Maximizing Options to Advance Informed Choice for HIV Prevention (MOSAIC) Gender and Youth Strategy

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MOSAIC
Maximizing Options to Advance Informed Choice for HIV Prevention

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Contents

Acknowledgments 3

Acronyms and abbreviations 4

Introduction 5

- Purpose 5
- Project background 5
- Using this document 7

Our vision and guiding principles 8

Operationalizing our commitment to gender integration and meaningful youth engagement 9

- How we work 9

Understanding and responding to the unique needs of AGYW 10

- What works for cisgender AGYW and research gaps 11
- What works for transgender AGYW and research gaps 12

Crosscutting issues: What can be done and what questions remain? 13

Meaningful youth engagement for optimized and sustained impact 21

Closing 21

Annex A. Principles for gender integration and MYE: A foundation for ethical, equitable, and effective access to HIV prevention products 22

Annex B. USAID and PEPFAR guidance 33

Annex C. NextGen Squad terms of reference 35

Annex D. Acting on MOSAIC Principles 41

Annex E. Gender Integration and MYE Tracker 42

Annex F. AGYW, HIV, and PrEP 46

Annex G. Crosscutting issues affecting AGYW access to and use of PrEP 48

Annex H. What do we know about engaging young people in research? 54

Annex I. Monitoring, evaluation, and learning guidance for a user-centered approach 55

References 57

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Acronyms and abbreviations

AGYW	Adolescent girls and young women
AMP	Acting on MOSAIC Principles
CAB	Cabotegravir
DREAMS	Determined, Resilient, Empowered, AIDS-free, Mentored and Safe
GBV	Gender-based violence
HPTN	HIV Prevention Trials Network
IPV	Intimate partner violence
LGBTQ	Lesbian, gay, bisexual, transgender, and queer
LIVES	Listen, inquire, validate, enhance safety, and support
MEL	Monitoring, evaluation, and learning
MOSAIC	Maximizing Options to Advance Informed Choice for HIV Prevention
MTN	Microbicides Trials Network
MYE	Meaningful youth engagement
NGS	NextGen Squad
PBFP	Pregnant and breastfeeding populations
PEP	Post-exposure prophylaxis
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PrEP	Pre-exposure prophylaxis
PZAT	Pangaea Zimbabwe AIDS Trust
RHI	Reproductive Health and HIV Institute
SOP	Standard operating procedure
STI	Sexually transmitted infection
USAID	U.S. Agency for International Development
Trans	Transgender

Introduction

Purpose

Adolescent girls and young women (AGYW) are among the groups most affected by HIV; half of all new cases of HIV in sub-Saharan Africa occur among girls and women ages 15–24. Power imbalances and inequitable social norms based on gender and age help drive young women's susceptibility to HIV. They also impede AGYW's ability to use HIV prevention measures, including pre-exposure prophylaxis (PrEP) products.

Because the lives of AGYW and their use of PrEP are shaped by factors related to both gender and age, the Maximizing Options to Advance Informed Choice for HIV Prevention (MOSAIC) project seeks to apply an intersectional lens to address these overlapping elements of their identities and experiences in one strategy document.[i] This Gender and Youth Strategy offers an analysis of the gender- and age-related barriers faced by — and the opportunities that could be leveraged in collaboration with — potential users of PrEP. It also provides a blueprint for using gender integration and meaningful youth engagement (MYE) strategies to understand, dismantle, and overcome those barriers while taking advantage of the many opportunities that arise when working with this dynamic, vibrant population to meet their own needs.

This document is meant to be used by implementers of the MOSAIC project and may be a useful resource for others implementing HIV research or projects with AGYW or other marginalized populations.

Project background

MOSAIC is a five-year (2021–2026) global project funded by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) through the U.S. Agency for International

Gender integration: Strategies applied in program design, implementation, monitoring, and evaluation to take gender considerations into account and to compensate for gender-based inequalities (Interagency Gender Working Group)[1]

Meaningful youth engagement: An inclusive, intentional, mutually respectful partnership between youth and adults whereby power is shared, respective contributions are valued, and young people's ideas, perspectives, skills, and strengths are integrated into the design and delivery of programs, strategies, policies, funding mechanisms, and organizations that affect their lives and their communities, countries, and the world (USAID Youth In Development Policy 2022 Update)[2]

Intersectionality: An analytical lens that considers and addresses how a person's overlapping identities contribute to experiences of oppression, privilege, and access. Using this lens improves programming by identifying — and strategically addressing — the ways in which inequalities can limit certain people's access to, participation in, and benefit from development interventions (USAID 2023 Gender Equality and Women's Empowerment Policy)[3]

MOSAIC from a youth perspective
"It's all about meeting people where they are (which is exactly where they'll be using prevention products). It's about understanding, meaningfully engaging, and being responsive and accountable to those for whom PrEP products have so much promise."
(Excerpt from MOSAIC blog post, "A project that really wants to know us": implementing a user-centered approach to PrEP product introduction")[4]

[i] While this strategy is focused on factors related to age and gender, many other intersecting factors — such as race, ethnicity, immigration status, class, and education levels — ultimately affect end users' access and experiences, and MOSAIC will be responsive to other factors that must be addressed for equitable, effective HIV prevention programming.

Development (USAID) to help AGYW[ii] and other women[iii] prevent HIV by accelerating introduction and scale-up of new and emerging biomedical prevention products. Our consortium is led by FHI 360 along with core partners Wits Reproductive Health and HIV Institute (Wits RHI), Pangaea Zimbabwe AIDS Trust (PZAT), LVCT Health, Jhpiego, and AVAC. Local partner leadership and engagement, particularly in sub-Saharan Africa, is intrinsic to the project's approach. The work is also supported by technical partners Afton Bloom, Avenir Health, Columbia University, Mann Global Health, RTI International, the University of Pittsburgh, and the University of Washington. Activities are informed by and implemented with the youth advocates who comprise the MOSAIC NextGen Squad (NGS).

Working closely with product developers, MOSAIC advances access to and uptake within a multiproduct market that includes options such as oral PrEP, the dapivirine ring (also called the PrEP ring), and cabotegravir long-acting injectable for PrEP (CAB PrEP). The MOSAIC Consortium works across Botswana, Eswatini, Kenya, Lesotho, Namibia, Nigeria, South Africa, Uganda, Zambia, and Zimbabwe.

The MOSAIC NextGen Squad is a team of paid youth advocates under the age of 30 from Eswatini, Kenya, Lesotho, Namibia, Nigeria, South Africa, Uganda, Zambia, and Zimbabwe. This dynamic group of young people shape and participate in MOSAIC project activities through local partners. They hold MOSAIC accountable to its plans, actions, and monitoring, evaluation, and learning efforts to be responsive to young people's needs, preferences, and lived experiences; be inclusive of the diversity of adolescent girls and young women; and meaningfully engage young people in research and research utilization.

As key staff in gender integration and MYE efforts, the NextGen Squad reviewed the MOSAIC Gender and Youth Strategy and developed their own terms of reference (see Annex C).

MOSAIC has five strategic priorities:

1. Promote a **user-centered approach** in which the needs and preferences of users — especially AGYW — are understood and addressed in product introduction and scale-up.
2. Conduct **research to expand the evidence base** on how to effectively enhance product availability, acceptability, uptake, and effective use.
3. Coordinate and provide technical assistance to global, national, and subnational stakeholders to **expedite product introduction in policy and programs** by addressing issues related to regulatory review, policy development, resource mobilization, supply chain, delivery models and platforms, monitoring and evaluation, surveillance, and demand generation.
4. Implement **research utilization** activities and establish mechanisms for rapid, effective **knowledge exchange** among key stakeholders to facilitate application of existing and emerging evidence on product introduction in policy and programs.
5. **Strengthen and sustain local partner capacity** to advocate for, design, and implement high-quality product introduction activities and research.

[ii] Youth are defined as people ages 10–29 under the USAID Youth in Development Policy 2022 Update.[2] While the age at which young people can access biomedical prevention products differs from country to country, MOSAIC is focused on AGYW ages 15–29.

[iii] MOSAIC end users include cisgender women, transgender women, and nonbinary people and transgender men assigned female at birth; in addition, specific underrepresented groups within these end-user populations include very young adolescents, sex workers, pregnant and breastfeeding individuals, those engaged in transactional sex, and individuals who use drugs.

A commitment to a user-centered approach is one of the project's strategic priorities. PrEP programs that address gender- and age-related barriers while leveraging opportunities are more successful programs. Therefore, we will underpin our end-user focused efforts with two approaches: gender integration and MYE.

Using this document

This Gender and Youth Strategy is organized to provide readers with an understanding of MOSAIC's big picture vision for gender integration and MYE, the evidence base that informs the vision, the staffing and strategies that help MOSAIC move toward this vision, and specific monitoring tools to capture and share progress. We offer more detail on each of these areas in the annexes.

- **Big picture vision**
    - Our overall gender integration and MYE goals are described in "Our vision and guiding principles." The principles summarized in this section are further defined in the full principles document in Annex A.
    - Donor policy documents that informed the vision and principles are summarized in Annex B.
- **Strategies and staffing**
    - Staffing and staff responsibilities that facilitate gender integration and MYE across MOSAIC are described in "Operationalizing our commitment to gender integration and MYE."
    - The terms of reference of the NextGen Squad, key staff in gender integration and MYE efforts, can be found in Annex C.
    - Annex D contains the Acting on MOSAIC Principles (AMP) tool, which is used to measure the alignment of activities with our principles across the MOSAIC project and supports central and country teams to identify where investments may be useful based on opportunities and gaps.
    - The tool used to track gender integration and MYE in our individual activities is available in Annex E. This tracker was developed to support internal management and qualitative data gathering on where and how MOSAIC is making investments in gender integration and MYE. It can also be a resource for qualitative reporting to the project's donor but is not a tool for generating quantitative reports. The tracker allows central and country teams to look across their work plans and (1) document where and how they are investing in gender integration and MYE, including to address opportunities and gaps that they identify using the AMP tool; (2) track progress over time; and (3) reflect on successes, challenges, lessons learned, and best practices.
- **Evidence base**
    - We summarize the evidence that informs MOSAIC's research and research utilization activities in "Understanding and responding to unique needs of AGYW" and Annex F.
    - "What can be done and what questions remain" addresses crosscutting gender issues that affect AGYW's use of prevention products, specifically as they relate to parents', caregivers', male partners', and health care workers' influence on use, as well as the effects of gender-based violence (GBV), transactional sex, and mental health issues. More detailed reviews on each of these issues can be found in Annex G.
    - "Meaningful youth engagement for optimized and sustained impact" is defined in the body of the report, with more details on engaging youth in research in Annex H.

- **Tracking our progress**
    - In addition to the AMP tool and the Gender Integration and MYE Tracker, we also use performance indicators to track progress. These indicators capture participation and staffing by youth and underrepresented groups in MOSAIC. Guidance on the indicators and age- and gender-disaggregated data can be found in Annex I.

Our vision and guiding principles

We envision MOSAIC as a platform for research and research utilization efforts that make a range of biomedical HIV prevention products more accessible to, easier to effectively use by, and more aligned with the lived experiences of individuals and communities with some of the highest HIV incidence rates in the world. Our approach is guided by the principles that direct our process and lead us toward outcomes that are ultimately more sustainable, equitable, and transformative. These principles not only inform how MOSAIC designs and implements programs and research, but also guide how the MOSAIC team and its partners operate and collaborate.

