integrate the CHARISMA intervention into PrEP services
- **PrEP providers and IPV counselors** seeking detailed guidance and tools to effectively implement the CHARISMA intervention
- **Policymakers and donors**, to better understand the investments required to support the CHARISMA intervention

**Table 1: CHARISMA Toolkit Components**

	<b>CHARISMA Toolkit Guide to Implementation and Adaptation</b>	<b>[This document]</b> A guide to implementing the CHARISMA intervention, with lessons learned from pilot testing and the RCT and guidance on how to adapt CHARISMA for different populations and settings
	<b>Counselor Training Curriculum</b>	A training facilitator's guide with materials for a 2.5 to 4-day training to equip counselors with the skills needed to implement CHARISMA, including understanding relationship dynamics, IPV, and PrEP and how to provide client-centered counseling that promotes women's agency
	<b>HEART Relationship Assessment</b>	A tablet- or paper-based questionnaire that assesses a woman's relationship, including identifying women experiencing or at risk of IPV, and recommends one of three CHARISMA counseling modules to use
	<b>Counselor Job Aid and Manual</b>	Resources to guide counselors through the key steps of the CHARISMA intervention, including the HEART relationship assessment, counseling modules, male partner engagement materials, and referrals to other services
	<b>Counseling Videos</b>	A series of videos that can be paired with counseling sessions to demonstrate key concepts around partner communication skills and discussing PrEP with male partners
	<b>Educational Materials for Male Partners</b>	Templates that can be adapted to local contexts and examples of other resources for women to share with their male partners about HIV prevention, PrEP, and relationships
	<b>Referral Templates</b>	Templates that can be adapted to facilitate referrals to other services (e.g., psychosocial support, social services), especially for those who are experiencing IPV

This Toolkit Guide includes six sections:

## **I. Introduction**

The current section provides a high-level summary of the CHARISMA intervention's goals, information on who could benefit from reading about and using the toolkit, and an overview of the toolkit structure.

## **II. Context for the CHARISMA intervention**

An overview of the context for the CHARISMA intervention, including:

- A summary of the evidence showing links between PrEP use, relationship dynamics, and IPV
- Evidence from the CHARISMA studies
- An overview of related guidance and resources

## **III. CHARISMA intervention delivery and related guidance**

Guidance on how to implement the CHARISMA intervention, including:

1. Lay counselor training and ongoing support
2. Relationship assessment
3. Counseling sessions
4. Male partner engagement
5. Referrals

## **IV. Guidance on intervention adaptation**

Key considerations to guide potential adaptation of the CHARISMA intervention for use across different:

- Healthcare delivery settings
- HIV prevention and treatment products
- Populations

## **V. Monitoring and learning**

Guidance on how to monitor and assess implementation of the CHARISMA intervention

## **VI. Appendix**

Additional resources, including:

- Contact information for the CHARISMA team
- Related resources and studies



## KEY TERMS, DEFINITIONS, AND LANGUAGE CLARIFICATIONS

**Clients:** Women seeking to use PrEP and recipients of the CHARISMA intervention

**Empowerment counseling:** Counseling that expands a person's capacity to make and act upon decisions affecting their lives by promoting agency and identifying power inequities

**Gender roles:** Communities and societies create social norms of behavior, values, and attitudes that are deemed appropriate for men and women and the relations between them. These roles are assigned by social rather than biological criteria. For example, childbearing is a female sex role because men cannot bear children. Although both men and women can rear children, child care is often socially assigned as a woman's role.<sup>1</sup>

**Gender norms:** How we as individuals, communities, and societies think about and reinforce the ways men and women should be, appear and act; what they should aspire to; and what roles they should play within the community and family<sup>2</sup>

**Gender-based violence (GBV):** GBV is violence that is directed at an individual based on biological sex, gender identity, or perceived adherence to socially defined norms of masculinity and femininity. It includes physical, sexual, and psychological abuse; threats; coercion; arbitrary deprivation of liberty; and economic deprivation, whether occurring in public or private life.<sup>3</sup>

**Intimate partner violence (IPV):** A type of GBV that includes psychological/emotional, physical, sexual, and economic abuse, stalking, and controlling behaviors by a current or former partner or spouse (adapted from CDC<sup>4</sup>)

**Lay counselors:** Trained, nonclinical professionals who offer HIV prevention-related counseling support

**Pre-exposure prophylaxis (PrEP):** This toolkit uses the term “PrEP” to refer to all ARV-based HIV prevention products used by people who are HIV negative to reduce risk of HIV acquisition, if used effectively and consistently. These products include oral PrEP (a daily oral pill that is available in many countries), as well as those in the development-to-market pipeline, such as intravaginal rings, long-acting injectables and implants, and multipurpose technologies (technologies that simultaneously prevent one or more sexually transmitted infections and unintended pregnancies).<sup>5</sup>

**PrEP disclosure:** The act of telling or disclosing the use of PrEP to another person, particularly an intimate partner

**PrEP effective use:** Continued, daily use of PrEP during periods of risk to ensure full protection against HIV transmission

**PrEP uptake/initiation:** The point at which a person begins to take PrEP

**Social harms:** Nonmedical negative social, emotional, physical, or economic consequences of study participation or use of a study product<sup>6</sup>

**PrEP-related social harms:** Nonmedical negative consequences of PrEP use, including difficulties in personal relationships, stigma or discrimination from family or community members, and IPV, if the violence is specifically related to PrEP use or study participation



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## II. Context for the CHARISMA Intervention

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## THE LINK BETWEEN HIV PREVENTION, RELATIONSHIP DYNAMICS, AND IPV

The CHARISMA intervention was developed in response to a growing body of evidence demonstrating that many women's ability to protect themselves from HIV is influenced by the dynamics of their relationships with male partners. Women have long reported that male condoms offer insufficient protection against HIV because many men prefer not to use them. Women in violent or controlling relationships find it even more challenging to negotiate use of male condoms and other HIV risk-reduction approaches.<sup>7-10</sup>

Pre-exposure prophylaxis (PrEP) offers women the potential to prevent HIV with more control and discretion. PrEP methods include oral PrEP — a daily pill; the monthly dapivirine vaginal ring, which received a positive regulatory opinion from the European Medicines Agency in July 2020 and was prequalified by the World Health Organization (WHO) in November 2020, paving the way for consideration by national regulatory authorities; and injectable long-acting cabotegravir, which proved highly effective against HIV in a clinical trial among cisgender women, with results announced in November 2020.<sup>11-13</sup> The daily persistent use of PrEP required for effective HIV prevention remains a challenge, particularly for young women in sub-Saharan Africa,<sup>14-19</sup> whose risk of HIV is driven, in part, by gender-based violence and other harmful gender norms and inequalities.<sup>20</sup>

Although women can use oral PrEP and the dapivirine ring without a male partner's knowledge, the evidence suggests that the approval or support of male partners is often desired, or even required, for safe, effective use.<sup>21-23</sup> Results from qualitative research among participants in the Partners PrEP Study in Uganda and the FEM-PrEP trial in Kenya and South Africa suggest that partner support for or acceptance of oral PrEP use facilitated daily pill taking, while adherence suffered with lack of support from partners.<sup>24-26</sup>

Data from clinical trials show that partner support is also important for consistent, sustained use of the dapivirine ring.<sup>23</sup> In the MTN-020/ASPIRE trial in Malawi, South Africa, Uganda, and Zimbabwe, 12% of women discontinued ring use at a partner's request, and a study in Uganda found ring removals due to partner influence among 34% of participants.<sup>27, 28</sup> ASPIRE participants whose partners were unsupportive of ring use and/or trial participation were 30% more likely to have low adherence to the dapivirine ring compared with those with supportive partners; disclosure of ring use was associated with partner support.<sup>28</sup>

Discussing oral PrEP use with male partners is difficult for many women, who worry that PrEP use will signal distrust of a partner, be interpreted as a signal of infidelity, or be mistaken for HIV treatment and treated as a sign of HIV-positive status.<sup>23</sup> Some women participating in clinical trials of the dapivirine ring considered discussing ring use with a male partner too risky, because

it might result in accusations of infidelity or lack of trust. Others thought using it without a partner's knowledge would be riskier, because a partner's unexpected discovery of the ring could result in violence or accusations of "witchcraft."<sup>29-32</sup>

Violence from an intimate partner affects an estimated 30% of women worldwide.<sup>33</sup> Experience of IPV is associated with poor health outcomes, including increased risk of HIV infection,<sup>33</sup> and with lower initiation and higher discontinuation of PrEP. Research in South Africa, for example, found a significant difference in oral PrEP uptake between those who had experienced IPV in the preceding year (54%) and those who did not (75%).<sup>34</sup> Oral PrEP interruptions were reported by 23.8% of those experiencing IPV, compared to 6.9% of those not experiencing IPV, in a demonstration project in Kenya and Uganda; in the Partners PrEP study, women who had experienced IPV during the three months preceding a PrEP clinic visit were 50% more likely to have low oral PrEP adherence.<sup>35,36</sup> ASPIRE trial participants who reported social harms by male partners, including IPV, also had lower adherence to the dapivirine ring.<sup>36</sup>

Given these findings, CHARISMA works at the intersection of the risk of HIV acquisition, relationship dynamics, and IPV to improve women's ability to effectively and safely use PrEP in the context of their relationships with male partners. The intervention aims to enable women using PrEP to reflect on the health of their relationships, build skills for more effective communication with male partners, and consider whether and how to discuss their PrEP use with partners. For women at risk of or experiencing IPV, the CHARISMA intervention provides first-line support, which includes empathetic listening, developing plans to promote their safety (and their children's safety, if needed), and offering referrals to additional services to address their needs.

## CURRENT GLOBAL GUIDANCE

Normative bodies, donors, and national governments increasingly recognize the links between HIV, relationship dynamics, and IPV, and have issued guidance on the topic. As a result, many HIV programs are being encouraged or required to incorporate IPV enquiry and first-line support into their work. The CHARISMA intervention meets and exceeds the requirements in World Health Organization (WHO) and U.S. President's Emergency Plan for AIDS Relief (PEPFAR) guidance for asking about and responding to disclosure of violence in healthcare settings. It is important for implementers of the CHARISMA intervention to be aware of the following additional resources for addressing IPV and other forms of GBV.

In 2013, WHO issued ["Responding to intimate partner violence and sexual violence against women: WHO clinical and policy guidelines."](#)<sup>37</sup> This guidance includes recommendations to ensure healthcare workers are trained on IPV, provide women-centered care, and identify those experiencing IPV. WHO has developed several resources to inform and support the integration of IPV detection and response into clinical services — including, but not limited to, HIV services:

- The WHO training curriculum, ["Caring for women subjected to violence: a WHO curriculum for training health care providers"](#) (2019),<sup>38</sup> and the WHO clinical handbook on IPV, ["Health care for women subjected to intimate partner violence or sexual violence: A clinical handbook"](#) (2014),<sup>39</sup> include detailed guidelines and tools for addressing IPV in clinical settings. They are designed for healthcare providers caring for women subjected to violence. Both resources promote the five-step LIVES (Listen, Inquire, Validate, Enhance Safety, and Support) approach. The CHARISMA study design was informed by LIVES, and the CHARISMA intervention incorporates this guidance.
- ["RESPECT women: Preventing violence against women"](#) (2019) is a WHO guide for policymakers and implementers that presents the RESPECT framework of evidence-based strategies and key considerations for effective violence prevention programming.<sup>40</sup>
- ["Gender-Based Violence Quality Assurance Tool"](#) (2018), developed by the U.S. Centers for Disease Control and Prevention (CDC), Jhpiego, and WHO, offers tools for strengthening and collecting data on post-GBV clinical health services.<sup>41</sup>
- Additional resources are updated in WHO's publications on violence against women, found at <https://www.who.int/reproductivehealth/publications/violence/en/>.

The 2021 PEPFAR Country Operational Plan endorses stronger links between HIV prevention, care, and treatment services and IPV prevention and clinical post-violence response services.<sup>42</sup> The guidance mandates that routine enquiry for IPV be conducted with all clients accessing oral PrEP services. Following routine enquiry, sites must offer appropriate support and referrals to violence response services. Implementing the PEPFAR guidance means that a program must meet the WHO's minimum requirements before its staff can ask clients about violence (see ["Readiness for CHARISMA"](#)). In addition, the guidance includes reporting metrics to track violence prevention and response activities.