- **Examine and challenge power.** To change the harmful systems and norms that continue to fuel the HIV epidemic, we must examine and challenge power and foster healthy interactions and relationships that enable us to scrutinize, and in some cases disrupt, existing hierarchies and binaries across the socioecological model and within the project itself.
- **Make all labor visible.** To be the change that we want to see more immediately, we must start by valuing and respecting the labor of everyone working to make MOSAIC a successful HIV prevention project.
- **Embrace diverse perspectives.** Ensuring that individuals with diverse perspectives have the opportunity to share them in ways that allow for full, authentic participation helps us acknowledge the complexity of humanity and facilitates our ability to make HIV prevention products responsive to that reality.
- **Prioritize responsiveness to local context.** Although HIV is a global epidemic, addressing it effectively requires understanding and responding to local priorities, preferences, and lived experiences.
- **Center the safety and well-being of those most affected by HIV.** Upholding each person's right to security and well-being creates an enabling environment for HIV prevention that increases the safety and affirms the dignity of people most affected by HIV.

MOSAIC works toward a world where a diversity of AGYW and other women…

…learn about biomedical prevention products in a nonstigmatizing environment where they feel safe and encouraged to ask questions and weigh personal preferences

…can knowledgeably compare a range of products and decide, for themselves, which one best meets their current needs

…are supported by providers, partners, parents, caregivers, friends, and community leaders to take the action that they view as best meeting their HIV prevention needs

…have access to a range of products and can move between products, with support, as their needs, preferences, and experiences change

Because the "how" is as important as the "what," MOSAIC is committed to a process for creating change that is principled, is led by and designed with young people, and acknowledges the lived realities of both those served by the project and those implementing and collaborating with it.

Operationalizing our commitment to gender integration and meaningful youth engagement

The core of our work on gender integration and MYE is organized under MOSAIC Result 1 (User-Centered Approach). However, this work is crosscutting, and our staffing structures underscore this reality.

How we work

Central level: A minimum of five MOSAIC staff members help inform and guide activities at the central level. These staff members work across the other strategic priorities and contribute directly to activities under Results 2–5. In addition to providing guidance centrally, those at the central level:

- Lead monitoring, learning, and evaluation related to gender integration and MYE across the project
- Create and facilitate opportunities to share promising practices across countries
- Backstop country teams
- Convene the global gender and youth team (which consists of all country leads and NextGen Squad members) and the stand-alone NextGen Squad
- Facilitate the annual AMP self-assessment process with central result teams

Country level: In each MOSAIC country, at least one staff person serves as the **gender and youth country lead**. Country leads focus on ensuring gender integration and MYE across all local activities. Many of these leads also serve as focal points for partnership and engagement with civil society and community stakeholders to ensure an integrated approach.

These leads:

- Contribute to global deliverables
- Mentor youth advocates, including NextGen Squad members and advocates from their country youth networks and advisory groups
- Directly engage young stakeholders and underrepresented groups
- Document promising practices in gender integration and MYE for scale-up across countries
- Lead local implementation of activities designed to shift gender norms, increase MYE, and address GBV
- Facilitate the annual AMP self-assessment process with their country teams

In addition to the gender and youth country leads, the MOSAIC team includes **youth advocates.** Most countries have a youth advocate who is a full-time MOSAIC team member and serves as a country representative on the MOSAIC NextGen Squad (see Annex C for their Terms of Reference). Some countries have a second youth advocate who serves as a general member of the NextGen Squad. In addition to their roles on the NextGen Squad, youth advocates also:

- Plan and implement events and campaigns
- Facilitate and support training of AGYW using the HIV Prevention Ambassador Training Package
- Support trained HIV Prevention Ambassadors to set up their own ambassador groups and train peers
- Liaise with stakeholders on healthy lifestyle programs and collaborate to inform the implementation of MOSAIC
- Prepare and make presentations about project activities to community groups, advisory boards, USAID, and broader consortium members

Understanding and responding to the unique needs of AGYW

Many gender-related and age-related barriers influence AGYW's willingness and ability to initiate and effectively use PrEP products.[5–10] These include individual barriers such as limited privacy and autonomy, lack of economic resources, lack of awareness, myths and misconceptions, and self-stigma. AGYW also face barriers to PrEP use that are informed by gender norms and gender- and age-related expectations and power dynamics. These barriers include lack of family and partner support and anticipated and experienced stigma, discrimination, and intimate partner violence (IPV) at the interpersonal and community levels and policies, laws, and access to resources at the societal level. Transgender AGYW experience additional barriers to information and services based on gender identity.[8] As a result, the number of both cisgender and trans AGYW who initiate prevention products is far below the number who could benefit from them.[11–13]

Norms around AGYW and PrEP use

Both globally and in countries where MOSAIC operates, studies have pointed to entrenched gender inequalities and restrictive gender norms around AGYW's sexuality that limit their choices, increase their susceptibility to HIV, and act as a barrier to PrEP uptake.[14–17] A study on PrEP engagement among cisgender AGYW in Eastern Zimbabwe found that young women grappled with the choice between "the social risks of stigmatization or risks of HIV acquisition."[17] Cisgender AGYW were also deterred from PrEP initiation due to community stigma and potential ostracization by being labeled as promiscuous, accused of infidelity, suspected of engaging in transactional sex, or suspected of living with HIV if they took PrEP.[16–21] Young transgender women's ability to prevent HIV — for example, negotiating decisions about sex and PrEP use — is also affected by gender power imbalances and is further complicated by transphobia-fueled violence, stigma, and discrimination in health facilities and rejection from society.[22,23]

While community leaders do not typically engage with AGYW on these topics and they are not preferred sources of information among AGYW, they do influence gender norms and can help to reduce stigma and foster support for AGYW's PrEP use among parents, partners, and health care workers.[16,24] Evidence on interventions that engage with parents, partners, and health care workers — including those that aim to transform harmful gender norms and power imbalances and reduce stigma — can be found in Table 1.

Given the unique experiences and needs of cisgender and transgender AGYW, these two groups are described separately. Annex F provides additional information about the barriers AGYW face to using HIV prevention products and their need for these products.

This section summarizes what we know and what we need to know about how to improve AGYW's access to and use of HIV prevention products. Much of the content comes from a scoping review on interventions that support cisgender and transgender AGYW's interest in, uptake of, and effective use of oral PrEP.[5] Although much of the real-world evidence to date comes from oral PrEP implementation and rollout, evidence from trials of the PrEP ring and CAB PrEP is also referenced where applicable.

What works for cisgender AGYW and research gaps

Oral PrEP uptake and continuation among cisgender AGYW in sub-Saharan Africa have been studied extensively. These studies have shown that comprehensive, youth-focused strategies can improve the effective use of HIV prevention products among this population. Interventions that are designed for youth, especially AGYW, have shown higher rates of success in comparison to interventions that targeted a general audience.[25,26] It is important to acknowledge AGYW's needs in PrEP programming and provide youth-centered support to increase rates of continuation in this population. Addressing holistic needs, using gender integration strategies, and integrating PrEP into other services are also promising approaches.

Effective strategies and remaining questions for cisgender AGYW

Holistic programming

- Recent evidence suggests that a holistic, community-based approach to PrEP program implementation among AGYW might be needed,[27,28] a conclusion also supported by the scoping review.[5]
- Tu'Washinidi, an intervention designed to promote oral PrEP uptake and continuation in the context of GBV and unequal relationship power, was implemented in DREAMS (Determined, Resilient, Empowered, AIDS-free, Mentored and Safe) safe spaces in Kenya.[29] This intervention improved both PrEP initiation and continuation among cisgender AGYW.[30]

Youth focus

- Programmatic layering in youth-focused spaces,[30] which is defined as deploying multiple interventions at the individual and community levels,[31] has been shown to result in the highest continuation rates among cisgender AGYW.[6,32–34]
- Interventions that targeted a more general audience often had lower rates of success among younger participants.[25,26] If an oral PrEP program is not youth-focused, it is important to acknowledge AGYW's needs and provide additional youth-centered support to counter the anticipated lower rates of continuation.

Gender integration

- HIV programs that use well-designed and implemented gender integration strategies have shown improvements in both gender and HIV outcomes among adults. These include improved gender equitable beliefs,[35,36] improved partner communication,[36,37] more equitable decision making and household task sharing,[37,38] and reduced IPV,[35–41] as well as increases in HIV prevention behaviors[35–40] and decreases in HIV incidence.[41] Although gender integration strategies have been applied in PrEP interventions and improved PrEP outcomes among AGYW (Table 1), more comprehensive, multilevel approaches are needed to truly transform power imbalances and inequitable gender norms.

Integration with other services

- Results from included studies found that it is feasible to integrate oral PrEP into a range of settings serving AGYW. For cisgender AGYW, these include settings where other sexual and reproductive health services are offered, such as family planning,[25,42–45] maternal and child health,[46] post-abortion care,[47] DREAMS programming,[32,48] and services for female sex workers.[49] The benefits of providing different service delivery options are evident from study results presented at recent conferences as well as the studies included in a scoping review.[5] For example, in one study from Kenya, AGYW preferred to access PrEP via drop-in-centers designed for sex workers and men who have sex with men over other clinical settings.[50]

Research gaps

Specific research gaps identified in the scoping review[5] include:

- Continuation remains a central challenge and warrants further exploration.[51] More consistent measures of continuation, stopping, and starting and a clearer metric defining success are needed.[52–54]
- Implementation research is needed on how to support AGYW's stopping and starting of PrEP products or moving between products.
- AGYW's lives are complex and reducing their exposure to HIV requires a multi-faceted approach. Research questions should consider that PrEP products should be offered as part of a comprehensive HIV prevention package that addresses the biological, behavioral, and structural needs of AGYW.
- HIV prevention product research can broaden what it measures. Recording outcomes beyond PrEP uptake or continuation (and ultimately HIV acquisition) could help determine whether AGYW are engaging in a range of prevention behaviors (e.g., condom use, less transactional sex, new prevention technology use) resulting from their program exposure, as well as assessing a program's impact on protective assets, such as increased social support networks, self-worth, and partner communication.[54]

What works for transgender AGYW and research gaps

Although the data are sparse, PrEP uptake seems to constitute a more substantive challenge for transgender AGYW than continuation. The scoping review demonstrated better outcomes when a program was responsive to the specific needs of trans AGYW,[5] highlighting the need for interventions tailored according to population. Key population-friendly spaces that offer holistic services are able to attract trans AGYW and support their effective continuation of PrEP.[55] Online apps were not tested extensively in the included studies but are used more frequently with transgender AGYW. Recent efforts seek to understand how specific channels (e.g., WhatsApp, Instagram, Grindr, word of mouth) may attract different segments of the trans AGYW population, including assessing which channels are more likely to identify potential users with a sexually transmitted infection (online apps) or a history of sex work (word of mouth).[56]

Effective strategies and remaining questions for transgender AGYW

While data are limited, each of these approaches show promise:

- Chatbots with transgender personas have been successful in helping trans AGYW understand PrEP and make appointments in Brazil.[57]
- Integration of PrEP for trans AGYW is feasible in existing lesbian, gay, bisexual, transgender, and queer (LGBTQ)-focused spaces in Thailand and the United States,[55,58] public facilities in Kenya and Thailand,[59,60] and new PrEP-focused comprehensive services designed for and implemented by key populations in Thailand.[26]

Research gaps

More data are needed to inform decision-making on investments in PrEP programs and service delivery for trans AGYW.[5] Even less research has been conducted among trans men and nonbinary individuals, leading to limited information on HIV prevention for these populations.

- Two large clinical trials with cisgender women have shown that the PrEP ring reduces HIV risk by about 30 percent.[61,62] Open-label studies and adherence analyses suggest that the chance of acquiring HIV is reduced by about 50 percent or more with consistent use of the ring.[63–65] Research on the PrEP ring to date has only included people who were assigned female at birth, and they were not asked about their gender identity. More research is needed to better understand uptake and continued use of the PrEP ring by trans men and nonbinary people assigned female at birth.
- A safety and efficacy trial found that CAB PrEP was highly effective in preventing HIV acquisition among trans women who have sex with men.[66] Implementation research will be needed to explore CAB PrEP uptake and continuation among trans AGYW in programmatic settings.
- Research is needed to determine what interventions successfully encourage uptake of different PrEP products, the most challenging step in the PrEP cascade for trans AGYW.
- Where transgender-specific research is not possible, efforts are needed to ensure that recruitment strategies, study design, and intervention components are trans-inclusive and that support mechanisms are responsive to the specific needs of trans AGYW.
- Study staff for HIV prevention product research centering cisgender AGYW need training to ensure that they avoid discriminatory behaviors toward trans participants (including misgendering and inappropriate questions) and provide sensitive and competent care (including using gender-affirming language and providing counseling on questions such as hormone interaction that may affect trans participants' decisions about product use).

Crosscutting issues: What can be done and what questions remain?

As described above, AGYW face many gender-related barriers to use of HIV prevention products that often intersect with age-related barriers. Often the same actors, such as parents or male partners, can be either barriers or facilitators of their use. Annex G summarizes what is known about the key crosscutting issues affecting AGYW's potential for exposure to HIV and use of prevention products, including relationships and interactions with parents and caregivers, partners, and health care workers; gender-based violence; transactional sex; and mental health.

Table 1 summarizes what we know about interventions to address these crosscutting issues and how we can incorporate them in prevention product policy, practice, and research.

Table 1. Crosscutting issues: evidence, implications for policy and practice, and questions for further research

Evidence	Implications for policy and practice	Questions for further research
PARENTS AND CAREGIVERS		
The Rethabile Family Caring Programme in Lesotho engages adolescent-caregiver pairs in weekly sessions and home practice activities designed to strengthen their relationships, improve communication, and help them develop strategies for addressing a range of issues, including HIV, violence, substance abuse, stress, depression, and harsh parenting practices. Among AGYW who participated in the program, sexual risk taking decreased, measures of self-efficacy and hope rose, and the ability to discuss sensitive topics with caregivers improved.[67] The Our Family Our Future intervention in South Africa engages adolescent-caregiver pairs in three weekly group sessions, one individualized family session, and take-home activities to prevent HIV, sexually transmitted infections (STIs), and depression among adolescents.[68] In a pilot randomized controlled trial, the intervention showed high acceptability and feasibility; reduced depressive symptoms; increased knowledge, motivation, intentions, and self-efficacy for protective HIV/STI behaviors; and improved family interactions and resilience. An efficacy trial of the intervention is currently ongoing. Data collected during the baseline showed that parents were more supportive of their adolescents using oral PrEP than the adolescents expected.[69] However, PrEP uptake was not measured as the product was not available to trial participants.	• Ensure that regulatory frameworks remove barriers, such as requirements for parental consent, for younger adolescents (under 18) as much as possible. • Encourage the uptake of PrEP-focused parenting materials, such as the Parenting module on PrEP, in DREAMS programs and existing family strengthening programs that aim to improve adolescent-caregiver communication on sexual health. • Strengthen referrals between family strengthening programs and PrEP service delivery points.	• How can parents be allies in supporting AGYW who are interested in PrEP products? • What types of adolescent-caregiver interventions show the most impact on PrEP uptake and effective continuation? • How can parent and caregiver engagement be leveraged to encourage AGYW participation in implementation research?

Evidence	Implications for policy and practice	Questions for further research
MALE PARTNERS		
Research shows that engaging men broadly, and male partners in particular, can have long-term positive effects on the gendered realities that contribute to high HIV prevalence among cisgender adult women in Africa at both the individual and societal levels.[70,71] For example, Stepping Stones, a community training program aimed at improving gender equity in relationships, has increased protective behaviors around sex and HIV.[40] Programs that engage men as clients, partners, and change agents have shown success in improving sexual and reproductive health outcomes and changing normative beliefs for cisgender adults in some countries.[72,73] Research among women and AGYW using oral PrEP or microbicides — including the PrEP ring — found that male partner acceptance of PrEP use and encouragement in the form of social support and medication reminders has a positive influence on use.[74–76] In fact, qualitative studies among male partners of adult ring users highlight that many men have a desire to be involved and support their partners' HIV prevention strategies.[77]	• Design communication and demand creation campaigns in ways that include men as partners of PrEP users and as PrEP users themselves. • Build collaborations with organizations and projects that engage cisgender men who partner with AGYW to promote coordination and gender synchronous work. • Encourage the uptake and use of successful male engagement programs where appropriate within MOSAIC activities and among collaborators. • Provide couples' and group counseling regarding PrEP uptake to dispel PrEP initiation stigma within a relationship and encourage effective use.	• Do ongoing efforts to engage male partners of cisgender AGYW change men's behavior, and if so, how does that affect PrEP use?[78] • How can the engagement of male partners influence the use of prevention products among trans women and trans AGYW? The research on this question is especially limited, particularly in Africa.[79] • What are the best ways to engage male partners as supporters of PrEP use while prioritizing the autonomy of PrEP users?
HEALTH CARE WORKERS		
Health care workers often serve as gatekeepers of biomedical HIV prevention, with their knowledge, attitudes, and beliefs about PrEP influencing their willingness to offer PrEP.[80–82] Research shows that health care worker bias, including moral stances on sexual activity among young unmarried women, often influence clinical guidance, and	• Conduct anti-stigma and discrimination training for all levels of staff in health facilities, including community health workers, receptionists, administrative staff, and guards, to reduce barriers for AGYW to access services. These trainings	• What is the impact of interventions that use a "total facility approach" — such as involving all staff, examining biases and values, and engaging staff to develop their own anti-

Evidence	Implications for policy and practice	Questions for further research
poor treatment of AGYW by clinic staff affects PrEP uptake.[80,83–86] A "total facility approach" of working with health facility staff in Ghana and Tanzania to develop stigma-reduction activities that address HIV stigma at multiple levels (individual client-provider interactions, interactions among staff, and institutional policies, procedures, and communications) and involving employees at all staff levels proved feasible and was well-accepted.[87] The stigma and discrimination reduction training component of the "total facility approach" was adapted to focus on PrEP stigma and AGYW and is being evaluated as part of the PREPARE Project in Pretoria.[80,84] In addition to addressing health care worker bias, effective youth-responsive approaches include creating linkages with community-based approaches that reach AGYW where they are, such as peer ambassadors, PrEP clubs, and mobile clinics;[34,88–91] creating spaces that foster confidence, privacy, and confidentiality, such as safe spaces in DREAMS programming and youth-friendly PrEP clinics;[32,55,83] and integrating PrEP into other services that AGYW readily seek out, such as sexual and reproductive services for cisgender AGYW and LGBTQ-focused spaces for transgender AGYW.[5,55,58]	should build awareness about clinic stigma toward AGYW and how that stigma affects AGYW clients and should encourage reflection on the biases and values underlying staff interactions with AGYW clients. Trainings should culminate in staff building a plan with actionable steps to identify and address biases. Training can be reinforced through job aids, mentorship, supportive supervision, and refresher training. • Create and operationalize guidance on nonjudgmental, confidential, and rights-based approaches to engaging AGYW and other underrepresented populations.	stigma activities — on provider bias and the uptake of PrEP by AGYW? • What is the impact of empathy building exercises, such as Empathways, on provider bias and the uptake of PrEP by AGYW?

Evidence	Implications for policy and practice	Questions for further research
GENDER-BASED VIOLENCE		
Relationships and exposure to GBV can be starting points for conversations about PrEP, particularly in cases where PrEP can support AGYW exposed to GBV.[92] The EMPOWER study investigated combination HIV prevention packages, including PrEP, for AGYW in Tanzania and South Africa. In the PrEP demonstration project, most stakeholders, including clinical staff and AGYW clients, thought GBV screening during HIV testing and prior to the offer of PrEP was acceptable and feasible if the principles of staff confidentiality, empathy, and nonjudgment were followed. However, uptake of referrals remained low.[93] Similarly, Microbicides Trials Network (MTN) 025/HOPE study sites in Malawi, South Africa, Uganda, and Zimbabwe demonstrated that using tailored standard operating procedures (SOPs) to identify and respond to GBV is feasible in PrEP research settings. Staff reported increased training, improved confidence, and more on-site support for vicarious trauma, and leadership reported increased staff skills in GBV response. However, social norms normalizing GBV and limited referral networks were a barrier in providing support to participants.[94] The Tu'Washinidi intervention promoted oral PrEP uptake and continuation among AGYW in Kenya who were at risk of IPV through empowerment-based support clubs, community sensitization meetings for male partners, and couples' PrEP	• Build understanding of the dynamics of IPV and GBV within MOSAIC teams and challenge the normalization of violence within ourselves and the communities where we work. • Adequately assess and address experiences of emotional IPV and its subdomains (verbal IPV and threats). • Engage AGYW through human-centered design processes to understand their GBV response needs and how they prefer to be actively engaged in responding to their peers who have experienced violence, prioritizing the foundational principle of GBV programming to "first, do no harm." • Strengthen the integration of GBV identification and response, including first-line support (for example, LIVES – Listen, Inquire, Validate, Enhance Safety, and Support) and robust referral networks, into PrEP services for AGYW during PrEP initiation and follow-up visits in line with PEPFAR minimum requirements for asking about violence, using tools such as the SOP and job aid for addressing GBV in PrEP services.	• What are the differential effects of various types of IPV on PrEP use (disaggregated by age, sex assigned at birth, and gender identity as well as by PrEP product)? • What strategies are effective for promoting nonviolent, gender-equitable, empowered relationships in adolescence? Do these strategies also affect PrEP use and disclosure among AGYW? • How can researchers improve operational definitions and the safety, ethics, and scientific quality of data collection on violence against adolescents, bearing in mind possible gender and age differences in disclosure and experiences? • What is the client and participant experience when GBV identification and response SOPs are implemented as part of PrEP service delivery?

Evidence	Implications for policy and practice	Questions for further research
education events. This multi-level intervention was implemented in DREAMS safe spaces and improved both PrEP initiation and continuation among cisgender AGYW.[30] The CHARISMA empowerment counseling intervention sought to help women in South Africa use new HIV prevention products by promoting effective partner communication and mitigating the risk of IPV. While the intervention was feasible and acceptable, a randomized controlled trial found that it did not have impacts on PrEP adherence or relationship dynamics over and above that of the standard of care. However, disclosures to male partners were significantly higher among women in the intervention.[95] CHARISMA was adapted into the self-administered CHARISMA Mobile website, which showed high acceptability, usefulness, safety, and confidentiality feedback results during pilot testing.[96] The PrEPARE Project in Pretoria adapted the Young Women's Health CoOP (YWHC) empowerment intervention to include information about PrEP, the importance of PrEP adherence, and sexual and reproductive health. The project aims to increase PrEP readiness, uptake, and adherence and reduce GBV, substance use, and HIV incidence among AGYW.[84] An evaluation of the intervention in ongoing.	• Challenge harmful gender norms that promote masculinity based on violence and control and build healthy relationships skills (e.g., communication and conflict resolution) to encourage partner support for PrEP initiation and continuation and to prevent IPV.	• How can violence response clinical services be used as entry points to PrEP use?