Few specific resources are available to support implementation in line with the PEPFAR guidance in HIV clinical settings. The CHARISMA project and the CHOICE collaboration developed a [Standard Operating Procedure and Job Aid for Addressing Partner Relationships and Intimate Partner Violence in Pre-Exposure Prophylaxis \(PrEP\) Services](#) for PrEP program staff to adapt and use.<sup>43</sup> In addition, USAID and CDC have developed trainings to prepare PEPFAR program staff to conduct routine enquiry and provide first-line support. The CHARISMA toolkit adds to this growing body of resources.

## HOW CHARISMA ADVANCES CURRENT GUIDANCE AND PRACTICE

**The CHARISMA intervention goes beyond the current global guidance requirements by addressing harmful relationship dynamics and providing women with strategies to anticipate and avoid IPV related to PrEP use.**

In the CHARISMA intervention, all clients seeking PrEP services receive a relationship assessment and relationship counseling. While existing guidance and interventions focus on IPV, CHARISMA can address a broader range of positive and negative relationship dynamics, including power dynamics, communication skills, disclosure of PrEP use, and additional types of violence beyond physical and sexual, including emotional and economic violence. In addition, it can help surface and address precursors to violence.

**CHARISMA may also contribute to improved quality of care in HIV clinical settings.** CHARISMA equips healthcare providers and lay counselors with knowledge and skills to provide women-centered care and to support clients to use PrEP. Quality of care was not evaluated by the CHARISMA studies, but qualitative data collected from CHARISMA participants will be analyzed to identify any insights into whether CHARISMA may have contributed to quality of care.



## DETERMINING WHETHER THE CHARISMA INTERVENTION IS RIGHT FOR YOUR SETTING

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### READINESS FOR CHARISMA

A clinic should not implement CHARISMA without meeting WHO's minimum requirements for asking about violence:<sup>37</sup>

- A protocol/SOP for asking about violence
- Providers who are trained on how to ask about IPV
- Providers who are trained to offer first-line support when violence is disclosed. First-line support "refers to the minimum level of (primarily psychological) support and validation of survivors' experience that should be received" by those who disclose violence to a health care or other provider. It shares many elements with "psychological first aid" in the context of emergency situations. The WHO uses the acronym LIVES<sup>39</sup> to help providers deliver first-line support:
  - **L**istening with empathy
  - **I**nquiring about the client's immediate needs and concerns
  - **V**alidating the client's experience
  - **A**ssessing and helping **e**nhance the person's safety
  - **L**inking the client to other **s**upport
- A private setting with confidentiality ensured where providers ask about IPV
- A process for offering referrals or links to other services.

In addition, a sufficient number of staff at an appropriate skill level to provide the counseling necessary in the CHARISMA intervention on an ongoing basis. The number of staff needed depends on the clinic volume; each staff person could expect to complete one, or at most two, CHARISMA counseling sessions in an hour.

Finally, administrative and management support to complete the tasks necessary to set up the CHARISMA intervention (e.g., training counselors, providing opportunities for peer-to-peer or other psychological support of counselors, creating referral networks if they do not already exist, and adapting referral letters and male partner educational materials). These tasks are further detailed in later sections of this toolkit.

With these required elements in place, CHARISMA was designed to help PrEP providers to:

- Assess women's relationships, including experiences of IPV
- Mitigate the risk of IPV related to PrEP use for women
- Improve uptake and effective use of PrEP by counseling women on relationship communication, healthier relationship dynamics, and decision-making about disclosure of PrEP use
- Engage the male partners of female PrEP users in decision-making about HIV prevention
- Improve the quality of counseling through training on important skills and content areas (e.g., active listening, recognizing symptoms of burnout, and the differences between gender and sex)

**As stated in the Introduction, the CHARISMA RCT found no measurable impact on adherence to PrEP or experience of IPV, so the intervention likely requires adaptation to achieve impacts on these outcomes.**

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## *FREQUENTLY ASKED QUESTIONS*

### **1. Who participated in the CHARISMA studies?**

The CHARISMA studies enrolled women in Johannesburg, South Africa, who were HIV negative, not pregnant, ages 18 to 45, and had male partners. In the pilot, women used dapivirine rings. In the RCT, women used oral PrEP.

### **2. How applicable is the intervention to other geographies, service delivery settings, products, and populations?**

The intervention was developed and tested with women ages 18 to 45 using dapivirine rings and oral PrEP in a research clinic setting in Johannesburg, South Africa, and was designed for potential scale-up to public health clinics. However, the intervention has the potential to be more widely applicable, and Section IV of this toolkit, "[Guidance on Adaptations](#)," outlines considerations for applications of the CHARISMA intervention in different healthcare delivery settings (e.g., community-based programs), with different HIV products (e.g., dapivirine rings, HIV antiretroviral therapies), and with different populations (e.g., female sex workers, adolescent girls under 18).

### **3. What is the relationship assessment and how is it used?**

The relationship assessment uses a tool developed for CHARISMA called the HEALthy Relationships Assessment Tool (HEART). The HEART identifies appropriate counseling modules for clients by assessing their responses to a series of questions on traditional values, partner support, partner abuse and control, partner resistance to HIV prevention, and individual

HIV prevention readiness. This tailoring of the counseling through HEART is critical to the CHARISMA intervention's success. The HEART focuses on a woman's primary partner and is not intended to assess multiple relationships or same-sex relationships.

4. **How can the intervention improve quality of care and/or change the norms of how care is delivered?**

The approach of the CHARISMA intervention shifts the roles of the lay counselor and client, which may be unfamiliar to some lay counselors. The client is considered the expert and decision-maker for her relationship and circumstance, while the lay counselor listens and offers support to empower her in making decisions and taking action. This shift in the relationship between lay counselors and clients takes place through dialogue and shared brainstorming and problem-solving tailored to the woman's relationship dynamic, determined by the relationship assessment results.

5. **Can the intervention be administered at a community level or in nonclinical settings?**

Appropriately trained community health workers with the relevant resources available could likely implement the CHARISMA intervention in non-clinic settings, although this was not tested in the CHARISMA study. Please see Section IV, "[Guidance on Adaptations](#)," for additional considerations if implementing in a community setting.

6. **Can CHARISMA be used in a clinic with limited resources, including human resources?**

Yes. The CHARISMA intervention intentionally uses lay counselors, rather than nurses or psychologists, to deliver the intervention. Not only does this reduce the human resource requirements, but it also improves the effectiveness of the intervention. Formative research in the CHARISMA pilot found clients relate better to lay counselors and therefore are more likely to discuss fears with and disclose violence to them than to more formal healthcare providers.

Moreover, the toolkit makes several suggestions throughout the document on solutions for lower-resource settings. These include using a self-administered relationship assessment, using paper versions of the assessment instead of an electronic version, and making videos available in waiting areas rather than showing them during the counseling sessions.

7. **What were the results of the RCT?**

The results of the RCT show that CHARISMA was highly acceptable to the participants who received the intervention. Nearly 88% said they had benefited greatly from the empowerment counseling, and almost 97% said it was important to provide the CHARISMA intervention along with PrEP. However, the RCT detected no statistically significant impact on adherence to oral PrEP use or experience of IPV. Disclosure of PrEP use to partners was significantly higher in the CHARISMA group (92%) at month 6 compared to the group receiving the standard screening,

support, and referrals for IPV (82%). Additional analyses of the RCT data suggest that the CHARISMA intervention may have increased PrEP adherence among women facing one of the specific relationship issues that the intervention is designed to address, but that finding was not statistically significant.

**8. What are the potential reasons why the RCT found few differences between the CHARISMA intervention group and the comparison group?**

Possible explanations for the lack of statistically significant differences between the two groups include:

- More study visits might have been needed to enable counselors to develop sufficient rapport with participants to have an impact on PrEP adherence, experience of IPV, or relationship dynamics.
- The CHARISMA RCT did not include an intensive male engagement component, which has been shown to be effective in reducing IPV, and it did not address some of the drivers of IPV, such as financial stress and social norms.
- Women who received the CHARISMA intervention may have felt more comfortable reporting experience of IPV, which may have masked the impact of the intervention.
- Our ability to measure the intervention's effect may have been diminished because the women in the comparison (standard of care) group received higher-quality IPV counseling than is typical in non-research settings. The prevalence of recent IPV among all study participants declined from 27% at baseline to 8% at month 6.

Further analysis and evaluation are needed to better understand the impact of CHARISMA and determine who might benefit from the intervention.

**9. Given the uncertainty about CHARISMA's impact, how can the intervention enhance PrEP programs?**

Although none of the eligibility criteria for the RCT were specifically related to violence or partner dynamics, 60% of participants faced at least one of the relationship issues that CHARISMA is designed to address, showing a need for relationship-focused counseling in PrEP delivery programs. The intervention was feasible for lay counselors to deliver with good quality and fidelity and was highly acceptable to participants, who reported many perceived benefits from the empowerment counseling. Even though CHARISMA was not more effective than our standard of care model in reducing IPV and increasing PrEP use, it could provide a good alternative where there is a demand or need for relationship counseling, especially when good referral resources are not available.



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# III. CHARISMA

## Intervention

## Delivery and

## Related Guidance

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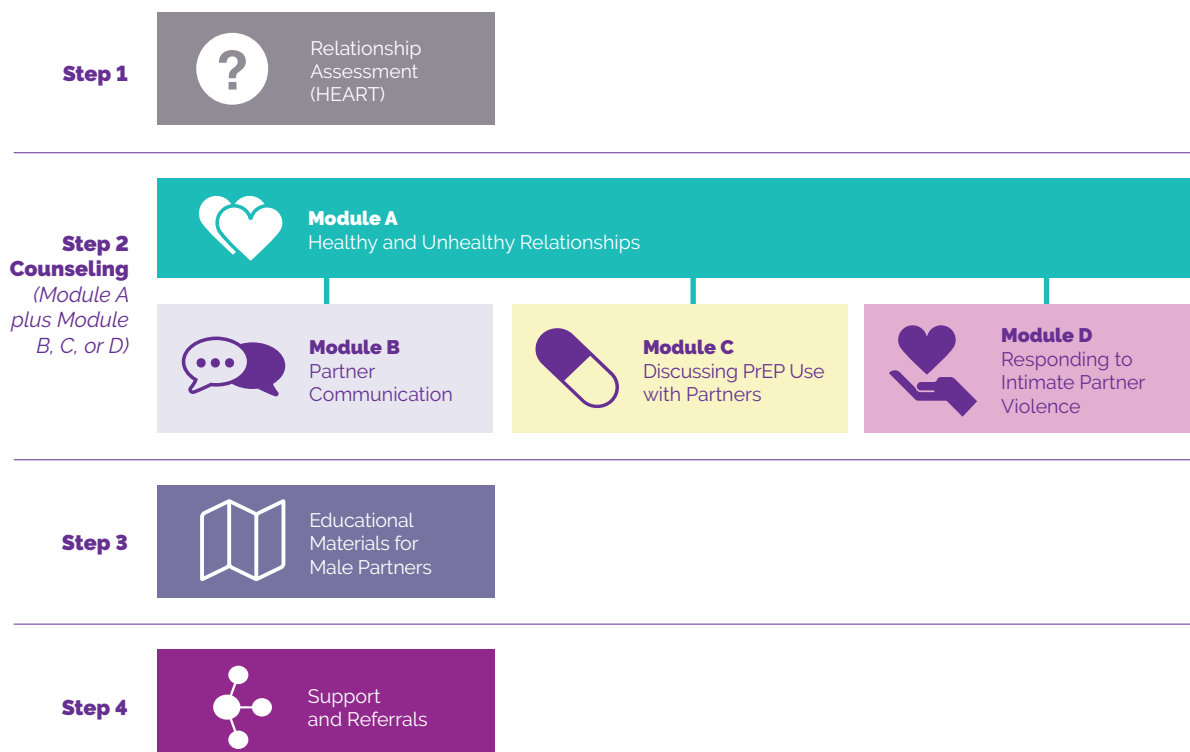
## TOOLS OVERVIEW

The CHARISMA intervention is designed for implementation with clients who are considering, initiating, or currently using PrEP. PrEP programs can adapt the CHARISMA intervention for use with clients in several possible situations:

- Clients initiating PrEP for the first time
- Clients using or re-initiating PrEP and facing challenges with adherence
- Clients who are eligible for PrEP but are declining it due to relationship or partner concerns
- Clients with a new partner whose HIV status is known or unknown
- Other clients who opt to receive the CHARISMA intervention when offered to improve their relationship dynamics

Counselors trained on CHARISMA conduct the intervention. The counselor begins by conducting a relationship assessment, and then provides the counseling on Healthy and Unhealthy Relationships (Module A), followed by one assessment-identified counseling module (Partner Communication, Discussing PrEP Use with Partners, or Responding to IPV). Modules A, B, and C include a video. Finally, the counselor ends the session by sharing educational materials for male partners and making necessary referrals. This flow is illustrated in Figure 1 (repeated here for reference).

**Figure 1: CHARISMA Intervention**



A series of tools was developed to help clinics and counselors successfully implement each step of the CHARISMA intervention. These tools are described in detail, along with key tips and considerations for their use, in this section. The tools can be found for download, adaptation, and use at <https://www.prepwatch.org/charisma/>. Figure 2 below provides an overview of each step and lists the tools used in the CHARISMA intervention.

**Figure 2: CHARISMA Intervention Tools**

Counselor Training and Support	1 Relationship Assessment	2 Counseling	3 Male Partner Materials	4 Referrals
<p>Train counselors on conducting the CHARISMA intervention, including screening, counseling, and follow-up (e.g., male partner engagement, referrals)</p> <ul style="list-style-type: none"> <li>• Counselor Training Curriculum and Presentations</li> <li>• CHARISMA Counseling Session Observation Form</li> </ul>	<p>Assess a woman's relationship dynamics to identify the relevant counseling module</p> <ul style="list-style-type: none"> <li>• HEART Relationship Assessment <ul style="list-style-type: none"> <li>- Long-form</li> <li>- Abridged</li> </ul> </li> </ul>	<p>Provide structured counseling session to address PrEP users' relationship dynamics, including IPV</p> <ul style="list-style-type: none"> <li>• CHARISMA Counseling Manual</li> <li>• CHARISMA Counseling Job Aid</li> <li>• CHARISMA Counseling Videos</li> </ul>	<p>Provide materials for partners to foster conversation and build understanding of oral PrEP use</p> <ul style="list-style-type: none"> <li>• Educational Materials for Male Partners</li> <li>• Male Partner Invitation Letter Template</li> </ul>	<p>Establish and sustain referral networks to connect women to other necessary services</p> <ul style="list-style-type: none"> <li>• Community Service Provider List Template</li> <li>• Referral Letter Template</li> </ul>

## COUNSELOR TRAINING AND SUPPORT

### PURPOSE

This section and associated tools provide detailed guidance for administrators and managers to train and support lay counselors to implement the CHARISMA intervention. This training builds the foundational skills necessary for counseling related to exposure to IPV. Ongoing support for lay counselors continues their development through observation, debriefing and psychosocial support, and peer support.



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## CHARISMA TOOLS

- A. **CHARISMA Counselor Training Curriculum:** The training curriculum includes detailed instructions and materials for facilitators to lead a training for counselors to effectively implement the CHARISMA intervention. The curriculum provides resources for a four-day comprehensive training and a 2.5-day minimum training and includes guidance on how to prioritize between sections and activities if time is limited.
  - B. **CHARISMA Counselor Training Presentations:** Three presentations are provided for use in counselor training.
- 

## CONSIDERATIONS FOR USE

Considerations for use of the counselor training and support include:

### Engage a broad range of participants in the initial training.

- Training set-up requires the thoughtful identification of a facilitator. The facilitator can be a clinic leader or counselor supervisor, and s/he should be experienced in inquiring about and responding to IPV, ideally using the World Health Organization's recommended LIVES (Listen, Inquire, Validate, Enhance safety and Support) approach.<sup>39</sup> The facilitator should be a good listener who elicits active participation from everyone at the training and establishes a safe, respectful training environment.
- In addition to the staff who will provide the counseling and oversee the counselors, site administrators and other providers involved in PrEP delivery should attend at least a portion of the introduction to the training to ensure they are aware of the content and scope of the intervention and its broad applicability to be responsive to the appropriate clients.

### Customize training content but maintain key elements.

- Training for CHARISMA was originally a four-day, in-person training for lay counselors or others who have some experience in the areas of gender, violence, youth-friendly services, and women-centered counseling (e.g., an ability to empathize with women in vulnerable situations, understanding the difference between socially constructed gender roles versus biological sex, active and compassionate listening, and a strict adherence to confidentiality standards). If counselors have already received training in gender, violence, youth-friendly services and women-centered counseling, this training will be a refresher. If the training timeline needs to be shortened, selected activities related to these themes can be removed, as outlined in the training curriculum. However, a minimum of 2.5-day in-person training is needed.

- Consider holding this training alongside other trainings where participants will already have the chance to get to know one another. This familiarity helps counselors to have deeper conversations on difficult topics.
- The most critical elements of the training include:
  - Understanding the importance of addressing relationship dynamics in the context of HIV prevention
  - Discussing the counselor's role in the CHARISMA intervention and how it differs from traditional roles
  - Building lay counselors' understanding of and sensitivity to gender roles and dynamics in relationships
  - Introducing the assessment and counseling topics and intervention materials
  - Practicing mock CHARISMA counseling sessions
- After the training, counselors should complete at least three practice sessions prior to counseling clients, practicing each module at least once.

### **Select lay counselors and other personnel with the appropriate experience.**

- CHARISMA counselors could include existing lay counselors, community health workers, or others with some base training in gender and HIV.
- Ideally, counselors experienced in the areas of gender and HIV will administer the CHARISMA intervention. Without this background, greater investment in training and ongoing observation and support will likely be necessary.
- Consider selecting lay counselors who have previously completed the WHO training curriculum, "[Caring for women subjected to violence: a WHO curriculum for training health-care providers](#)."<sup>39</sup> The CHARISMA training curriculum highlights areas of overlap with the WHO curriculum.
- Counselor and clinic managers should have additional skills beyond those of the lay counselors, including a history of management, strong and positive relationships with employees, and experience overseeing the implementation of new initiatives or programs.

### **Provide ongoing learning and psychosocial support for lay counselors.**

- Counselors should participate in practice counseling sessions at the outset and should be periodically observed in counseling sessions on an ongoing basis to maintain quality of care. In the initial months, observation should occur more frequently. In the CHARISMA studies, counselors were observed during their first five sessions and one in every 10 counseling sessions thereafter. Counselors should obtain the client's consent for the session to be observed.

- Informal peer-to-peer debrief and support meetings can help lay counselors share lessons learned, problem solve around challenges, and offer psychosocial support to one another. During the CHARISMA studies, these meetings were held weekly and as needed for urgent cases.
- Counselors should be reminded of the symptoms of vicarious trauma, burnout, exhaustion, and emotional challenges due to the content of their work. These challenges are covered in the training (see the CHARISMA Counselor Training Curriculum), as well as the WHO's ["Caring for women subjected to violence: a WHO curriculum for training health-care providers."](#)<sup>39</sup> Counselors can help to identify these symptoms in themselves or with peers in order to seek appropriate medical assistance and maintain self-care. Appropriate psychological support should be made available (whether on site or by referral) to lay counselors. The CHARISMA studies offered on-site meetings with a social worker once per month to counselors (as a group or individually) early in the study. As counselors strengthened coping skills, they met with social workers on a quarterly basis.

## 1. RELATIONSHIP ASSESSMENT

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### PURPOSE

The first step in the CHARISMA intervention is a relationship assessment for PrEP clients, using the HEAlthy Relationships Assessment Tool (HEART), administered by lay counselors using a tablet or laptop. The purpose of the assessment is to efficiently assess a client's relationship dynamics and determine the appropriate counseling module to meet her needs.

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### CHARISMA TOOLS

- HEART – Long-form:** The HEAlthy Relationships Assessment Tool (HEART) is a 32-item survey (reduced from a previous 42-item version) that assesses a client's relationship across five dimensions: traditional values, partner support, partner abuse and control, partner resistance to HIV prevention, and individual HIV prevention readiness.<sup>44</sup> The electronic version of HEART is programmed on a tablet or laptop, and an algorithm auto-calculates results and identifies the recommended counseling module for the client. A paper version is also available but does not include auto-calculations. The long-form version of the HEART was used in the CHARISMA studies. In post-RCT analyses, all five dimensions of the HEART were associated with one or more outcomes of interest. The relationships between each scale and outcomes are summarized in Table 2.

In Table 2, up arrows indicate that higher scale scores were associated with higher outcome levels. For example, a higher score on partner abuse and control was associated with greater likelihood of reporting any controlling behaviors, abusive behaviors, physical violence, and sexual violence. Down arrows indicate that higher scale scores were associated with lower outcome levels. For example, a higher score on partner abuse and control was associated with lower levels of partner communication. The number of arrows indicate the strength of the relationship. No arrows indicates no association between scale scores and outcomes.

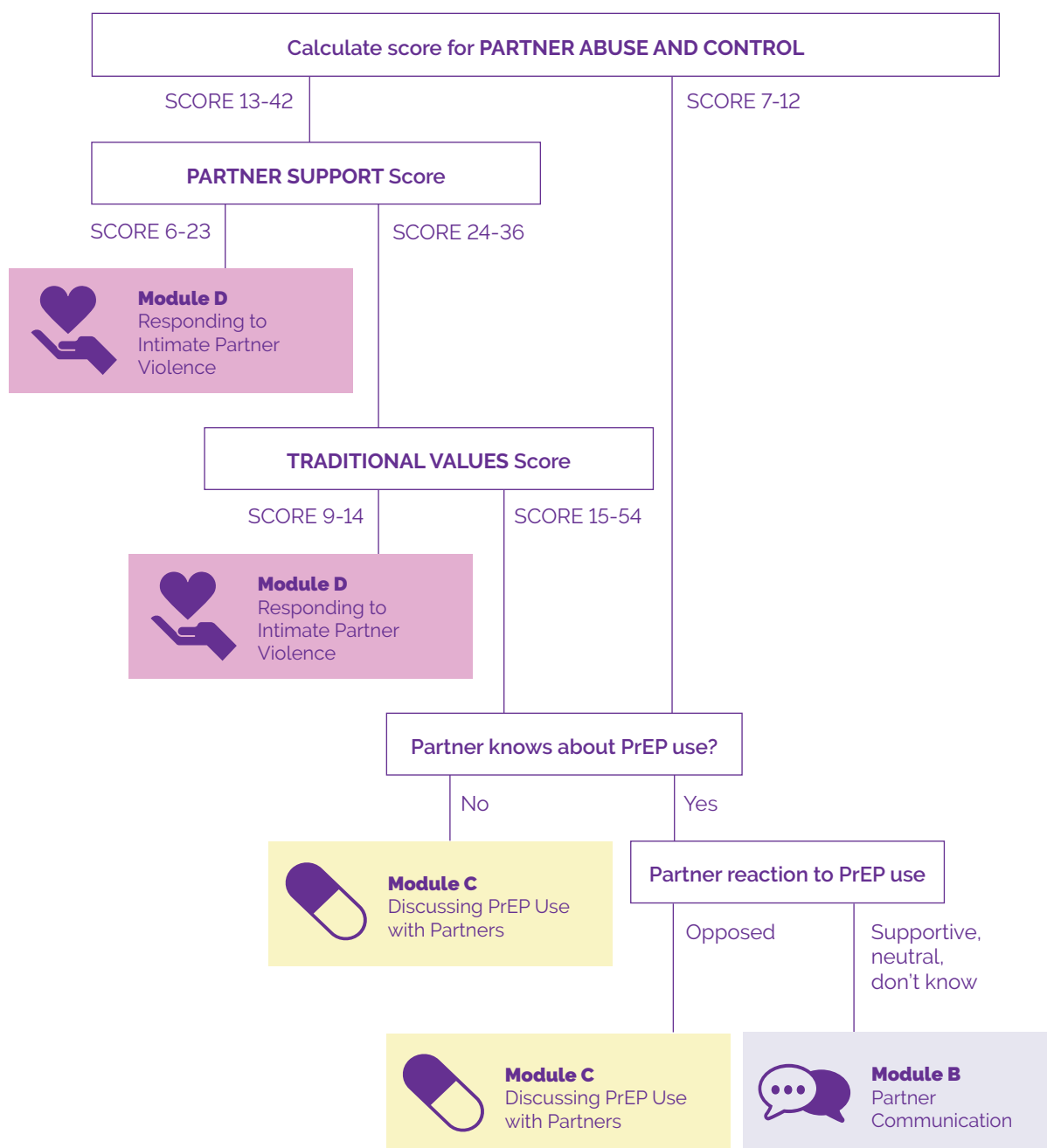
**Table 2: Relationships Between HEART Scale Dimensions and CHARISMA Outcomes**

		OUTCOME					
		Controlling Behavior	Emotional Abuse	Physical Violence	Sexual Violence	Partner Communication	Full Disclosure of PrEP Use
SCALE DIMENSION	Traditional Values					↓	
	Partner Support	↓ ↓ ↓	↓ ↓ ↓	↓ ↓ ↓	↓ ↓ ↓	↑ ↑ ↑	↑ ↑
	Partner Abuse and Control	↑ ↑ ↑	↑ ↑ ↑	↑ ↑ ↑	↑ ↑ ↑	↓ ↓	
	Partner Resistance to HIV Prevention	↑ ↑	↑ ↑ ↑	↑ ↑ ↑	↑ ↑	↓ ↓	↓
	HIV Prevention Readiness				↓ ↓	↑ ↑	↑

Figure 3 shows the algorithm that the tablet/laptop uses to determine which counseling module to recommend. This algorithm works for both the long-form and abridged versions of the HEART.