Evidence	Implications for policy and practice	Questions for further research
MENTAL HEALTH		
Research shows a strong association between behaviors that increase potential exposure to HIV and unmet mental health needs.[97–100] Substantial evidence indicates that women, and AGYW in particular, face a higher burden of depression, especially in lower- and middle-income countries.[101–105] Depression can reduce PrEP adherence among adults, and both depression and post-traumatic stress disorder are associated with decreased PrEP adherence among AGYW and other women in the postpartum period.[106] However, research on the association between depressive symptoms and PrEP adherence among AGYW is still limited. Most studies that examined this question suggest that the integration of mental health screening and treatment into PrEP programs may improve PrEP effectiveness among African women; however, more research is needed.[107]	• Integrate mental health screening into PrEP programs. • Establish referral networks to provide mental health and psychosocial support services to participants with depressive symptoms.	• How can mental health and psychosocial support be integrated into HIV prevention services? • What effect does the integration of mental health and psychosocial support into HIV prevention services have on PrEP use among AGYW, particularly for those with depression (disaggregated by age, sex assigned at birth, and gender identity and by PrEP product)?
TRANSACTIONAL SEX		
Some interventions have shown a reduction in transactional sex among AGYW; however, few were specifically designed to address transactional sex[108] and none were designed in the context of PrEP products. The most effective way to address the links between HIV and transactional sex is in combination with HIV prevention and social and economic empowerment programming and not through stand-alone programs on transactional sex.[108]	• Assess the context in which transactional sex occurs (see questions in the next column). • In contexts where transactional sex increases cisgender or transgender AGYWs' likelihood of acquiring HIV, ensure AGYW can access PrEP products within an HIV combination prevention package.	Assess the context with the following questions: • What is the prevalence of transactional sex in this context (among cisgender AGYW, among transgender AGYW)? • What are the specific motivations for engaging in transactional sex (including gender norms and expectations)?

Evidence	Implications for policy and practice	Questions for further research
Evaluation results from the DREAMS partnership in Kenya show that school support reduced the likelihood of engaging in transactional sex among adolescent girls, and a package of school support, youth entrepreneurship, and social support programs (e.g., parenting, male partner, GBV prevention) reduced the likelihood of engaging in transactional sex among young women.[109]	• Address the multiple, interrelated motivations for transactional sex in HIV combination prevention programs. • Encourage critical reflection on gender norms and power dynamics as they relate to transactional sex and HIV prevention, including recognizing the power and agency of AGYW, promoting gender-equitable relationships, and building positive gender norms around love and care. • Integrate messaging about transactional sex related to relationship dynamics and short- and long-term aspirations and costs in interpersonal communication (e.g., help AGYW reframe their long-term aspirations toward self-reliance).	• How do cisgender and transgender AGYW see themselves in these relationships (i.e., how do they perceive their level of power or agency)? • Under what conditions do these relationships increase the likelihood of acquiring HIV (among cisgender AGYW, among transgender AGYW)?

The MOSAIC project has begun to address many of the policy and practice implications and research gaps identified in Table 1. The following box outlines a few examples of gender integration activities across the result areas of MOSAIC.

Illustrative gender integration activities under MOSAIC

- **User-centered approach:** Engage AGYW through human-centered design processes to explore the acceptability and feasibility of a post-exposure prophylaxis (PEP) to PrEP resource package.
- **Research:** Analyze the effects of various types of IPV on PrEP use patterns in the CATALYST study.
- **Policy and programs:** Analyze existing PrEP policies around pregnant and breastfeeding populations (PBFP) and create tools to support countries to advocate for the inclusion of PrEP in national policies for PBFP.
- **Demand generation:** Update and roll out tools such as the HIV Prevention Ambassador Training Package and Empathways for underrepresented populations.
- **Local partner capacity:** Train local partners on concepts related to gender, gender integration, and power dynamics based on their capacity assessments.

Meaningful youth engagement for optimized and sustained impact

In the same way that we must be systematic and intentional in countering the effects of harmful gender norms, we must also acknowledge that young people have been sidelined and denied the opportunity to be the architects of their own futures. Based on intersecting stigmas, this is especially true for AGYW, who deal with the double burden of being young and female (and, for some, young and transgender).

Thus, all efforts to address gender-related barriers and leverage opportunities for change among cisgender and transgender AGYW will be improved by employing MYE. According to the USAID Youth In Development Policy 2022 Update,[2] MYE can be defined as,"… an inclusive, intentional, mutually respectful partnership between youth and adults whereby power is shared, respective contributions are valued, and young people's ideas, perspectives, skills, and strengths are integrated into the design and delivery of programs, strategies, policies, funding mechanisms, and organizations that affect their lives and their communities, countries, and the world." The Global Consensus Statement on Meaningful Adolescent and Youth Engagement adds that "meaningful adolescent and youth engagement recognizes and changes the power structures that prevent young people from being considered experts regarding their own needs and priorities, while also building their leadership capacities."[110]

Youth engagement can also be referred to as youth involvement, youth participation, youth voice, and youth in governance. The evidence on how to engage young people in research is described in Annex H. The ways in which the NextGen Squad is integrated in the design and implementation of MOSAIC activities both locally and globally is described in Annex C, and performance indicators to capture participation and staffing by young people in MOSAIC are listed in Annex I.

Closing

The MOSAIC Gender and Youth Strategy will be a core component of all Result 1 activities and will inform all other activities throughout MOSAIC's operation. Efforts to disseminate and sensitize all MOSAIC consortium members and result leads on the strategy will begin in Quarter 1 of 2023, but refresher training on the strategy and continued reviews of the strategy to determine areas for growth will occur throughout the life of the project.

We believe that this ambitious strategy will not only influence how MOSAIC operates but also strengthen the impact of MOSAIC research and research utilization activities. By following the approaches, and particularly the principles, outlined in this strategy, MOSAIC will ensure that the project's thought leadership on a combined approach to gender integration and MYE will ultimately influence the broader field of HIV research and programming, helping move the needle toward gender equity and young people's determination of their own destinies.

Annex A. Principles for gender integration and MYE: A foundation for ethical, equitable, and effective access to HIV prevention products

Introduction

In support of the overall vision for MOSAIC, we have developed a set of principles that will guide the project and inspire action across the HIV prevention field. These principles are the foundation of — and will support progress toward — an ethical, equitable, and effective project that generates and uses research to improve access to HIV prevention products through a commitment to gender equity and meaningful youth engagement (MYE).[iv] These principles not only inform how MOSAIC designs and implements programs and research, but also guide how the MOSAIC team and its partners operate and collaborate. Each of these intersecting principles helps us articulate, develop, and be accountable for using approaches that prioritize transparent interactions and sustainable collaborations and systems.

Underpinning these principles is a commitment to Good Participatory Practice[111] and the belief that facilitating equitable access to high-quality, stigma-free, comprehensive HIV prevention services is part of promoting and protecting human rights — particularly the right to health. The principles also align with taking a trauma-informed[v] approach to interacting with marginalized communities. They recognize that the "Nothing about us without us" philosophy is what makes HIV programs effective, in part by shining a light on the need to challenge the underlying power dynamics that fuel the HIV epidemic.

Understanding these principles will help all of MOSAIC — its implementers, government partners, service delivery personnel and institutions, donors, advocates, and civil society organizations — identify existing strengths and areas for growth. Operationalizing these principles will be an ongoing component of the project, based in self-assessment via the Acting on MOSAIC Principles (AMP) tool to identify and track areas for organizational growth among all MOSAIC partners.

Principles

1. Examine and challenge power.
2. Make all labor visible.
3. Embrace diverse perspectives shared in authentic voices.
4. Prioritize responsiveness to local context, preferences, and lived experiences.
5. Center the safety and well-being of individuals and communities most affected by HIV.

For each of the MOSAIC principles, we state **why the principle is important**, with links to useful references, and **what it means** in the context of MOSAIC. We also describe the **truths underlying** each principle. These truths are the building blocks that will help MOSAIC operate according to each principle. They are directly referenced in the annual AMP tool that each country team and central result team will use to support the operationalization of the principles.

[iv] While these principles emphasize youth engagement and gender integration, many other intersecting factors — such as race, ethnicity, immigration status, class, education levels — ultimately affect end users' access and experiences, and MOSAIC is committed to being responsive to other factors that must be addressed for equitable and effective HIV prevention programming.

[v] Trauma-informed care calls for a change in organizational culture to emphasize understanding, respecting, and appropriately responding to the effects of trauma at all levels.[112]

1. Examine and challenge power

Full principle	To change the harmful systems and norms that created and fuel the HIV epidemic, we must examine and challenge power and foster healthy interactions and relationships that enable us to scrutinize, and in some cases disrupt, existing hierarchies and binaries across the socioecological model and within the project itself.
Why is this important?	Power is often defined as having control, authority, or influence over others ("power over") or the ability to achieve one's goals ("power to").[113] It can also refer to control over resources — such as finances, knowledge, information, time, and attention. When power is not examined or challenged, the outcomes created by unequal distribution of power cannot be interrogated or altered.[114] Unequal distribution of power often occurs within and helps to maintain hierarchies. Hierarchies are systems in which people or groups are ranked one above the other according to status or authority. Although hierarchies can be important (e.g., advanced levels of clinical training allow some health care workers to safely perform a specific medical procedure), they can also be used to reinforce and validate systems where the traditionally well-resourced and powerful are considered worthy of regard while others, and their opinions, are considered to have limited value. For example, a Ministry of Health official may decide to encourage men to come to reproductive health clinics by prioritizing couples, thereby making single women wait longer. Or an adult leader of a youth group may decide where to convene young people without input from youth themselves, leading to meeting locations that young women cannot access safely during evenings. In each of these cases, the belief that a more powerful person knows best results in an approach that does not meet the real needs of those who are meant to benefit. Binaries, which often contain and hide hierarchies, can play the same role.[115] Binaries often distinguish between those with more and those with less power, thereby deciding whose voice matters and whose does not. They can also force individuals to choose from two options that either lack nuance or simply do not fit, potentially leaving out entire populations who may benefit from HIV prevention research and programs. For example, the pervasive gender binary (male/female) is a specific construct that assumes each person's gender is "apparent at birth, stable over time, salient and meaningful to the self, and a powerful predictor of a host of psychological variables."[116] The fact that these assumptions are often untrue does not prevent this binary from dictating many social and legal outcomes (e.g., who can inherit, who can marry, who is given parental leave after birth) and identifying those who do not fit within the binary as "other."[117] Examining and challenging power, including the hierarchies and binaries that reflect and support it, is critical to the success of MOSAIC because concentrated, unequal power is a root cause of the HIV epidemic that perpetuates the conditions that result in a disproportionate burden of HIV among those with less power.[118] Challenging power within our own operations and the systems that we work in will contribute to a broader shift in how power is used and who has access to that power, allowing MOSAIC to lead by example.

Demonstrating a commitment to this principle	Examining power means analyzing how a system is designed, by whom, and for whom the system works and does not work. To challenge power means to expose imbalances of power by explicitly addressing them and trying to re-balance the system in a way that acknowledges each person's right to the resources and freedoms they need to survive and thrive. In our efforts to examine and challenge power, it is crucial that we all work to understand and amplify the voices of those with less power, regardless of context. This work involves having difficult, and often uncomfortable, conversations. (It is important to recognize that unsafe and uncomfortable conversation are distinct from one another; proactively creating conversation ground rules to avoid making those with less power feel unsafe is an important first step.) Rethinking hierarchies and binaries ensures that we do not simply go along with past constructs because they exist. Instead, we must question the purpose these constructs serve and be mindful of the negative consequences they may engender, working to take corrective action whenever possible. Even when hierarchies and binaries play a valuable role, they should not keep us from valuing the unique contributions that come from diverse perspectives, which will all be important if we are to respond effectively to the complexities of real life.
Underlying truths	• Understanding existing power dynamics and their contributions to inequality is the first step toward changing them. • Pushing back on power in its current distribution, including by rethinking hierarchies/binaries, is part of addressing the inequities that created the HIV epidemic. • Changing culture to allow for difficult conversations and shifts in power is an important step. • Continually asking ourselves questions about our actions will enable us to realign them toward challenging power. • Choice, collaboration, and empowerment are key aspects of a trauma-informed approach, and all require challenging power.