The electronic version of HEART is programmed on a tablet or laptop, and an algorithm (see Figure 3) auto-calculates results and identifies the recommended counseling module for the client. If a tablet or laptop is not available, the counselor can administer and score the abridged HEART assessment on paper. Additional details about administering and scoring the HEART on paper are included in the CHARISMA Counseling Manual.

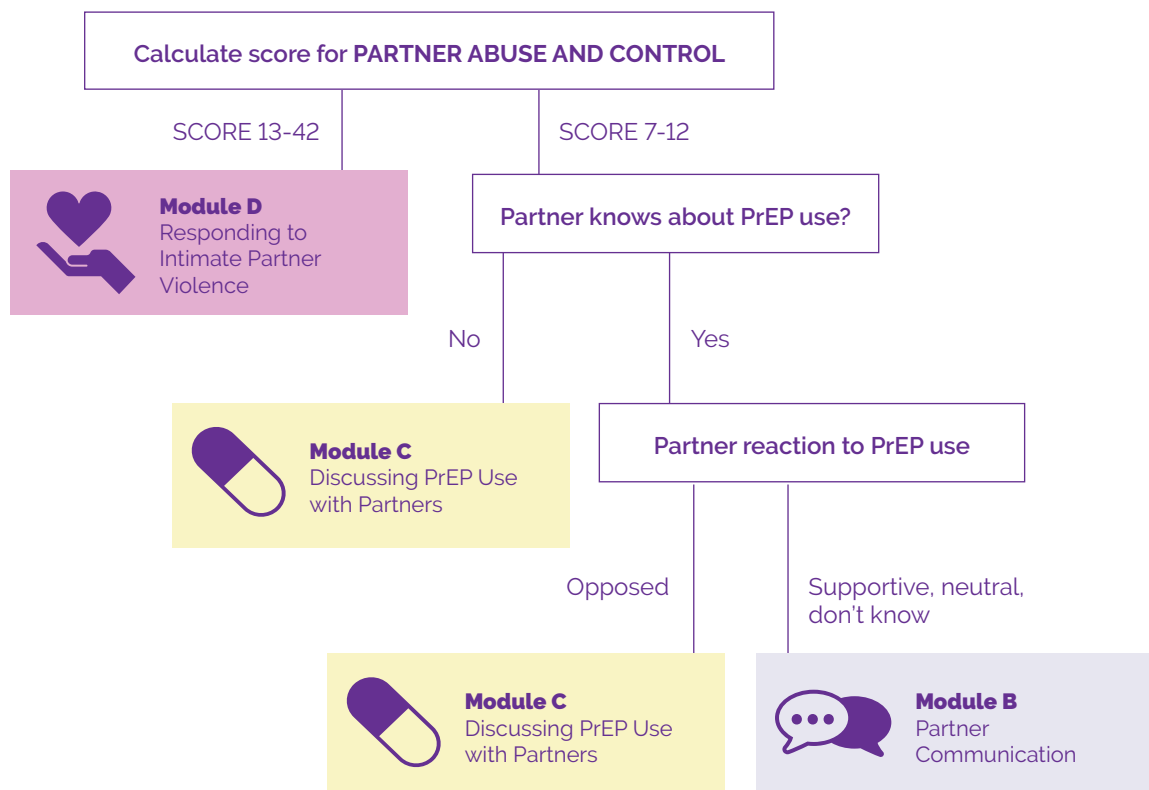
**Figure 3. Algorithm for Using HEART Scores to Select a CHARISMA Counseling Module**



- B. **HEART – Abridged:** In settings where there is less time to administer the HEART, an abridged version of the HEART can be used. This version of the HEART includes 22 items from the first three dimensions (traditional values, partner support, and partner abuse and control). In post-RCT analysis, these three scales used together best identified women who reported experiencing some form of emotional abuse or physical violence in their relationships, based on the WHO Violence Against Women Survey questions. Note that the abridged version provides slightly less information a counselor can use to assess a woman's relationship.

If a tablet or laptop is not available, the counselor can administer and score the abridged HEART assessment on paper. If the HEART is being administered and scored on paper and time is very limited, at a minimum, the “partner abuse and control” dimension should be completed. In that situation, the counselor can use Figure 4 as a guide through the process of deciding which counseling module to offer. Additional details about administering and scoring the HEART on paper are included in the CHARISMA Counseling Manual.

**Figure 4. Algorithm for Using HEART Partner Abuse and Control Score to Select a CHARISMA Counseling Module**



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## CONSIDERATIONS FOR USE

Considerations for use of the HEART relationship assessment include:

### Select the version of HEART that is feasible for your setting.

- Two versions of the HEART are included in the materials: a long-form and an abridged version.
  - The abridged version covers a narrower range of partner dynamics than the long-form version. However, both versions have strong reliability and are recommended for use.
  - The long-form version is 32 items and the abridged version is 22 items. There is a minimal time difference (2 to 4 minutes more) to complete the long-form version.
  - The long-form version provides additional information to the counselor about the nature of the woman's relationship, which helps inform the counseling. The additional questions also help the client reflect on her own relationship in more detail.
  - In settings where it is not possible to administer and score the HEART on a laptop or tablet, the abridged HEART is the most feasible option.

### Pilot the HEART before using.

- Social and cultural norms around gender and relationships are important to capture in order to appropriately assess a relationship. It is possible that not all of the questions in the HEART will remain culturally relevant across different geographies and populations. We suggest the following process to review the HEART for cultural relevance:<sup>45</sup>
  - Identify people who are similar (in age, sex, language, and sexual orientation) to the clients intended to receive CHARISMA.
  - Ask them if they are willing to help you "test" the HEART.
  - If yes, in a one-on-one interview, administer the HEART, asking the participant to "think-aloud" as she responds to each item.
  - Once she has provided a response to an item, ask for more information, including whether the item is:
    - Easy to understand
    - Comfortable to respond to honestly
    - Relevant to her situation

- If any items are challenging, ask her to provide suggestions on how to modify them.
- Conduct one or more rounds of interviews with four or five individuals per round. Focus only on items that are problematic to three or more participants per round.
- Modify items only if multiple participants have suggested a similar change.
- The HEART is currently available in English. However, it can also be translated to other languages. Ideally, translation of key terms would be discussed and decided on. Then, the HEART should be translated and back translated by separate professional translators. The back translation should be compared to the original English to identify any discrepancies and assess whether the intended meaning of each statement has been maintained. Adjustments should be made to the translation as needed, and then the translated version should be tested with a few native speakers to ensure clarity.

**Install the HEART on tablets or laptops but keep paper versions on-hand as back-up.**

- The REDCap programming for the HEART is available as part of this toolkit.
- The HEART should be installed on all tablets or laptops, and tablets/laptops should be monitored throughout the day to ensure they are in working order and available for use.
- In clinics where tablets/laptops are readily available, keep a fully-charged tablet/laptop and paper versions of the HEART on hand in case of a power outages.
- In clinics where tablets/laptops are not readily available, lay counselors can use paper versions of the HEART but keep a single tablet/laptop on hand that lay counselors can use to enter results and have the results quickly and easily auto-calculated to determine the appropriate assessment module. Calculating responses on paper assessment forms can be time-consuming. Directions for this hand-calculation are included in the paper-based HEART.
- If HEART is set up on tablets/laptops, communicate clearly with clients how the data will be used and/or stored. Note that the data does not need to be stored beyond the counseling session for the CHARISMA intervention.

**Do not rush the assessment process.**

- The time to administer the HEART assessment is typically 10 to 15 minutes.
- The relationship assessment offers an opportunity to better understand clients' relationship and tailor counseling.



- Do not rush clients and try not to provide additional information to avoid inadvertently influencing HEART results.
- If a client is having trouble answering a question, it is okay to leave it blank and return to it at the end of the assessment session. However, it is important that clients answer all of the questions in the HEART by the end of the assessment.

**Following the assessment, do not immediately share the recommended module with the client. Instead, transition immediately to Module A: Healthy and Unhealthy Relationships.**

- The counselor should calculate the client's score and identify the recommended counseling module. However, the counselor should not share the results at this time. Instead, counselors should wait until after completion of Module A: Healthy and Unhealthy Relationships Counseling.
- Use Module A: Healthy and Unhealthy Relationships to better understand the client's relationship. All clients receive this counseling module to begin to self-identify unhealthy and abusive dynamics in their relationships. If a client discloses an experience of violence during Module A, the counselor may decide to offer Responding to Intimate Partner Violence (Module D) to the client, even if the HEART recommended another module.

## 2. COUNSELING

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### *PURPOSE*

The counseling tools include four modules:

- **Module A: Healthy and Unhealthy Relationships** helps a client to identify healthy and unhealthy relationship characteristics. It asks her to reflect on her own relationships using what she's learned.
- **Module B: Partner Communication** helps a client build partner communication skills by understanding the different ways people communicate (e.g., words, voice, and body language), using "I" statements and other de-escalation strategies to avoid or de-escalate conflict.
- **Module C: Discussing PrEP Use with Partners** explores the woman's partner's knowledge of and attitude toward her use of PrEP and facilitates decision-making and planning about whether and how she will tell her partner about PrEP use. Includes tips for discussing PrEP use with her partner or using PrEP without his knowledge.
- **Module D: Responding to IPV** helps a client recognize the cycle of violence, mitigate risk, and plan for acute instances of violence.

All clients receive Module A, and then receive one of the three remaining modules (Modules B, C, or D) based on their HEART results. Counseling for Module A plus Module B/C/D is intended to take place in one session following the assessment.

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### *CHARISMA TOOLS*

1. **Counseling Job Aid:** This Job Aid is a tabletop flip chart with counselor and client-facing pages. The counselor pages include key steps and messages to cover in each counseling session, including the HEART assessment, all four counseling modules, educational materials for male partners, and referrals. Each section includes both client-facing pages with images and high-level summaries and counselor pages with guidance on steps to implement the intervention.
  2. **Counseling Manual:** The Counseling Manual provides detailed information on the counseling modules, including time estimates, objectives, details on each counseling module, and suggested language to use with clients. This resource will be shared in the initial counselor training and can be used as a reference guide for counselors. With time and practice, counselors will no longer need to reference the manual and can rely solely on the job aid.
  3. **Counseling Videos:** A series of videos that show realistic relationship conversations and dynamics are provided for use in the counseling modules. These can be shown using the same tablet on which HEART is administered or available online for access on clients' smartphones via Wi-Fi at the clinic.
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### *CONSIDERATIONS FOR USE*

Considerations for use of the counseling materials include the following:

#### **Update the counseling job aid.**

- The job aid currently includes materials that are not specific to any geography. However, we recommend using locally developed and relevant materials when possible for the educational materials for male partners. Local referral processes should also be reflected in the job aid and counseling manual.

#### **Laminate the counseling job aid.**

- The job aid can become worn, but lamination extends the lifespan of materials.
- Moreover, lamination enables counselors to write on the client side of the job aid with a dry erase marker. This can be helpful for capturing what is discussed and prompting further reflection.

- Writing on the job aid can take additional time, so counselors should do so only when it is helpful.
- Keep dry erase markers and erasers available by tying them to clipboards or the job aid.
- The pages of this job aid should be spirally bound at the top of each page to allow the job aid to sit on a tabletop in the shape of a tent, with the client page and counselor pages facing the respective users.

### **The length of counseling sessions will vary by client.**

- The estimated length of an entire session using counseling on Partner Communication (Module B) is 55 to 85 minutes. (Note that the estimated length of each type of session includes administration of the HEART assessment, Module A, and either Module B, C, or D, as well as distribution of educational materials and making referrals.)
- The estimated length of an entire session using counseling on Discussing PrEP Use with Partners (Module C) is 70 to 95 minutes.
- The estimated length of an entire session using counseling on Responding to IPV (Module D) is 75 to 95 minutes.
- For clients identified as needing the Responding to IPV (Module D) counseling, spend additional time on the Module A: Healthy and Unhealthy Relationships counseling to reflect on the client's relationship and identify signs of unhealthy dynamics or violence. Helping the client recognize these dynamics is a more effective approach than telling the client that she is a "victim" of IPV. This approach may also make clients more responsive to counseling.
- The intention is for each client to receive Module B, C, or D (only one of the three). However, a counselor who thinks that a client would benefit from content from multiple modules can modify the counseling session accordingly. For example, a woman experiencing IPV would receive Responding to IPV (Module D) but may also benefit from content in Discussing PrEP Use with Partners (Module C). Alternatively, the counselor could plan to see the client at her next clinic visit to administer additional modules.
- Some clients may become emotional during counseling sessions. Act respectfully and use your best judgment on how to move forward with the counseling session. Allow clients to gather their thoughts and settle their emotions. If necessary, pause the counseling session. Have tissues readily available.

### 3. EDUCATIONAL MATERIALS FOR MALE PARTNERS

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#### PURPOSE

Clients can share the educational materials with their male partners to build understanding of PrEP and other HIV prevention methods, address misperceptions about PrEP, and invite male partners to participate in PrEP counseling and/or attend couples counseling. The materials also address intimate partner violence. Clients should be offered these materials after counseling if they are interested in sharing them with their male partners.

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#### CHARISMA TOOLS

- A. **Templates for Educational Materials for Male Partners:** Included in the folder of resources (found here: <https://www.prepwatch.org/charisma/>) are customizable templates that you can adapt for clients to share with male partners. It is advised you use existing materials from the Ministry of Health in your country or other local organizations, if available. If they are not available, the templates included here can be customized for your setting. These resources were created by the South African National Department of Health, which has generously shared them for adaptation by others. The templates include:
- a. **Invitation to Counseling:** An invitation letter from the clinic to a male partner encouraging him to come for counseling on services offered by the clinic, such as couples counseling, PrEP counseling, HIV testing and counseling, etc. The template will need to be updated based on the services provided at your clinic. This invitation should be included in the package of educational materials with the permission of the client.
  - b. **PrEP Fact Sheet:** A two-sided flyer with information on what PrEP is and how to start using PrEP. Available in dark and bright color options.
  - c. **PrEP Brochure:** A Z-fold brochure of FAQs for PrEP. Available in dark and bright color options.
  - d. **PrEP Pocketbook:** A 14-page, pocket-sized “booklet” that uses graphics and images to answer questions about PrEP. Questions include what PrEP is, how PrEP is used with other HIV prevention efforts, what the side effects are, and how to take PrEP. Available in dark and bright color options.
  - e. **PrEP Palm Card:** A small “palm-sized” flyer with the most essential information about PrEP. Available in dark and bright color options.

- f. **PrEP Posters:** A series of posters that may be used in a clinic setting to inform all clients, including men, about PrEP. Available in dark and bright color options.
- B. **Examples of Educational Materials for Male Partners:** developed by others but used in the CHARISMA intervention. These are additional materials that can be shared with male partners, although they cannot be easily adapted. Using materials provided by your Ministry of Health or other local organizations may be more appropriate.
- a. **PrEP Roadmap (Source: [South African National Department of Health](#)):** An example of a "roadmap" to help individuals consider if oral PrEP is right for them, based on the local options available for HIV testing, treatment, and prevention. Developing a similar roadmap could be useful in your community.
  - b. **HIV Medical Male Circumcision Brochure (Source: [HIVSA](#)):** An informative brochure on medical male circumcision that could be included as another mechanism for HIV prevention for male partners.
  - c. **Community Awareness Poster from Raising Voices (Source: [SASA!](#)):** A poster encouraging communities and couples to be aware of and support each other through mutual respect.
  - d. **Community Support Poster from Raising Voices (Source: [SASA!](#)):** A poster encouraging communities to challenge violence in relationships.
  - e. **Supplemental Community Engagement for Violence Prevention Materials from Raising Voices (Source: [SASA!](#)):** The Raising Voices, SASA! website has numerous publicly available, community-oriented materials about violence awareness and prevention that could be used for broader community engagement on GBV prevention. These supplemental materials can be found online at <http://raisingvoices.org/activism/media-communications/sasacommats/>.

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## CONSIDERATIONS FOR USE

Considerations for use of the educational materials for male partners include:

### **Use materials available in your context or adapt these materials for use.**

- Determine whether materials are already available and adapted for your target audience on the topics of PrEP, gender equality, GBV, and HIV prevention. Potential sources of these materials could be your organization, other local organizations, the national Ministry of Health in your country, or PEPFAR.
- If these materials are not available, adapt the CHARISMA intervention templates with your organizational information. Determine if documents like the example materials should also be developed.
- To ensure materials are readily available, develop a process for storing and tracking inventory for these materials. Also, review them on a quarterly basis to ensure the information is up-to-date.

### **Encourage male partners to visit a clinic for counseling and PrEP and seek out male support.**

- Sometimes men do not want to go to the same clinic as their partners, so encourage them to visit your clinic or any other clinic offering similar services. Have information available for recommended, alternative clinics.
- Including materials/brochures from local organizations that support men (e.g., male support groups or counseling for men) can help men find support for their relationships and health.

### **Consider offering selected materials, rather than the full package.**

- In many cases, offering a subset of materials that directly relate to issues raised in a counseling session will be more useful than sharing all the materials. Ask clients if they would prefer a full set or subset of the materials.
- Testing has shown that men prefer the "dark" color palette rather than the "bright" color palette for the educational materials for male partners. Both versions have been included in this toolkit.

### **Consider the wider community context.**

- In addition to male partner engagement, community engagement is also critical to empowering clients to use PrEP. The CHARISMA intervention did not establish sufficient evidence to make any recommendations on how best to perform community engagement. However, it is recommended that you consider how best to engage your community to begin shifting social norms related to PrEP use. Such changes would result in additional benefits beyond increased PrEP adherence.

- The educational materials for male partners may be useful in facilitating this community engagement.
- The [HIV Prevention Ambassador training package and toolkit](#) and the [HIV Prevention Ambassador training package and toolkit for Adolescent Girls and Young Women](#) can be used for peer education, advocacy, and raising community awareness about PrEP and gender issues.<sup>46,47</sup>

## 4. REFERRALS

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### PURPOSE

The referral tools facilitate referrals to additional medical, legal, and social services that are responsive to a client's specific needs, particularly in response to experiences of violence. While not all clients will need referrals, they may have friends or family who could benefit from knowledge of these organizations. A network of referrals to support clients experiencing violence must be established prior to implementing CHARISMA.

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### CHARISMA TOOLS

- A. **Community Service Providers List Template:** A template for a list of referral organizations, including health, social, and legal services, to be used as a reference for lay counselors when making referral recommendations.
  - B. **Referral Letter Template:** A referral letter for clients to take to the referral organization for continued services, to be modified appropriately to include your organization's information.
- 

### CONSIDERATIONS FOR USE

Considerations for use of the referrals include:

**A referral network is critical to implementing the CHARISMA intervention. Guidance on how to set up a referral network if one is not already in-place is as follows.**

- Hold a stakeholder meeting to educate organizations on the CHARISMA intervention and encourage participation in the referral network.
- Regularly assess organizations on their ability to be a strong partner by considering:
  - Quality of care and services
  - Availability to accept referrals and treat clients in an appropriate amount of time

- Affordability of services for a variety of socioeconomic backgrounds
- Accessibility of services to where clients live and work and/or outside of the view of community members.
- Know the requirements of service providers to accept clients based on whether they are local or foreign, as these vary greatly among organizations, and ensure that a variety of clients could receive services.
- Ensure a breadth of service providers within each category of services (i.e., health, social, and legal services).
- Collect the contact information of selected referral organizations and update the Community Services Provider Template.
- On an annual basis, assess the referral list; remove, add and/or update organizations' information as necessary.
- In rural areas where there may be fewer referral organizations, ensure counselors have the appropriate level of training to respond to experiences of violence. If they do not have this experience, consider whether you are able to responsibly implement CHARISMA.

**Extra attention is typically necessary to support clients to link to additional services.**

- It can be difficult for clients to follow through on referrals. Additional support can help, including: walking clients to the referral site, calling ahead to make an appointment for them, and following up with the client to ask about her experience with the referral agency. This is sometimes referred to as a "warm referral."
- To track referral provider quality, consider regularly soliciting feedback from clients you have referred to these services or sending a staff member to the referred services as a "test case" to understand the experience and identify challenges. This is one mechanism for ensuring ongoing updates of your referral network of care.
- If a client has a negative experience with referral services, follow up with the referral agency to provide feedback and offer the client an alternate referral.
- The organizations to which you are referring should have a high quality of care; otherwise, the likelihood of future follow-up may be reduced. If your organization is able, consider helping referral organizations build their capacity to further improve the quality of care and the success of referrals. Aim to establish memorandums of understanding (MOUs) with organizations in your referral network.
- If, over time, an organization is unable to provide quality care, it should be removed from the referral list and replaced with an alternate provider.





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## IV. Guidance on Intervention Adaptation

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The CHARISMA intervention was evaluated with HIV-negative women, ages 18 to 45, using oral PrEP or the dapivirine ring in a research clinic in Johannesburg, South Africa. Use of the CHARISMA intervention in different healthcare delivery settings (i.e., community-based delivery or low-resource settings), for different HIV products (i.e., new-to-market PrEP products or HIV treatment), or among different populations (i.e., adolescent girls under age 18, sex workers, pregnant and breastfeeding women, men who have sex with men) requires adaptation of the tools.

The following high-level guidance draws from the experience of the CHARISMA studies team. However, these adaptations face significant limitations and have not been tested, meaning the use and effectiveness of the CHARISMA intervention with different settings, products, or target populations is unknown. All adaptations should still meet the WHO's minimum requirements for asking about and responding to violence. If you adapt and implement the CHARISMA intervention, please share your experience by email [info@charismaproject.org](mailto:info@charismaproject.org).

## **ADAPTATIONS FOR DIFFERENT HEALTHCARE DELIVERY SETTINGS**

The CHARISMA intervention was designed for delivery at a health facility with sufficient resources to use tablets or laptops and sufficient human resource capacity (e.g., lay counselors present at health facility) to implement the intervention. Adaptations could be made to implement the intervention in a community setting or in a lower-resource setting. Key considerations for these different settings are outlined below.

### **Community-based delivery**

- CHARISMA counseling must occur in a private space, even if an enclosed client room is not available in a clinic. Lack of privacy may limit the client's ability to disclose violence or discuss other private matters that affect one's ability to use PrEP.
- Many lay counselors and community health workers (CHWs) in rural settings already informally support and advise people on issues beyond their core areas of expertise, including issues related to violence. Moreover, some PrEP programs enlist lay counselors and CHWs to follow up with PrEP clients who have missed appointments and are struggling to use PrEP as instructed. The CHARISMA intervention may provide lay counselors and CHWs with additional training and resources to promote effective PrEP use and address violence, but it is important to ensure that an appropriate investment is made in training and supporting CHWs to tackle these challenging topics.

## Family planning services

- Efforts are currently underway in some countries to increase access to PrEP among adolescent girls and young women (AGYW) by making oral PrEP available in family planning service settings. Both WHO and the 2021 PEPFAR Country Operational Plan guidance endorse better integration of HIV prevention and family planning services in high HIV prevalence settings. Family planning providers and clinics that integrate PrEP will have to meet the WHO's minimum requirements for asking about and responding to violence.
- Family planning clinics would also be appropriate settings for implementing CHARISMA. In fact, family planning providers may already be well-versed in conducting client-centered empowerment counseling and discussing issues related to male engagement in women's health, making them ideal candidates for delivering the CHARISMA intervention.
- Family planning clinics that do not have sufficient resources to use tablets or laptops or sufficient human resource capacity (e.g., lay counselors on staff) to implement the intervention can consider the adaptations described for lower-resource settings.