2. Make all labor visible

Full principle	Larger systems change takes time. To be the change that we want to see more immediately, we must start by focusing on areas within our control, including how we value and respect the labor of everyone working to make MOSAIC a successful HIV prevention project.
Why is this important?	One way in which hierarchies and binaries function in a workplace setting is that the labor of those in the nonprivileged groups is often unacknowledged or undervalued. Considering research specifically, beliefs regarding what should be counted as knowledge (for example, the work of scientists, versus the efforts of those, such as community health workers, with less education but potentially more lived experience) reflect hierarchies. Hierarchies regarding what is valuable are also passed on through the types of products most valued: peer-reviewed journal articles published, grants awarded, and leadership positions achieved. Not only are these types of labor traditionally performed by cisgender men, older, wealthier, and more educated individuals, and those who are members of dominant religious/racial/ethnic groups — reinforcing ideas about who contributes — but they are also only one component of a much larger whole (i.e., a research study that required thousands of participants, hundreds of staff, and dozens of analysts). Elevating these types of labor alone erases others' efforts that ultimately contribute to these more visible products but are also of value in and of themselves. Other forms of labor are equally or more important to setting up healthy and productive societies. For example, emotional labor,[vi] which is disproportionately taken up by cisgender women and people of color,[vii] is rarely officially recognized or compensated but allows for the large-scale cooperation necessary for effective collaboration and is particularly important during periods of stress and uncertainty, such as the COVID-19 pandemic.[119] This type of labor is all the more important in a project designed to support those made vulnerable to HIV and other negative outcomes by societal norms and structures, in which being witness to and responding appropriately when faced with trauma and other difficult lived experiences is part of everyday work.
Demonstrating a commitment to this principle	Making labor visible means that while we work to change access to positions that have long been seen as powerful (e.g., principal researcher, manager, doctor), we simultaneously acknowledge that any work done by individuals in these positions is dependent on the equally vital labor of many others. By making all forms of labor visible — be it mentorship, effective note-taking, serving as a sounding board, strong copy editing, supportive supervision, setting up and breaking down for events, or custodial duties — we start a conversation about who is contributing and widen our understanding (while better aligning it to reality) of the kinds of skills and tasks necessary for a world in which everyone can thrive.

[vi] Emotional labor is defined by the Oxford Dictionary as "the mental activity required to manage or perform the routine tasks necessary for maintaining relationships and ensuring smooth running of a household or process."
[vii] Research on the disproportionate burden of emotional labor did not include a review of transgender or nonbinary persons.

	Making all labor visible also means the diversity of people with important additions to conversations on collective health and wellness — including those who may have less formal education, such as community health care workers, advocates, and end users — also have the opportunity to raise and amplify their voices in research design, policy creation, and the planning and implementation of demand generation activities. On the level of personal interaction and organizational functioning, making labor visible also applies to emotional labor. Acknowledging and systematically sharing the work of emotional labor prevents those who are de facto "human givers" (generally those socialized to see their contributions to society as support to others) from always taking on this generally unpaid role.[120] Making labor visible also entails checking in and caring for ourselves, and building structures that allow for this care, when our labors become overwhelming. Burnout is currently a public health crisis and has caused widespread resignations across the health sector. Acknowledging and protecting boundaries to respect well-being — for example, considering mental health and work/life balance as we set timetables for production — allows each of us to operate in a way that more fully acknowledges our humanity, our colleagues' humanity, and the humanity of those MOSAIC serves, lessening risks of burnout and improving collaboration and morale.
Underlying truths	• Emotional labor is labor. • Making all labor visible is the first step toward making all labor valued. • Burnout prevention is part of acknowledging labor.

3. Embrace diverse perspectives shared in authentic voices

Full principle	Ensuring that individuals with diverse perspectives are at the table and have the opportunity to share in ways that allow for full, authentic participation helps us acknowledge the complexity of humanity and facilitates our ability to make HIV prevention products responsive to that reality.
Why is this important?	Embracing multiple perspectives and forms of knowledge, particularly from people and groups led by and based in communities most directly affected by HIV,[viii] also allows us to "gain better, more detailed, more accurate, and ultimately more truthful knowledge."[115] For example, strong public calls for access to the ring to meet the needs of cisgender adolescent girls, young women, and other women in Africa allow conversations on U.S. President's Emergency Plan for AIDS Relief (PEPFAR) support for this product to reflect real end users' priorities, not only the evidence weighed by American institutions for American women. Notably, international advocates have also called attention to the U.S. Food and Drug Administration's historic failures to consider Black American women's unique needs. Documenting and synthesizing multiple

[viii] See note (iii) on populations that will be the focus of MOSAIC.

	perspectives, including practice-based knowledge,[ix] can generate more holistic and nuanced learning and prompt action in programs and policies. In addition, a greater diversity of authors in peer-reviewed literature is shown to increase the impact of publications.[122] Embracing diverse perspectives is about not only who is allowed at the table, but also what and how they can share and still be considered "contributors." The gendered, ageist, and false binary between emotion and reason typically associates reason with masculinity and older individuals and emotion with femininity and youth.[123] In an attempt to be "objective" or "neutral," we may try to remove emotion from our work. However, emotion is part of the human experience that shapes how we interact with the world, including why and how we do the work that we do. Valuing and elevating emotion allows us to recognize people as "living, feeling bodies in the world"[115] and is especially pertinent to this body of work. Truly opening space to new presences and new ideas about what is valuable requires each of us to check our own beliefs and perceptions. Although we may strive for "objectivity," particularly in research, the reality is that the decisions we make and the evidence and knowledge products we produce are shaped by our own perspectives, culture, and context.[123] For example, we may believe that data are objective; however, research is conducted by individuals, and individuals make choices at each step of the research process that can reinforce their own perspectives and affect research outcomes and their utilization.[124] In addition, our interpretations of "objective" quantitative measures evolve over time; for example, there are current questions as to whether tenofovir-diphosphate (TDF) levels of 700 fmol/punch, estimated to be equivalent to greater than or equal to four pills per week, consistently demonstrate this level of product use.[125] Examining and disclosing how our own perspectives inform the decisions we make and where questions remain about our interpretations are important steps toward transparency.
Demonstrating a commitment to this principle	Embracing diverse perspectives means generating and communicating research findings and all other information in a way that acknowledges the humanity and human experiences of the diverse individuals involved. It also means interpreting findings that are "objective" through the lens of individual users' holistic experience of pre-exposure prophylaxis (PrEP) use; for example, moving beyond dried blood spot TDF levels as the last word in adherence and instead describing not only the quantitative data but also how users felt about themselves during the process and how their adherence levels affected their lives and vice versa. It also means ensuring that those with diverse perspectives get the opportunity to have those perspectives documented and synthesized in products made widely available and

[ix] "Practice-based knowledge is the cumulative knowledge and learning acquired by practitioners through designing and implementing programmes in different contexts — including insights gained from observations, conversations, direct experiences and monitoring."[121]

	used to inform conversations. This requires efforts to build inclusive infrastructure, such as offering interpretation at meetings and building our own skills to work successfully with interpreters and translators to improve communication for all.
Underlying truths	• More voices, representative of greater diversity (with a focus on end users and their communities), supported to participate fully at the table leads to more effective programming and research that asks the right questions. • Creating space for authentic voices, including by being transparent in decision-making, facilitates meaningful contributions. • More types of data, including qualitative data, and knowledge products create a more complete picture that is easier for many to articulate. • Recognizing biases toward our own preferred data sources creates opportunities to learn and grow together and come closer to effective solutions.

4. Prioritize responsiveness to local context, preferences, and lived experiences

Full principle	Although HIV is a global epidemic, addressing it effectively requires understanding and responding to local context, particularly local priorities, preferences, and lived experiences.
Why is this important?	When we consider context, we avoid creating interventions or presenting data points that exist outside of the reality of people's lived experiences and the larger culture/systems in which those interventions are implemented or from which data points arise.[115] Building context into what we do means acknowledging the lived experiences, preferences, and priorities of the communities the project is meant to serve as well as the systems in which those individuals exist *and* the culture and systems in which the research team exists (see Principle 3). The types of contextual understanding that elevate lived experiences encompass not only the legal structures, political tensions, economic realities, religious beliefs, health systems, gender norms, and other aspects of a specific place. They also describe, using the insights of end users, advocates, and implementers, how those aspects together create the realities to which individuals, and programs designed to meet their needs, must be responsive. Without this step, specific decisions could be made that are logical on paper but not responsive to real needs among users or that do not acknowledge end users in the messy complexity that is part of being human. For example, AGYW have needs and aspirations for healthy sexual relationships; incorporating pleasure in sexual health programs, such as affirming human sexuality and the reasons why people have sex, has been shown to have positive effects on sexual health knowledge and attitudes and safer sex practices.[126]
Demonstrating a commitment to this principle	Being responsive to local context, preferences, and lived experiences means working to make more choices available. No two people are the same, and no one person remains static over time. More choices create an opportunity for more responsiveness; working to provide access to more choices respects and responds to the diversity of end users' needs. This principle also means we need to acknowledge that context and personal preferences are important elements of choice and product use that must be considered

	valuable to product introduction. Components of end users lives that they themselves may struggle to talk about due to stigma — such as drug use, gender-based violence (GBV), and sexual desire and pleasure — are all the more important to engage with as a project seeking to respond to end users' realities. This principle demands that we constantly ask ourselves whether our research designs are responsive to local context and if our findings are presented in context or could easily be misinterpreted. For example, the statement "young women's continuation rates of oral PrEP are significantly lower than those of their older peers," is easy to take out of context. One could extrapolate that young women are disinterested in their health or simply unreliable partners in their own health. When we collect and generate data, we must help the end user frame the data in the context from which it was generated. This approach leads to knowledge products that ask the reader to acknowledge the bigger systems at play, such as, "Young women's continuation rates of oral PrEP are significantly lower than those of their older peers in interventions that do not include asset building and tailored support that takes into account their disproportionate burden of stigma for PrEP use and partnerships compared to those 5+ years older."
Underlying truths	• Defining priorities locally and using local priorities to make choices is an effective approach to epidemic control. • Preferences, including preferences for pleasure and intimacy, matter. • Choice is an important part of responsiveness to local lived experiences, which will always be diverse. • Responsiveness to lived experiences requires acknowledging that many factors — including enabling environment, substance use, mental health, and violence — shape HIV prevention product use and can and should be addressed. • Narratives on "what works" and what does not should be framed in context, especially when talking about stigmatized groups.

5. Center the safety and well-being of individuals and communities most affected by HIV

Full principle	Everyone has the right to security and well-being,[127] and upholding these rights creates an enabling environment for HIV prevention that increases the safety of and affirms the dignity of people most affected by HIV.
Why is this important?	In research and health care, the principle of "do no harm" is one of the most foundational. For example, researchers have an ethical obligation to minimize participants' exposure to harm,[x] considering both their physical and mental health, and maximize their benefits throughout the study process.[128] This process includes study design and informed consent procedures, as well as the introduction of mechanisms to monitor for unintended consequences.