## Lower-resource settings

- Many communities may not have an easily accessible referral network. In such settings, we encourage lay counselors to follow the minimum first-line support outlined by WHO clinical and policy guidelines on ["Responding to intimate partner violence and sexual violence against women."](#)<sup>36</sup> If this is not possible, someone else in the health-care setting should be made available to provide this support.
- If tablets or laptops are unavailable, paper versions of the HEART assessment can be used. Counseling videos will either need to be skipped, or, if Wi-Fi is available in a clinic, may be accessed by smartphone.
- Maintaining a budget for the minimal costs for: 1) printing educational materials for male partners, to provide opportunities for education and implementation of the action plans developed in the counseling sessions, and 2) printing counseling manuals and printing and laminating the counseling job aid.
- The CHARISMA intervention is designed to be implemented by lay counselors, which contributes to the feasibility of implementing the intervention in low-resource settings where many clinics face capacity restraints for highly skilled healthcare personnel (e.g., nurses, psychologists).
- The CHARISMA team is planning to develop and test self-administration of the HEART relationship assessment in the next phase of this project. There are several considerations related to self-administration of the HEART:

- Self-administration could further reduce the total time required to administer the CHARISMA intervention. Self-administration also has the potential to reduce the burden on the counselor and to elicit more candid responses from clients.
- The potential drawbacks of self-administration are that a client may not fully understand the statements or how to respond without clarification and assistance from a counselor. In addition, a counselor might have a less complete understanding of a woman's relationship if the counselor did not complete the HEART with the client.
- Self-administration of the HEART needs to be thoroughly tested for feasibility and acceptability and to ensure the results are similar to those generated with the counselor-administered version of the HEART.
- Selected counseling videos could be viewed in a clinic's waiting area after a self-administered assessment, assuming a tablet is available for automatic determination of a client's counseling module, which also indicates which video she should watch.

## **ADAPTATIONS FOR DIFFERENT HIV PRODUCT TYPES**

Opportunities could also be leveraged to use the CHARISMA intervention with delivery of other HIV prevention and treatment products beyond oral PrEP. If using the CHARISMA intervention for additional product types, lay counselors will need to be trained on new product types so that they can adequately determine the implications of each product type and adapt the CHARISMA counseling. Moreover, the training and counseling manuals, counseling job aid, and HEART relationship assessment would need to be appropriately updated to reflect these different products. Supplementary educational materials for male partners would also need to include materials on the different product type(s). Key considerations for these different products are outlined below.

### **New-to-market PrEP products**

- As additional PrEP products — such as the dapivirine vaginal ring and injectables — become available, CHARISMA will need to be adapted to include these new methods. The intervention was initially developed for women using dapivirine rings, so the relationship dynamics and considerations for ring use are already incorporated in the intervention design. However, the intervention tools in this toolkit refer only to oral PrEP and would need to be updated to include the dapivirine ring. It would also be beneficial to update the counseling content to address choosing an HIV prevention method (e.g., oral PrEP or dapivirine ring) based on what may be best for the client, considering her relationship dynamics with her male partner.

- CHARISMA could also be adapted for any multipurpose prevention technologies (MPTs) that eventually enter the market. For MPTs formulated to protect against HIV infection and unintended pregnancy, the intervention materials will need to be adapted to account for the additional benefits the MPT offers as well as relationship dynamics pertaining to both HIV prevention and family planning use. These benefits includes the fact that some women may find it easier to talk to their partners about using a product that offers both contraceptive and HIV prevention benefits, while others may be comfortable disclosing use of a family planning product, but not an HIV prevention product. Still, some may prefer not to disclose use of an MPT at all.

### **HIV treatment**

- HIV-positive women are at increased risk of IPV, and disclosing HIV-positive status can trigger a violent reaction or abandonment by a partner.
- Counseling on relationship dynamics and violence prevention and planning remain highly relevant for HIV-positive clients and may require minimal adaptation. Resources for disclosing HIV-positive status and/or use of ART already exist and could be used to adapt the PrEP disclosure counseling modules.
- Providing the materials on oral PrEP use in the educational materials for male partners could still be helpful to HIV-negative male partners. Additional materials on living positively, HIV treatment, and HIV treatment in the context of a serodiscordant relationship should be included.

## **ADAPTATIONS FOR DIFFERENT POPULATIONS**

CHARISMA was designed for implementation with adult cisgender women in heterosexual partnerships. It can be used for other populations, such as adolescent girls under 18, men who have sex with men, transgender women, and subpopulations of adult cisgender women, such as female sex workers and pregnant and breastfeeding women. These groups are priority populations for PrEP services in many countries and may benefit from the CHARISMA intervention. Core topics such as communication, conflict de-escalation, and role-playing disclosure are anticipated to still be relevant, though the case studies used should be adapted to reflect the unique realities of each population. However, when using the intervention with populations where underlying gender and power dynamics are different than those experienced by cisgender, heterosexual adult women (i.e., in a relationship between men who have sex with men), further adaptations may be necessary. Key considerations for adapting the CHARISMA intervention to different populations are outlined below.

## Adolescent girls under 18

- There are perceptions that healthcare workers are especially judgmental of adolescent girls seeking PrEP or contraception due to the implied sexual activity. While the CHARISMA training and intervention aim to ensure empathy toward and respect for all women, this bias may be harder to overcome. Moreover, this perception may make it less likely that adolescent girls will be open about relationship dynamics or experience with violence with their counselors.<sup>48</sup> To address this challenge, training young women approximately ages 20 to 26 as CHARISMA counselors could make it easier for adolescent girls to be open about their experiences. Supplementing the CHARISMA counseling with training on youth friendly-service delivery could further address providers' negative attitudes about adolescent girls being sexually active (see training materials available at <https://www.prepwatch.org/prep-planning/training-materials/>).
- Experience in relationships and the characteristics of a relationship can vary dramatically for a younger population. Therefore, not all materials (e.g., videos) will be as relatable for adolescent girls. A program focused on adolescent girls, such as DREAMS, could invest in developing adolescent-specific videos.
- Younger women may differ from older generations in the language they use to discuss relationships and intimacy, as well as the value they place on traditional practices, including gender roles and norms.
- Adolescent girls may face additional restrictions in their movements and living situations that further limit their ability to discreetly take oral PrEP daily.
- In addition to male partners, parents or other caretakers also influence the ability of adolescent girls and young women to initiate and use PrEP. Module C on Discussing PrEP Use with Partners could be updated to include deciding whether to discuss PrEP use with parents/caretakers.<sup>47,48</sup>
- The intervention would need to be adapted to measure and respond to the unique needs of young women whose lifestyles are characterized by mobility, transition, and change, particularly in regard to intimate relationships.

## Key populations

- Members of key populations, including female sex workers, men who have sex with men, and transgender women, experience high rates of violence from various perpetrators, including law enforcement, family members, paying and nonpaying partners, and other members of society. While CHARISMA is intended to support providers to identify and respond to IPV, providers trained to implement CHARISMA will also be equipped to provide first-line support and appropriate referrals if members of key populations disclose violence from non-intimate partners.

- Stigmatizing attitudes and discriminatory behaviors of healthcare providers toward key populations may deter them from disclosing critical information to providers (e.g., information about sexual partners or experience with violence) and from receiving the high-quality care they need (e.g., a provider who believes violence is inherent to sex work or deserved by female sex workers may not provide appropriate support to female sex workers experiencing violence). Providers delivering PrEP services and offering the CHARISMA intervention to key population members should receive training to help them increase their empathy and identify any stigmatizing attitudes toward key populations, recognize their unique needs and vulnerabilities, and build interpersonal skills in order to provide high-quality services free of discrimination.
- Implementing CHARISMA with key populations will require adapting or adding routine enquiry questions about other forms of IPV that clients may experience. For example, in addition to asking whether a partner has ever made you feel afraid, bullied or insulted you, threatened to hurt you, or tried to control you, it may be important to ask, "Has your partner ever called you names, used slurs against you, or threatened to out you as a sex worker/man who has sex with men/transgender woman?"
- Facilities offering the CHARISMA intervention to key population members should also review the agencies to which they refer clients for post-GBV services to determine which will provide key population-friendly services to survivors of violence. As needed, and as resources allow, facility staff may also train other post-GBV service providers to offer key population-friendly support.

### **Female sex workers**

- Female sex workers may want to discuss their PrEP use with some sexual partners and not others. The CHARISMA counseling manual and job aid will need to be adapted to support decision-making about discussing PrEP use with different types of partners (e.g., paying vs nonpaying).

### **Men who have sex with men**

- IPV is increasingly recognized an issue for men who have sex with men. Aspects of CHARISMA could be beneficial for this population but have not been tested under these differing gender and power dynamics, including legal frameworks and GBV service provision agencies that may not acknowledge that IPV between same-sex couples exists and are therefore unable or unwilling to provide support to survivors of same-sex IPV. Extensive adaptations to the intervention tools would be needed before implementing the intervention with men who have sex with men.
- Men are often told that they should not be victims of violence, and men who have sex with men seeking support often feel shame for not living up to masculine ideals. Therefore, programs that seek to create space for



men who have sex with men to disclose violence should also provide education and counseling that normalizes seeking support and acknowledges how common such violence can be.

### **Transgender women**

- GBV service provision agencies are typically established to meet the needs of cisgender women and therefore may be unable or unwilling to provide support to transgender women survivors.
- Consider asking additional routine enquiry questions about forms of IPV that trans women may experience. For example, in addition to asking whether a partner has ever made you feel afraid, bullied or insulted you, threatened to hurt you, or tried to control you, it may be important to ask:
  - Has your partner ever called you names, used slurs against you, or threatened to out you as transgender?
  - Has your partner ever criticized your sexual performance, criticized your clothing, or asked you to act more masculine?
  - Has your partner tried to control your transitioning process?
  - Has your partner ever told you that no one else would want to be with someone like you because you are transgender?

### **Pregnant and breastfeeding women**

- When discussing IPV and considering safety planning for pregnant women, counselors will want to keep in mind the safety of both the woman and the unborn baby.
- Safety measures for breastfeeding women may be needed for both the woman and her child(ren). For example, the counselor may advise that the woman build a supply of extra milk — either refrigerated or frozen — that can be given to her baby in a bottle if she has to leave suddenly.

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# V. Monitoring and Learning

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The routine monitoring and learning questions are a brief set of indicators and questions that a delivery site can use to self-assess the quality of intervention implementation. These questions are intended as guideposts to ensure the implementation of CHARISMA is effective. Note that the questions were not part of the CHARISMA study. It is highly recommended that your organization develop and integrate a CHARISMA intervention monitoring and evaluation (M&E) plan into your organizational M&E plan, including data collection sources, processes, and responsibilities. For PEPFAR implementers, new plans should be in accordance with PEPFAR and USAID guidance for monitoring, evaluation, and learning.

## ROUTINE MONITORING

PrEP implementers can track the following suggested indicators to improve service delivery and monitor the impact of CHARISMA. Potential data sources include your clinic's routine data collection, data collection on PEPFAR indicators, observation, or client surveys. Neither the indicator list, nor suggested data sources, are exhaustive. Suggested key indicators (with suggested sources) are:

1. % of clients receiving CHARISMA and type of module received (client surveys OR routine data collection on clinic forms)
2. Counseling quality (client surveys OR observations)
3. Intervention fidelity, i.e., delivery as intended (client surveys OR observations)
4. Intervention acceptability (client surveys)
5. PrEP uptake (routine data collection)
6. IPV referrals (routine data collection) depending on the data collection processes, this indicator can be further disaggregated to:
  - a. IPV cases identified (routine data collection)
  - b. IPV referrals made (routine data collection)
  - c. IPV referrals accessed (routine data collection)

An occasional client "satisfaction" survey may also be useful in collecting inputs for some of these indicators, particularly during the early parts of implementation or during times of transition. We recommend administering a brief survey to a subset of CHARISMA clients annually or semiannually to monitor the quality and potential impact of CHARISMA and estimate overall indicators.<sup>c</sup> Survey questions should cover the client's perception of the counselor's skill throughout the session, the time required for and content delivered during the session, perceived effectiveness of the counseling session, and the perceived importance of the CHARISMA intervention overall.

<sup>c</sup> While the size of the CHARISMA clients surveyed will vary based on resources available to support this survey, a sample size of 100 participants will give you a 95% confidence interval with +/- 10%.

For PEPFAR partners, the table below lists indicators that might be used to assess the implementation of the CHARISMA intervention while minimizing additional data collection burden. The table below lists these indicators and describes how they can be used by the CHARISMA intervention.

**Table 3. How PEPFAR Indicators Can Be Used to Assess CHARISMA Implementation**

PEPFAR Indicator	Definition and Most Relevant Disaggregation <sup>49</sup>	How CHARISMA can use the indicator
<b>PrEP_NEW</b>	<p>Number of individuals who were newly enrolled on oral PrEP to prevent HIV infection in the reporting period</p> <ul style="list-style-type: none"> <li>Age/sex</li> </ul>	<ul style="list-style-type: none"> <li>With a goal of increasing PrEP uptake and effective use, the CHARISMA intervention aims to directly increase this indicator in the short- and medium-term (i.e., month-to-month).</li> <li>Understanding the patterns and trends affecting this indicator can help you identify opportunities to improve the implementation of the CHARISMA intervention at your clinic.</li> </ul>
<b>GEND_GBV</b>	<p>Number of people receiving post-gender-based violence clinical care based on the minimum [PEPFAR] package</p> <ul style="list-style-type: none"> <li>Violence service type by age/sex, for sexual violence and for physical and/or emotional violence</li> </ul>	<ul style="list-style-type: none"> <li>Data should be collected continuously at the point of service delivery. The CHARISMA intervention may increase reported incidents of violence, and therefore the number people receiving GBV care, in the short- and medium-term.</li> <li>This indicator can indicate whether the CHARISMA intervention is identifying clients with unreported experiences of IPV who are being referred and taking up those referrals.</li> <li>The CHARISMA intervention may also increase the proportion of IPV survivors who are taking up referrals.</li> </ul>
<b>PrEP_CURR</b>	<p>Number of individuals, inclusive of those newly enrolled, who received oral PrEP to prevent HIV during the reporting period</p> <ul style="list-style-type: none"> <li>Age/sex</li> </ul>	<ul style="list-style-type: none"> <li>With a goal to increase effective use of PrEP, the CHARISMA intervention aims to directly increase this indicator over the medium-term (i.e., over several months).</li> <li>Understanding the patterns and trends impacting this indicator can help you identify opportunities to improve the implementation of the CHARISMA intervention at your clinic. (It is important to note that PrEP-CURR simply captures the number of clients using PrEP in a particular reporting period; it is not a measure of effective use since clients are not expected to continue PrEP use for a specific period of time. Therefore, fluctuations in PrEP_CURR must be interpreted with caution.)</li> </ul>

The inputs for these indicators should come from client forms/files, tracking spreadsheets, or other logs and databases already in use for ongoing data collection.

## LEARNING QUESTIONS

A learning question is any question related to an organization's or program's work which, when answered, will help the program or organization work more effectively. Learning questions can be used for multiple purposes, such as filling knowledge gaps, testing assumptions, providing feedback on implementation, indicating progress toward goals, and assessing impact (adapted from USAID Learning Lab "Learning Agenda").<sup>50</sup>

Learning questions are suggested if your organization has the time and resources available to collect data and reflect on implementation progress. Learning questions are separate from regular, weekly monitoring. Rather, they should be discussed on a quarterly basis by a core implementation team, including site leaders overseeing implementation and lay counselors directly offering the intervention. More frequent reflection may be helpful during the first year of implementation or during key transitions.

To assess your clinic's progress in effectively implementing CHARISMA, reflect on the following questions:

- To what extent are clients seeking PrEP services able to receive CHARISMA counseling? Why or why not?
- Are clients satisfied with the CHARISMA intervention? Why or why not?
- What are we learning about effective ways to implement the counseling? What is ineffective in implementation? How can we be more efficient in our delivery without compromising quality?
- To what extent and in what ways has the intervention enabled clients to use PrEP?
- To what extent has the intervention enabled clients experiencing IPV to seek additional support?
- Have any social harms occurred as a result of the intervention? If so, what are they and how can they be prevented?
- What surprises or unintended consequences have we seen?
- Given the answers to the above questions, how should we adjust our implementation of CHARISMA?
- [If an adaptation has been made] What evidence exists that the intervention adaptation has been acceptable and has achieved its intended impact?

Use the routine monitoring indicators, reported staff experiences and observations, and a client satisfaction survey to help answer these questions.

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# VI. Appendix

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## HOW TO CONNECT

To request support in implementing the CHARISMA intervention, ask questions about the CHARISMA studies, or provide feedback, please contact [info@charismaproject.org](mailto:info@charismaproject.org).

## CHARISMA PILOT STUDY RESULTS

The CHARISMA pilot sought to measure the acceptability and feasibility of the CHARISMA intervention that integrates delivery of HIV prevention (specifically, the dapivirine vaginal ring) with counseling on partner communication and IPV among providers and research participants. The pilot ran from June 2016 to May 2018 and included 95 participants in Johannesburg, South Africa. The outcomes measured by the pilot study include the feasibility and acceptability of the intervention, as well as the adherence to the ring among CHARISMA participants in comparison to other participants in the HOPE trial. The intervention proved feasible and acceptable to participants and staff. For further information on the CHARISMA pilot findings, please refer to:

- [Impact of the 'CHARISMA' intervention pilot on partner disclosure, IPV, and adherence](#)<sup>51</sup>

## CHARISMA RCT STUDY RESULTS

The CHARISMA RCT sought to measure the effectiveness of the CHARISMA intervention on oral PrEP adherence; partner communication and support; and IPV and other social harms. A total of 407 HIV-negative, nonpregnant women ages 18 to 45 participated in the study from September 2018 to March 2020 in Johannesburg, South Africa.

The results of the RCT show that CHARISMA was highly acceptable to the participants who received the intervention. Nearly 88% said they had benefited greatly from the empowerment counseling, and almost 97% said it was important to provide the CHARISMA intervention along with PrEP. However, the RCT detected no statistically significant differences in adherence to oral PrEP, experience of IPV, or partner communication and support among women who received CHARISMA counseling compared to those who received the standard screening, support, and referrals for IPV. The only statistically significant difference between the two groups was that disclosure of PrEP use to partners was about 10% higher among women who received the CHARISMA intervention (92% vs. 82% in the standard of care group). No new HIV infections occurred among study participants in either group.

Additional analyses of the RCT data suggest that the intervention may have increased PrEP adherence among study participants who reported any of the following: recent experience of IPV, a partner's controlling behavior, nondisclosure of oral PrEP use, or partner opposition to its use; however, that result was not statistically significant.

Possible explanations for the lack of effect seen in the RCT are that more study visits might have been needed to enable counselors to develop sufficient rapport with participants to have an impact or that the intervention did not address some of the individual, interpersonal, and structural factors contributing to IPV or low PrEP use. For example, the CHARISMA RCT did not include an intensive male engagement component, which has been shown to be effective in reducing IPV and encouraging PrEP use. The intervention did not address drivers of IPV, such as financial stress or social norms, or other potential barriers to PrEP use, such as community rumors or lack of support from friends and relatives.

It is also possible that CHARISMA had an impact on IPV that we were unable to measure. Women who received the intervention may have been more comfortable reporting experiences of IPV, which could have masked the impact of CHARISMA. In addition, our ability to observe the intervention's effect may have been diminished because the women in the comparison (standard of care) group received higher-quality IPV counseling than is typical in non-research settings. The prevalence of recent IPV declined among all participants, from 27% at baseline to 8% at month 6.

Further analysis and evaluation are needed to better understand the impact of CHARISMA and determine who might benefit most from the intervention.





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# References

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- <sup>1</sup> Gender terminology. Washington, DC: USAID; 2007 [cited 2020, Aug 20]. Available from: [https://pdf.usaid.gov/pdf\\_docs/Pnadt089.pdf](https://pdf.usaid.gov/pdf_docs/Pnadt089.pdf).
- <sup>2</sup> Swanton B, Clarke J, Toth C. GREAT Project how-to guide. Washington, DC: Institute for Reproductive Health; 2016 [cited 2020 Aug 20]. Available from: [http://irh.org/wp-content/uploads/2016/06/GREAT\\_Project\\_How-to-Guide.pdf](http://irh.org/wp-content/uploads/2016/06/GREAT_Project_How-to-Guide.pdf).
- <sup>3</sup> United States strategy to prevent and respond to gender-based violence globally. Washington, DC: U.S. Agency for International Development; 2012 [cited 2020, Aug 20]. Available from: [https://pdf.usaid.gov/pdf\\_docs/PDACT888.pdf](https://pdf.usaid.gov/pdf_docs/PDACT888.pdf).
- <sup>4</sup> Preventing intimate partner violence. Atlanta: U.S. Centers for Disease Control and Prevention; 2019 [cited 2020 Aug 20]. Available from: <https://www.cdc.gov/violenceprevention/intimatepartnerviolence/fastfact.html>.
- <sup>5</sup> PrEPWatch. Research pipeline. New York: AVAC; 2020 [cited 2020 Aug 20]. Available from: <https://www.prepwatch.org/nextgen-prep/research-pipeline/>.
- <sup>6</sup> 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. Available from: [https://journals.lww.com/aidsonline/Fulltext/2019/11150/Social\\_harms\\_in\\_female\\_initiated\\_HIV\\_prevention.13.aspx](https://journals.lww.com/aidsonline/Fulltext/2019/11150/Social_harms_in_female_initiated_HIV_prevention.13.aspx).
- <sup>7</sup> Swan H, O'Connell DJ. The impact of intimate partner violence on women's condom negotiation efficacy, *J Interpers Violence*. 2012;27(4): 775–92. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4451787/>.
- <sup>8</sup> Kacanek D, Bostrom A, Montgomery ET, Ramjee G, deBruyn G, Blanchard K, et al. Intimate partner violence and condom and diaphragm nonadherence among women in an HIV prevention trial in southern Africa. *J Acquir Immune Defic Syndr*. 2013;64(4): 400–8. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/24165561>.
- <sup>9</sup> Pettifor AE, Measham DM, Rees HV, Padian NS. Sexual power and HIV risk, South Africa. *Emerg Infect Dis*. 2004;10(11): 1996–2004. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3328992/>.
- <sup>10</sup> García-Moreno C, Jansen HAFM, 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 [cited 2020 Jan 15]. Available from: <https://www.who.int/reproductivehealth/publications/violence/24159358X/en/>.
- <sup>11</sup> WHO expands recommendation on oral pre-exposure prophylaxis of HIV infection (PrEP) policy brief. Geneva: World Health Organization; 2015 [cited 2020 Jan 15]. Available: <https://www.who.int/hiv/pub/prep/policy-brief-prep-2015/en/>.
- <sup>12</sup> ipmglobal.org. Dapivirine ring. Silver Spring, MD: International Partnership for Microbicides; 2020 [cited February 3, 2020]. Available from: <https://www.ipmglobal.org/our-work/our-products/dapivirine-ring>.
- <sup>13</sup> HPTN 084 study demonstrates superiority of injectable cabotegravir to oral FTC/TDF for the prevention of HIV in cisgender women in sub-Saharan Africa. Durham, NC: HIV Prevention Trials Network; 2020 [cited 2020 20 Nov]. Available from: <https://www.hptn.org/news-and-events/announcements/hptn-084-study-demonstrates-superiority-of-injectable-cabotegravir-to>.