[x] In this document, harm is defined as any negative consequences — social, physical, economic, or otherwise — experienced by MOSAIC partners, collaborators, and research participants. More specific definitions of harm may be utilized in research studies to ensure that preventive measures and documentation are appropriate.

	However, unintended consequences can occur regardless of intention. Lessons from oral PrEP rollout have demonstrated that research, policy, and program decisions, such as providing oral PrEP to key populations only, can, for example, reinforce or even increase stigma against a product and the people who use it.[129] In turn, individual-level beliefs and perceptions, provider bias, and community-level stigma and norms affect the uptake and continued use of oral PrEP.[130] Safe, consistent use of PrEP can also be affected by harmful gender norms and power imbalances at the relationship level.[131] For example, in some settings, male partners feel threatened by their female partners having access to an HIV prevention product they can use autonomously, and a PrEP program could unintentionally increase relationship tension and the risk of intimate partner violence (IPV).[132] In addition, the possibility of IPV arising from a controlling partner who associates PrEP with infidelity affects the willingness of some users to disclose PrEP use and, ultimately, to use PrEP consistently or at all.[133] Project activities — particularly those promoting gender equality — may also face resistance at the institutional and community levels. Such resistance can range from passive forms, such as omitting the experiences of transgender and nonbinary people in HIV prevention or denying that HIV is an issue for AGYW, to more active forms, such as supporting a project activity but covertly attempting to undermine it or using violence to suppress activities or people.[134] Because of the potential for harm, questioning whether each potential action may cause harm as well as monitoring for unintended consequences is central to a rights-based and ethical prevention product project. The information gathered should be used to determine the path forward, including establishing protocols that guide violence prevention and response.
Demonstrating a commitment to this principle	As new HIV prevention products are introduced, research, program, and policy activities should take special care to reduce the potential for harm, including stigma, discrimination, violence, and other social harms. In practice, this means: 1. Training all those who will assist clients or research participants directly to ask about violence (as part of routine enquiry in the case of PrEP services) and provide first-line support (for example, LIVES – Listen, Inquire, Validate, Enhance Safety, and Support)[135] as needed. 2. Training all those who will assist clients or research participants to examine their own biases and beliefs and provide services in a way that does not penalize clients who do not conform to those beliefs 3. Assessing potential risks to safety and well-being as part of all research and programming and using this information to make “go” or “no go” decisions where safety is the priority — for example, making a “no go” decision if the potential harms outweigh the benefits. 4. If a “go” decision is made: a. Developing strategies to prevent, mitigate, and respond to the identified risks; for example, in a male engagement program, building partnerships with community leaders, addressing the concerns of

	male partners, informing female partners of potential risks, training or counseling partners to build healthy relationship skills, and establishing mechanisms to identify and respond to IPV b. Continuously monitoring for and adjusting in the face of unintended consequences
Underlying truths	• Stigma/discrimination must be addressed so individuals can safely show up as their whole selves and be respected as such. • Vicarious trauma must be prevented and proactively addressed. • Traumatic experiences are widespread among project staff, partners, and participants, and project planning should proactively reduce the possibility of re-traumatization and support resilience and well-being. • Avoiding harm should be a guiding light that is prioritized above other objectives. In some cases, this may mean that activities are reshaped or stopped completely; in all cases, unintended consequences must be monitored.

Glossary

Enabling environment	Youth are surrounded by an environment that maximizes their assets, agency, access to services and opportunities, and ability to avoid risks, while promoting their social and emotional competence to thrive (USAID Youth In Development Policy 2022 Update).[2]
Economic violence	Acts such as controlling finances; stealing money; or restricting, exploiting, or sabotaging access to other resources, such as housing, food, property, employment, and transportation.
Emotional violence	Acts such as constantly belittling, humiliating, or undermining an individual's sense of self-worth/self-esteem; other "controlling" behaviors, such as restricting a person's mobility and/or access to family, friends, information, or services.
Gender	A culturally defined set of economic, social, and political roles, responsibilities, rights, entitlements, and obligations associated with being female or male, as well as the power relations between and among women and men, and boys and girls. The definition and expectations of what it means to be a woman or girl and a man or boy, and sanctions for not adhering to those expectations, vary across cultures and over time and often intersect with other factors such as race, class, age, and sexual orientation. Transgender individuals, whether they identify as men or women, are subject to the same set of expectations and sanctions (Interagency Gender Working Group).[1]
Gender-based violence (GBV)	Violence that is directed at an individual based on their biological sex, gender identity (e.g., transgender), or behaviors that are not in line with social expectations of what it means to be a man, woman, boy, or girl (e.g., men who have sex with men, female sex workers). GBV includes physical, sexual, and psychological abuse, threats, coercion, arbitrary deprivation of liberty, and economic deprivation, whether occurring in public or private life (FY 2014: PEPFAR Updated Gender Strategy).[136]
Gender equality	Concerns women and men as well as gender and sexual minorities. Equality involves working with all genders, including men and boys, and women and girls, to bring about changes in attitudes, behaviors, roles, and responsibilities in homes, workplaces, and

	communities. Genuine equality means more than parity in numbers or laws on the books; it means expanding freedoms and improving overall quality of life so that equality is achieved for all genders (USAID Youth In Development Policy 2022 Update).[2]
Gender identity	A person's deeply held sense of self and what they call themselves, including woman, man, or gender diverse (USAID 2023 Gender Equality and Women's Empowerment Policy).[3]
Gender integration	Strategies applied in programmatic design, implementation, monitoring, and evaluation to take gender considerations into account and to compensate for gender-based inequalities (Interagency Gender Working Group).[1]
Gender synchronization	An approach to gender integration that involves working with men and women, and boys and girls, in an intentional and mutually reinforcing manner to overcome inequalities, promote gender-equitable attitudes and behaviors, and promote positive outcomes.
Gender-transformative interventions	These interventions seek to transform gender relations to promote gender equity by fostering critical examination of inequalities and gender roles and norms; recognizing and strengthening positive norms that support equality and an enabling environment; promoting the relative position of women, girls, and marginalized groups; and transforming the underlying structures and policies that perpetuate gender inequity (Interagency Gender Working Group Gender Integration Continuum).[137]
Inclusion	Specific measures are in place to support the participation of youth who may face greater discrimination and barriers to their full participation. There is a clear understanding of why youth may be marginalized, excluded, and silenced in the first place. Negative/harmful attitudes are addressed at both a societal and an individual level (USAID Youth In Development Policy 2022 Update).[2]
Intimate partner violence (IPV)	Any behavior by a current or former intimate partner within the context of marriage, cohabitation, or any other formal or informal union that causes physical, sexual, or psychological harm (Violence Against Women Prevalence Estimates, 2018).[138]
Meaningful youth engagement (MYE)	An inclusive, intentional, mutually respectful partnership between youth and adults whereby power is shared, respective contributions are valued, and young people's ideas, perspectives, skills, and strengths are integrated into the design and delivery of programs, strategies, policies, funding mechanisms, and organizations that affect their lives and their communities, countries, and the world (USAID Youth In Development Policy 2022 Update).[2]
Physical violence	Any act that causes physical harm as a result of unlawful physical force (e.g., acts of physical aggression, such as slapping, hitting, kicking, and beating).
Sex	The designation of a person as male, female, or intersex based on a cluster of anatomical and physiological traits known as sex characteristics (USAID 2023 Gender Equality and Women's Empowerment Policy).[3]
Sexual violence	Any act of sexual aggression or coercion, including forced intercourse, attempt to obtain a sexual act, and unwanted sexual comments or advances.
Youth	Defined as ages 10-29 (USAID Youth In Development Policy 2022 Update) [2] While the age at which young people can access biomedical prevention products differs from country to country, MOSAIC is focused on AGYW ages 15–29.

Annex B. USAID and PEPFAR guidance

MOSAIC aligns with the five strategic pillars and three enablers in the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) Five-Year Strategy.[139] Through the MOSAIC Gender and Youth Strategy, the project promotes health equity for priority populations (Strategic Pillar 1).

Strategic Pillar 1: Health Equity for Priority Populations[139]

PEPFAR will remain deeply committed to ensure all ages, genders, and population groups at risk for infection know their HIV status, receive life-saving HIV prevention and treatment services, and are virally suppressed if they are living with HIV. […] For HIV/AIDS (which mirrors many other global health threats because HIV/AIDS thrives amongst the most marginalized populations) — the largest global prevention and treatment gaps remain in adolescent girls and young women, children, and key populations. Addressing inequities in these populations will also have impact on new infections. Countries must know and close their inequity gaps.

- **Focus Area 1:** Advancing gender-equitable programming
- **Focus Area 2:** Launching a youth-focused movement to prevent HIV acquisition for the next generation
- **Focus Area 3:** Leading the global movement to end AIDS in children
- **Focus Area 4:** Transforming key population service delivery through key population leadership
- **Focus Area 5:** Doubling down on a holistic combination prevention approach
- **Focus Area 6:** Dismantling structural barriers to HIV/AIDS care

MOSAICS's approach to gender integration is also aligned with and informed by the focus on gender equality as an aspect of the Human Rights Action Agenda of PEPFAR 3.0,[140] as well as the PEPFAR Gender Strategy.[136] It is also in line with the U.S. Agency for International Development (USAID) 2023 Gender Equality and Women's Empowerment Policy[3] and the U.S. Strategy to Prevent and Respond to Gender-based Violence,[141] which both globally put forward principles, such as "do no harm," that shape the MOSAIC approach to addressing gender-based violence (GBV).

Objectives of USAID's 2023 Gender Equality and Women's Empowerment Policy [3]

- Reduce gender disparities in who accesses, controls, and benefits from economic, social, political, legal, educational, health, and cultural resources, as well as wealth, opportunities, and services.
- Strive to eliminate gender-based violence and mitigate its harmful effects on individuals and communities, so all people can live free from violence.
- Increase the capability of women and girls to fully exercise their rights, determine their life outcomes, assume leadership roles, and influence decision-making in households, communities, and societies.
- Advance structural changes that address the root causes of gender inequality and promote equitable gender norms.

The PEPFAR 3.0 Human Rights Action Agenda[140] defines success as: (1) expanded access to nondiscriminatory HIV prevention, treatment, and care for all people, including LGBT [lesbian, gay, bisexual, and transgender] people; (2) increased civil society capacity to advocate for and create enabling environments; and (3) increased gender equality in HIV services and decreased GBV.

The action agenda recommends the following activities:

1. Provide gender-equitable HIV prevention, care, treatment, and support.
2. Implement GBV prevention services and provide services for post-GBV care.
3. Implement activities to change harmful gender norms and promote positive gender norms.
4. Promote gender-related policies and laws that increase legal protection.
5. Increase gender-equitable access to income and productive resources, including education.

Our approach to meaningful youth engagement aligns with the **USAID Youth In Development Policy 2022 Update**,[2] which provides the following guiding principles:

1. Apply meaningful youth engagement and leadership in the design and delivery of projects and strategies.
2. Recognize that youth are not homogeneous. Promote meaningful inclusion of diverse groups of young people to ensure equity and address systemic barriers to participation based on gender, race, ethnicity, disability, sexual orientation, and gender identity/expression.
3. Recognize, map, and plan holistically with local systems to involve the private sector, community organizations, faith-based organizations, governments, and families in youth programming.
4. Integrate intergenerational approaches to strengthen youth participation in decision-making with local leaders and systems. Recognize the traditional roles that youth play in their communities and families, and meaningfully address youth-adult power dynamics in interventions.
5. Protect and support young people's overall well-being by building resilience to shocks, reducing harmful practices, and supporting mental health and wellness while applying trauma-informed approaches.
6. Apply conflict sensitivity and Do No Harm principles, while recognizing that engaging young people as partners in peacebuilding and humanitarian activities is critical to success in fragile environments.
7. Create pathways for youth who have experienced marginalization or disenfranchisement to access opportunities for development.
8. Promote responsible use of technology by and for youth by leveraging digital literacy, appropriate skills development, and digital citizenship opportunities, while reducing risks for digital harm.

Annex C. NextGen Squad terms of reference

Maximizing Options to Advance Informed Choice for HIV Prevention (MOSAIC) is a five-year (2021-2026) global project funded by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) through the U.S. Agency for International Development (USAID) to help adolescent girls and young women (AGYW) and other women[xi] prevent HIV by accelerating introduction and scale-up of new and emerging biomedical prevention products.

The NextGen Squad (NGS) is a team of paid youth advocates under the age of 30 from MOSAIC countries.[xii] Each young person is hired by the local implementing partner (e.g., FHI 360, Jhpiego, LVCT Health, Pangaea Zimbabwe AIDS Trust [PZAT], or Wits Reproductive Health and HIV Institute [RHI]) in the MOSAIC country and is mentored and supported by that local partner.

This terms of reference (TOR) document describes the role of the NGS in the MOSAIC project, the systems in place to ensure accountability to the NGS, and the support that will be available to NGS members. It is a living document that can be revised as needed during the life of the MOSAIC project.

Goal: To shape, participate in, and hold MOSAIC accountable to its plans, actions, and monitoring, evaluation and learning efforts to:

1. Be responsive to young people's needs, preferences, and lived experiences
2. Be inclusive of the diversity of AGYW
3. Meaningfully engage young people in research and research utilization

Objectives

The TOR for the NGS include the following objectives:

Overall

1. **Review MOSAIC work plans and activity implementation plans (or summaries thereof), as requested, to facilitate alignment with young people's priorities and preferences**. Illustrative activities include:
    - Provide feedback and "critiques with upgrades"[xiii] on specific components of the MOSAIC work plan on a yearly basis.
    - Review activity implementation plans with a focus on the strategies and resources dedicated to meaningful youth engagement (MYE).

2. **Support MOSAIC to engage with and capacitate young people so that they feel comfortable and confident participating in project activities.** Illustrative activities include:
    - Train other youth on skills such as protocol review.
    - Mentor other young people on how to contribute on community advisory boards or how to participate in paper writing.

[xi] MOSAIC end users include cisgender women, transgender women, and nonbinary people and transgender men assigned female at birth; in addition, specific underrepresented groups within these end-user populations include very young adolescents, sex workers, pregnant and breastfeeding individuals, those engaged in transactional sex, and individuals who use drugs.

[xii] Youth advocates have a Grade 12 or equivalent education and 0–2 years of work or volunteer experience supporting community, youth, gender, and/or HIV-related projects.

[xiii] Critiques with upgrades refers to providing constructive feedback with concrete suggestions for improvement.

- Regularly check in with youth community advisory board members (including those who are part of the CATALYST study) to understand what barriers exist to meaningful and comfortable collaboration, sharing any recommended actions with other local MOSAIC staff as needed.

3. **Provide MOSAIC with reality checks.** Illustrative activities include:
    - Speak up if activities do not seem to meaningfully engage young people (e.g., if the engagement seems more tokenistic/insincere than real).
    - Share what young people are experiencing in their interactions with MOSAIC activities and staff, both the positive and areas for improvement.
    - Participate in pause, reflect, and learn activities.
4. **Help MOSAIC "do no harm" by sharing any fears, concerns, or observations related to unintended consequences of MOSAIC activities.** Illustrative activities include:
    - Share anything that suggests youth helping in the implementation of MOSAIC activities are experiencing either vicarious trauma (e.g., trauma that comes from seeing/hearing about others' pain) or burnout.
    - Share any information on harms shared, informally or formally, by youth engaged by MOSAIC activities.
5. **Support young people to act as HIV Prevention Product Ambassadors.** Illustrative activities include:
    - Conduct HIV Prevention Ambassador training.
    - Mentor and/or supervise other ambassadors.

Research

6. **Support MOSAIC to collect information in a way that centers young people's voices.** Illustrative activities include:
    - Contribute to survey instruments or other research/monitoring tools.
    - Support recruitment of diverse young people for studies or other activities.
7. **Help design protocols that align to local realities for young people and answer their pressing questions.** Illustrative activities include:
    - Lead youth consultations in your country (for CATALYST study countries).
8. **Serve as data collectors and/or support data entry.** Illustrative activities include:
    - Attend data collector trainings.
    - Support peers to enroll in research activities.
    - Conduct peer-to-peer interviews.
    - Enter data.
9. **Support data interpretation.** Illustrative activities include:
    - Help plan data interpretation events.
    - Support data analysis and identify themes in qualitative data.

Research utilization

10. **Contribute to knowledge products that are accessible to young people.** Illustrative activities include:
    - Help write blog posts, articles, or other knowledge products.
    - Review blog posts, articles, or other knowledge products to provide insights on their accessibility to young people.
    - Lead the development of vlogs or other social media content related to the findings or activities under MOSAIC (or develop content for social media that can accompany other knowledge products).
    - Identify and help create knowledge products describing promising practices for gender integration and MYE based on their experiences with MOSAIC.
11. **Ensure that knowledge products are contextualized.** Illustrative activities include:
    - Review knowledge products to make sure that findings are not taken out of context (e.g., "young people do not consistently use oral PrEP" becomes "young people without an enabling environment in which to use oral PrEP struggle to use oral PrEP consistently").
    - Provide recommendations on how other local efforts to encourage AGYW pre-exposure prophylaxis (PrEP) use could be integrated into knowledge products (e.g., "local group X will find this interesting; let's include ideas in this document related to how they might use the findings in their work").
12. **Disseminate information, experiences, and perspectives through youth networks and global channels.** Illustrative activities include:
    - Share information via social media accounts.
    - Host events online.
    - Keep other youth advocates updated on MOSAIC activities.
    - Participate in panels and presentations at the local, regional, and global levels.

Approach for achieving objectives

The NGS members will engage in activities locally as well as globally and will be supported at both levels. Across local and global activities, when they participate in MOSAIC activities as NGS members, they will:

- Be given clear instructions that describe the expected outcomes. If NGS input is sought from another country (whether this be for a global or country-specific activity), such requests will come through a central gender and youth staff person ("principal OG" [original generation]) who will be in charge of receiving and communicating these requests to the NGS. All those making requests will provide the following information about their request:
    - Timeline
    - The ask/product
    - Why the NGS is uniquely placed to provide the needed inputs
    - What the requester will do to support the NGS as they give feedback (e.g., have a meeting to go over a product)

    - The requester's commitment to letting the NGS know how their feedback was incorporated and, if any element was not incorporated, why (this will occur within seven days of the completion of the product)
    - Whether this request is optional[xiv]

- Be provided with adequate time to complete tasks (tasks should be given at least 14 days in advance; whenever possible, timelines should be co-developed)
- Be given the support that they need to meaningfully engage with the task, including the potential to work with gender and youth country leads on tasks as needed
- Be provided with information regarding protocols/norms for any meetings they will attend so that they understand and prepare prior to the engagement
- Continually be provided with constructive feedback to improve their knowledge and ability to participate in MOSAIC activities

To ensure that requests for NGS input do not become overwhelming and that they have a clear communication channel for requesting additional clarity or help, the principal OG will track NGS requests and their completion. To share tasks for individual NGS members evenly, the principal OG will ask all NGS members which tasks are of interest and will support the building of capacity (especially between NGS members).

When tasks are made at the central level, gender and youth country leads will be copied and kept up-to-date about NGS activities.

When opportunities are available for NGS members, these opportunities will be circulated via Teams, email, and/or WhatsApp. Anyone can circulate an opportunity to the NGS. Should NGS members wish to engage in an opportunity, they should contact the principal OG and their country gender and youth country lead. The principal OG and/or country lead will then provide the support needed or the principal OG will seek that support from others in the MOSAIC project. Types of support include presentation dry-runs prior to webinars.

Local activities

Local activities will be dictated by work plans and could include:

- Planning and implementing events and campaigns
- Facilitating and supporting training of AGYW using the HIV Prevention Ambassador Training Package
- Supporting trained HIV Prevention Ambassadors to set up their own ambassador groups and train peers
- Liaising with stakeholders on healthy lifestyle programs and collaborating with them to inform the implementation of MOSAIC
- Preparing and giving presentations about project activities to community groups, advisory boards, USAID, and broader consortium members

Support provided locally could include:

[xiv] Based on tight turn-around times, we do not anticipate that all members of the NGS will complete each request made of the NGS. In addition, if some requests are not project priorities, NGS members will have the option to engage or not engage, based on their workloads.

- Human resources support (e.g., onboarding)
- Mentorship from the local gender and youth country lead (Mentorship may include project/time management, building competencies for engagement in formal workplaces, and support for both completing activities and reporting on their outcomes.)
- Information technology support (providing a computer and other necessary electronic equipment)
- Reviewing documents with NGS members to facilitate comprehension
- Revising documents to ensure they are youth-friendly before they are assigned to NGS members for review
- Working with local teams to ensure that they engage with NGS members in accessible ways that promote comprehension and full participation

Global activities

Globally, NGS members will:

- Be convened virtually on a monthly basis. During these meetings, NGS members will participate in facilitation, presentation, note-taking, timekeeping, and all aspects of efficient and productive meeting experiences.
- Be given opportunities after each NGS meeting to reflect on that meeting and be provided access to open channels for information sharing and feedback
- Attend a Global All Gender and Youth Staff meeting every quarter. During these meetings, NGS members will work with the gender and youth country lead to prepare a short update on activities to engage youth in their countries. Templates for these presentations will be provided.
- Attend trainings on topics such as:
    - Identifying burnout
    - Psychological first aid (LIVES) for survivors of violence
    - Prevention product ambassador training
    - Protocol review
    - Conference abstract and paper writing
    - Sexual orientation and gender identity
    - Safeguarding
- Regular completion of activity surveys that allow MOSAIC to determine whether/how NGS members are engaging with other projects or research

Support provided to NGS members from the MOSAIC central youth/gender team includes:

- Virtual training on the topics listed above
- Opportunities to share their ideas, challenges, and successes across the MOSAIC project and outside of the MOSAIC project
- Links to professional development/exchange program opportunities external to MOSAIC
- Opportunities to provide anonymous feedback on the overall process of NGS participation
- Revision of documents to ensure they are youth-friendly before they are assigned to NGS members for review
- Working with result team leads to ensure that they engage with NGS members in accessible ways that promote comprehension and full participation

Participants

The NGS is comprised of youth advocates from MOSAIC countries. One youth advocate from a MOSAIC country is a full-time MOSAIC team member and serves as a country representative on the NGS. Some countries have a second youth advocate who serves as a general member of the NGS.