- <sup>14</sup> Celum CL, Delany-Moretlwe S, Baeten J, van der Straten A, Hosek S, Bukusi EA, et al. HIV pre-exposure prophylaxis for adolescent girls and young women in Africa: from efficacy trials to delivery. *J Int AIDS Soc.* 2019; 22(Suppl 4): e25298. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6643076/>.
- <sup>15</sup> Celum C, Mgodini N, Bekker L-G, Hosek S, Donnell D, Anderson PL, et al. PrEP adherence and effect of drug level feedback among young African women in HPTN 082. 10th IAS Conference on HIV Science; July 21–24, 2019; Mexico City, Mexico. Available from: <http://programme.ias2019.org/Abstract/Abstract/2328>.
- <sup>16</sup> Gill K, Dietrich J, Gray G, Pidwell T, Kayamba F, Bennie T, et al. Pluspills: an open label, safety and feasibility study of oral pre-exposure prophylaxis (PrEP) in 15–19 year old adolescents in two sites in South Africa. 9th IAS Conference on HIV Science; July 23–26, 2017; Paris, France. Available from: <http://programme.ias2017.org/Abstract/Print/?abstractid=5678>.
- <sup>17</sup> Kyongo JK, Kiragu M, Karuga R, Ochieng C, Ngunjiri A, Wachihi C, et al. How long will they take it? Oral pre-exposure prophylaxis (PrEP) retention for female sex workers, men who have sex with men and young women in a demonstration project in Kenya. 22nd International AIDS Conference; July 23–27, 2018; Amsterdam, the Netherlands. Available: <http://programme.aids2018.org/Abstract/Abstract/8788>.
- <sup>18</sup> Rousseau-Jemwa E, Bekker L-G, Bukusi E, Delaney-Moretlwe S, Omollo V, Travill D, et al. Early persistence of HIV pre-exposure prophylaxis (PrEP) in African adolescent girls and young women (AGYW) from Kenya and South Africa. *AIDS Res Hum Retrovirus.* 2018;34(S1): 68. Available from: <https://onlinelibrary.wiley.com/doi/full/10.1002/jia2.25327>.
- <sup>19</sup> Omollo V, Oduyo J, Travill D, Rousseau E, Kidoguchi L, Bekker L-G, et al. PrEP reinitiation after interruption by adolescent girls and young women in Kenya and South Africa. *J Int AIDS Soc.* 2019;22(S5): 32. <https://onlinelibrary.wiley.com/doi/full/10.1002/jia2.25327>.
- <sup>20</sup> Mannell J, Willan S, Shahmanesh M, Seeley J, Sherr L, Gibbs A. Why interventions to prevent intimate partner violence and HIV have failed young women in southern Africa. *J Int AIDS Soc.* 2019;22(8): 1–6. Available from: <https://onlinelibrary.wiley.com/doi/full/10.1002/jia2.25380>.
- <sup>21</sup> Montgomery ET, Stadler J, Naidoo S, Katz AWK, Laborde N, Garcia M, et al. Reasons for nonadherence to the dapivirine vaginal ring: narrative explanations of objective drug-level results. *AIDS.* 2018;32(11):1517–25. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6230508/>.
- <sup>22</sup> Hartmann M, Palanee-Phillips T, O'Rourke S, Adewume K, Tenza S, Mathebula F, et al. The relationship between vaginal ring use and intimate partner violence and social harms: formative research outcomes from the CHARISMA study in Johannesburg, South Africa [abstract]. *AIDS Care.* 2019; 31(6): 660–6. Available from: <https://pubmed.ncbi.nlm.nih.gov/30309246/>.
- <sup>23</sup> Lanham M, Wilcher R, Montgomery ET, Poole R, Schuler S, Lenzi R, et al. Engaging male partners in women's microbicide use: Evidence from clinical trials and implications for future research and microbicide introduction. *J Int AIDS Soc.* 2014;17(3 Suppl 2): 19159. Available from: <https://onlinelibrary.wiley.com/doi/full/10.7448/IAS.17.3.19159>.

- <sup>24</sup> Ware NC, Wyatt MA, Haberer JE, Baeten JM, Kintu A, Psaros C, et al. What's love got to do with it? Explaining adherence to oral antiretroviral pre-exposure prophylaxis for HIV-serodiscordant couples. *J Acquir Immune Defic Syndr*. 2012;59:463-68. Available from: [https://journals.lww.com/jaids/Fulltext/2012/04150/What\\_s\\_Love\\_Got\\_to\\_Do\\_With\\_It\\_\\_Explaining.6.aspx](https://journals.lww.com/jaids/Fulltext/2012/04150/What_s_Love_Got_to_Do_With_It__Explaining.6.aspx).
- <sup>25</sup> Corneli A, Perry B, Agot K, Ahmed K, Malamatshe F, van Damme L. Facilitators of adherence to the study pill in the FEM-PrEP clinical trial. *PLOS One*. 2015;10(4): e0125458. Available from: <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0125458>.
- <sup>26</sup> Corneli A, Perry B, McKenna K, Agot K, Ahmed K, Taylor J, et al. Participants' explanations for nonadherence in the FEM-PrEP clinical trial. *J Acquir Immune Defic Syndr*. 2016;71(4):452-61. Available from: [https://journals.lww.com/jaids/Fulltext/2016/04010/Participants\\_\\_Explanations\\_for\\_Nonadherence\\_in\\_the.17.aspx](https://journals.lww.com/jaids/Fulltext/2016/04010/Participants__Explanations_for_Nonadherence_in_the.17.aspx).
- <sup>27</sup> Nassuuna I, Bayigga J, Masawi S, Onyango M, Kusemerewa S. Empowering trial participants to use the dapivirine vaginal ring: experience from an open label extension trial in South Western Uganda. *HIV Research for Prevention (HIVR4P)* 2018; October 21–25, 2018; Madrid, Spain. Available from: <https://www.professionalabstracts.com/hivr4p2018/iPlanner/#/presentation/1476>.
- <sup>28</sup> Roberts ST, Nair G, Baeten JM, Palanee-Phillips T, Schwartz K, Reddy K, et al. Impact of male partner involvement on women's adherence to the dapivirine vaginal ring during a Phase III HIV prevention trial. *AIDS Behav*. 2019;24(5): 1432–42. Available from: <https://doi.org/10.1007/s10461-019-02707-1>.
- <sup>29</sup> U.S. Agency for International Development, Dalberg Design, International Partnership for Microbicides. Dapivirine ring design guide: human-centered design research to increase uptake and use. Washington, DC: USAID; 2019 [cited 2020 Aug 20]. Available from: [https://www.usaid.gov/sites/default/files/documents/1864/V15\\_original\\_new.compressed\\_508\\_fixed\\_final.pdf](https://www.usaid.gov/sites/default/files/documents/1864/V15_original_new.compressed_508_fixed_final.pdf).
- <sup>30</sup> Laborde ND, Pleasants E, Reddy K, Atujuna M, Nakyanzi T, Chitukuta M, et al. Impact of the Dapivirine Vaginal Ring on sexual experiences and intimate partnerships of women in an HIV prevention clinical trial: managing ring detection and hot sex. *AIDS Behav*. 2018;22(2): 437–46. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5866044/>.
- <sup>31</sup> Atujuna M, Newman PA, Wallace M, Eluhu M, Rubinam C, Brown B, et al. Contexts of vulnerability and the acceptability of new biomedical HIV prevention technologies among key populations in South Africa. *PLoS One*. 2018;13(2):e0191251. Available from: <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0191251>.
- <sup>32</sup> Govender E, Abdool Karim Q. Understanding women and men's acceptability of current and new HIV prevention technologies in KwaZulu-Natal, South Africa [abstract]. *AIDS Care*. 2018;30(1): 1311–14. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/29914270>.
- <sup>33</sup> World Health Organization. Violence against women: a global health problem of epidemic proportions. June 20, 2013. Available from: [https://www.who.int/mediacentre/news/releases/2013/violence\\_against\\_women\\_20130620/en/](https://www.who.int/mediacentre/news/releases/2013/violence_against_women_20130620/en/).
- <sup>34</sup> Lanham M, Ridgeway K, Stankevitz K, Jenkins S, Pillay D, Murire M, et al. Intimate partner violence as a barrier to uptake of oral pre-exposure prophylaxis for HIV prevention in South Africa. 6th Sexual Violence Research Initiative Forum; October 21–25, 2019; Cape Town, South Africa.

- <sup>35</sup> Cabral A, Baeten JM, Ngure K, Velloza J, Odoyo J, Haberer JE, et al. Intimate partner violence and self-reported pre-exposure prophylaxis interruptions among HIV-negative partners in HIV serodiscordant couples in Kenya and Uganda. *J Acquir Immune Defic Syndr*. 2018;77(2): 154-59. Available from: [https://journals.lww.com/jaids/Fulltext/2018/02010/Intimate\\_Partner\\_Violence\\_and\\_Self\\_Reported.5.aspx](https://journals.lww.com/jaids/Fulltext/2018/02010/Intimate_Partner_Violence_and_Self_Reported.5.aspx).
- <sup>36</sup> Roberts ST, Haberer J, Celum C, Ware NC, Mugo N, 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. Available from: [https://journals.lww.com/jaids/Fulltext/2016/11010/Intimate\\_Partner\\_Violence\\_and\\_Adherence\\_to\\_HIV.12.aspx](https://journals.lww.com/jaids/Fulltext/2016/11010/Intimate_Partner_Violence_and_Adherence_to_HIV.12.aspx).
- <sup>37</sup> Responding to intimate partner violence and sexual violence against women: WHO clinical and policy guidelines. Geneva: World Health Organization; 2013 [cited 2020 Aug 20]. Available from: <https://www.who.int/reproductivehealth/publications/violence/9789241548595/en/>.
- <sup>38</sup> Caring for women subjected to violence: a WHO curriculum for training health-care providers. Geneva: World Health Organization; 2019 [cited 2020 Aug 20]. Available from: <https://www.who.int/reproductivehealth/publications/caring-for-women-subject-to-violence/en/>.
- <sup>39</sup> Health care for women subjected to intimate partner violence or sexual violence: A clinical handbook. Geneva: World Health Organization; 2014 [cited 2020 Aug 20]. Available from: <https://www.who.int/reproductivehealth/publications/violence/vaw-clinical-handbook/en/>.
- <sup>40</sup> World Health Organization. RESPECT women: Preventing violence against women. Geneva: World Health Organization; 2019 [cited 2020 Aug 20]. Available from: <https://www.who.int/reproductivehealth/publications/preventing-vaw-framework-policy-makers/en/>.
- <sup>41</sup> Jhpiego, US Centers for Disease Control and Prevention, World Health Organization. Gender-based violence quality assurance tool. Baltimore, MD: Jhpiego; 2018 [cited 2020 Nov 15]. Available from: <https://www.who.int/reproductivehealth/publications/post-violence-care-in-health-facilities/en/>.
- <sup>42</sup> PEPFAR 2021 country operational plan guidance for all countries. Washington, DC: President's Emergency Plan for AIDS Relief; 2020 [cited 19 Jan 2021]. Available from: <https://www.state.gov/wp-content/uploads/2020/12/PEPFAR-COP21-Guidance-Final.pdf>.
- <sup>43</sup> FHI 360, RTI International. Standard operating procedure and job aid for addressing partner relationships and intimate partner violence in pre-exposure prophylaxis (PrEP) services. Durham (NC): FHI 360; 2020 [cited 2020 Aug 20]. Available from: <https://www.prepwatch.org/resource/sop-job-aid-ipv-prep-services/>.
- <sup>44</sup> Tolley EE, Zissette S, Martinez A, Palanee-Phillips T, Mathebula F, Tenza S, et al. Development and initial validation of a simple tool to screen for partner support or opposition to HIV prevention product use. *PLoS One* (forthcoming).
- <sup>45</sup> Zissette S, Atujuna M, Tolley ET, Okumu E, Auerbach JD, Hodder SL, et al. Cognitive testing of an instrument to evaluate acceptability and use of pre-exposure prophylaxis products among women. *Appl Cogn Psychol*. 2020;34(1):78-84. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7003830/>.

<sup>46</sup> OPTIONS Consortium, EPIC, RISE, CHOICE. HIV Prevention Ambassador training package and toolkit. Durham (NC): FHI 360; 2020 [cited 2020 Nov 15]. Available from: <https://www.prepwatch.org/resource/ambassador-training-package-toolkit/>.

<sup>47</sup> OPTIONS Consortium. OPTIONS HIV Prevention Ambassador training package for adolescent girls and young women. Durham (NC): FHI 360; 2019 [cited 2020 Nov 17]. Available from: <https://www.prepwatch.org/resource/ambassador-training-package/>.

<sup>48</sup> Lanham M, Stankevitz K, Ridgeway K, Mireku M, Nhamo D, Pillay D, et al. Healthcare providers' attitudes and experiences delivering oral PrEP to adolescent girls and young women: Implementation research to inform PrEP rollout in Kenya, South Africa, and Zimbabwe. 10th IAS Conference on HIV Science; July 21-24, 2019; Mexico City, Mexico. Available from: <http://programme.ias2019.org/Abstract/Abstract/1207>.

<sup>49</sup> PEPFAR. Monitoring, evaluation, and reporting indicator reference guide, MER 2.0 (Version 2.4). Washington, DC: PEPFAR; 2019 [cited 2020 Aug 20]. Available from: <https://www.state.gov/wp-content/uploads/2019/10/PEPFAR-MER-Indicator-Reference-Guide-Version-2.4-FY20.pdf>.

<sup>50</sup> USAID Learning Lab. Learning agenda. Washington, DC: USAID.

<sup>51</sup> Montgomery E, Roberts ST, Reddy K, Tolley B, Hartmann M, Wilson E, et al. Impact of the 'CHARISMA' intervention pilot on partner disclosure, IPV, and adherence. 27th Conference on Retroviruses and Opportunistic Infections; March 8-11, 2020; Boston (MA), USA. Available from <https://www.croiconference.org/abstract/impact-of-the-charisma-intervention-pilot-on-partner-disclosure-ipv-and-adherence/>.