Name	Organization	Country	Role
Tema Mkhonta	FHI 360	Eswatini	Country Representative
Marie Merci Niyibeshaho	LVCT Health	Kenya	Country Representative
Margaret Akinyi Atieno	LVCT Health	Kenya	Member
Nts'ebo Lerotholi	Jhpiego	Lesotho	Country Representative
Febbe Amutenya	Jhpiego	Namibia	Country Representative
Adaobi Olisa	FHI 360	Nigeria	Country Representative
Celi Nkambule	Wits RHI	South Africa	Country Representative
Chantel Manganye	Wits RHI	South Africa	Member
Rubuna Nagai	FHI 360	Uganda	Country Representative
Luwi Katoka	FHI 360	Zambia	Country Representative
Sanele Ngulube	PZAT	Zimbabwe	Country Representative
Havana Mtetwa	PZAT	Zimbabwe	Member

Annex D. Acting on MOSAIC Principles

What is this tool?

The Acting on MOSAIC Principles (AMP) tool is meant to assess a team's **alignment to the principles** of gender integration and meaningful youth engagement. It assesses alignment to each principle by the populations that MOSAIC serves. The AMP tool will help you understand how closely your team aligns with these principles and how alignment differs across the groups that MOSAIC seeks to engage. After your team reviews its scores, you will be asked to decide, based on the local opportunities and gaps that the team considers priorities, where to make investments. As teams continue to use this tool over time, we can document changes that demonstrate accountability to young people and a commitment to gender equity and can see growth in individual teams and across the project.

The AMP tool will also help the gender and youth country lead(s) and/or the central gender and youth team identify areas where support may be useful across countries. For example, if Country A identifies additional efforts under Principle 5 as an important area for investment and Country B has a high score under Principle 5, these findings indicate an opportunity for sharing between countries A and B. The tool also allows the project to **document gaps** in current services to advocate for additional support with leadership, where appropriate. At both an aggregate level and the team level, the results of this tool will indicate where more resources are required. For example, if MOSAIC at an aggregate level has its lowest scores in activities to engage sex workers, this finding could indicate a need to dedicate more resources to reaching sex workers if they are identified as a priority population.

This tool does not provide a grade. MOSAIC's principles are aspirational. We will not align perfectly to any of them. In addition, the scores under this tool do not result in the need for a team to take a predefined set of actions. Instead, they indicate where investments could be made."

Who should use this tool?

Among country teams, the gender and youth country lead(s) should guide this process. They will engage others, as appropriate, to complete each section of the tool (e.g., under the section on Research, the country lead(s) will work with local MOSAIC research team members). Among central teams, small teams from each result should work with their central gender and youth backstop to complete the relevant sections. This tool is specific to MOSAIC, so only those working on MOSAIC should be engaged.

Please write to info@prepnetwork.org if you would like to access the AMP tool.

Annex E. Gender Integration and MYE Tracker

Introducing the Gender Integration and Meaningful Youth Engagement Tracker

What is this tool?
The MOSAIC Gender Integration and Meaningful Youth Engagement Tracker (also called the Gender and Youth Tracker for short) was developed to support the documentation and management of MOSAIC investments in gender integration and meaningful youth engagement. The tracker allows each country team and central result team to look across their work plans and (1) document where and how they are implementing gender integration and meaningful youth engagement strategies; (2) track progress over time; and (2) reflect on successes, challenges, lessons learned, and best practices.
How do you use this tool?
Among country teams, the gender and youth country lead(s) should complete the tracker once per quarter. They will engage others, as appropriate, to complete each section of the tool (e.g., under the section on Result 2, the country lead(s) will work with local MOSAIC research team members). Among central teams, the result backstops on the central gender and youth team should complete the tracker once per quarter with other members of that result, as needed. The completed trackers should be shared with the central gender and youth team backstops, who will store them on SharePoint to be referred to when identifying, synthesizing, and sharing successes, challenges, lessons learned, and best practices.
What is gender integration?
Strategies applied in programmatic design, implementation, monitoring, and evaluation to take gender considerations into account and to compensate for gender-based inequalities. In this document, primary forms of gender integration are 1) addressing gender-based violence (GBV); 2) changing beliefs or norms; 3) engaging men; 4) engaging underrepresented groups. These may occur together.
What is meaningful youth engagement?
An inclusive, intentional, mutually respectful partnership between youth and adults whereby power is shared, respective contributions are valued, and young people's ideas, perspectives, skills, and strengths are integrated into the design and delivery of programs, strategies, policies, funding mechanisms, and organizations that affect their lives and their communities, countries, and the world.
Who are youth?
Youth are defined as people ages 10–29 under the USAID Youth in Development Policy 2022 Update. While the age at which young people can access biomedical prevention products differs from country to country, MOSAIC is focused on adolescent girls and young women ages 15–29.
Who are underrepresented populations?
Individuals who identify as: transgender women, transgender men and nonbinary individuals assigned female at birth, sex workers, pregnant and breastfeeding people, people who inject drugs, and people with disabilities.

Gender Integration and Meaningful Youth Engagement Tracker

Team (Country, Central Result Area, etc.)

Workplan activity name	Gender integration activities	Status	Meaningful youth engagement activities	Status	Considerations
Insert the activity names of all high-level activities from your work plan.	Type a description of the gender integration activities as actually implemented in each quarter. Bold activities that seek to address gender-based violence, change beliefs or norms, engage men, or engage with underrepresented groups.	Select from dropdown menu.	Type a description of the meaningful youth engagement activities as actually implemented in each quarter.	Select from dropdown menu.	• What successes occurred during the reporting period? • What challenges were encountered and what strategies were employed to address them? • If an activity was not implemented as planned, briefly describe why. • What were key lessons learned and/or best practices? • What are other things to consider?
Result 1: User-Centered Approach					
R1.1 Articulate, operationalize, and demonstrate accountability to principles of gender integration and meaningful youth engagement across MOSAIC activities.	Q1: Q2: Q3: Q4:		Q1: Q2: Q3: Q4:		
Result 2: Product Introduction Research					
R2.1 Assess feasibility and acceptability of novel PrEP indicators for monitoring and evaluation.	Q1: Q2: Q3: Q4:		Q1: Q2: Q3: Q4:		
R2.2 Design and initiate the CATALYST study for registered PrEP products.	Q1: Q2: Q3: Q4:		Q1: Q2: Q3: Q4:		

Workplan activity name	Gender integration activities	Status	Meaningful youth engagement activities	Status	Considerations
R2.3 Generate PrEP cost data.	Q1: Q2: Q3: Q4:		Q1: Q2: Q3: Q4:		
R2.4 Conduct systematic reviews and formative research on acceptability, values, and preferences for new products.	Q1: Q2: Q3: Q4:		Q1: Q2: Q3: Q4:		
R2.5 Conduct analyses of existing survey and/or program data to inform introduction studies, policy, and strategic programming.	Q1: Q2: Q3: Q4:		Q1: Q2: Q3: Q4:		
R2.6 Conduct HIV drug resistance studies.	Q1: Q2: Q3: Q4:		Q1: Q2: Q3: Q4:		
R2.7 Conduct studies to inform and evaluate PrEP tools and interventions.	Q1: Q2: Q3: Q4:		Q1: Q2: Q3: Q4:		
R2.8 Design and initiate focused product introduction studies.	Q1: Q2: Q3: Q4:		Q1: Q2: Q3: Q4:		
Result 3: Product Introduction Policy and Program					
R3.1 Pipeline management/market development	Q1: Q2: Q3: Q4:		Q1: Q2: Q3: Q4:		

Workplan activity name	Gender integration activities	Status	Meaningful youth engagement activities	Status	Considerations
R3.2 Policy & program	Q1: Q2: Q3: Q4:		Q1: Q2: Q3: Q4:		
R3.4 Demand and marketing	Q1: Q2: Q3: Q4:		Q1: Q2: Q3: Q4:		
R3.5 HIV drug resistance	Q1: Q2: Q3: Q4:		Q1: Q2: Q3: Q4:		
Result 4: Research Utilization/Knowledge Management					
R4.1 Design and introduce research utilization and knowledge management strategies to support new biomedical prevention product introduction.	Q1: Q2: Q3: Q4:		Q1: Q2: Q3: Q4:		
Result 5: Local Partner Capacity Strengthening					
R5.1 Strengthen local partner capacity to design and implement biomedical prevention product introduction activities and research.	Q1: Q2: Q3: Q4:		Q1: Q2: Q3: Q4:		

Annex F. AGYW, HIV, and PrEP

Cisgender AGYW

Cisgender adolescent girls and young women (AGYW) are disproportionately affected by HIV globally.[7,31] Although HIV incidence has declined overall across sub-Saharan Africa, incidence among cisgender AGYW has either stabilized or increased.[142] Cisgender girls and young women younger than 25 years are estimated to account for 50 percent of new HIV infections in sub-Saharan Africa and are five to 14 times more likely to be living with HIV than their male peers.[7,31] A range of factors drive cisgender AGYW's increased susceptibility to HIV, including biological, behavioral, social, and structural factors.[32,142–144] Harmful gender norms, gender-based violence, and economic and educational inequalities are a few of these factors.[32,142–144]

Significant investments and efforts have been made to support AGYW's access to HIV prevention products, such as the oral pre-exposure prophylaxis (PrEP) component of the DREAMS (Determined, Resilient, Empowered, AIDS-free, Mentored and Safe) core intervention package funded by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR).[31] Unfortunately, multiple individual, social, and structural barriers can impede AGYW's desire and ability to initiate oral PrEP.[6,7] As a result, the number of cisgender AGYW who initiate oral PrEP is significantly lower than the number who could potentially benefit from this product.[11–13] Individual barriers to AGYW PrEP use include a lack of familiarity with taking daily medication,[145] the perceived burden of daily pill taking,[146] and limited perception of personal need for HIV prevention (in line with normal neurocognitive development).[145] Social barriers include a lack of support for oral PrEP use from parents, caregivers, and/or partners,[147,148] as well as broader stigma and discrimination. Demonstration projects with cisgender AGYW across sub-Saharan Africa have reported sharp decreases in oral PrEP use in the months immediately following initiation, often despite continued exposure(s) to HIV.[25,32,149–152]

Newer HIV prevention products such as the dapivirine ring (PrEP ring) and cabotegravir long-acting injectable for HIV prevention (CAB PrEP) expand the range of products that cisgender AGYW can choose from and switch between to meet their needs and suit their lifestyles. Research on product values and preferences suggest that the PrEP ring and CAB PrEP may be beneficial for end users seeking longer-acting methods, discretion, and minimal partner negotiation.[9,153] A clinical trial in Africa has shown that the PrEP ring has a favorable safety profile among users ages 15-21, with no safety or acceptability concerns among AGYW.[10] Results from an ongoing trial of CAB PrEP among AGYW in Africa are anticipated in 2023.

Transgender AGYW

As of 2020, transgender women globally were 34 times more likely to acquire HIV compared to other adults.[108] Trans AGYW also experience a disproportionate burden of HIV, including when compared to older trans women.[154] Transgender AGYW's increased susceptibility to HIV is multifaceted, driven by many of the same factors that affect cisgender AGYW but further complicated by harmful gender norms and transphobia-fueled violence, stigma, discrimination in health facilities, and rejection from society.[22,32,142–144]

Global estimates for HIV prevalence are 19.9 percent among trans women and 2.6 percent among trans men; 30 percent of transgender women in sub-Saharan Africa are estimated to be living with HIV.[155] Stigma and discrimination reduce access to employment and health care as well as social, legal, and medical gender affirmation.

Investments in the initiation and continued use of oral PrEP through DREAMS have traditionally targeted cisgender AGYW and lacked programming for transgender and nonbinary individuals.[31] Trans AGYW experience additional barriers to information and services based on gender identity[8] and often have much lower oral PrEP initiation rates than men who have sex with men who are offered oral PrEP in the same settings.[156] Two studies that measured PrEP uptake found that 53 percent of trans AGYW offered oral PrEP in a large government hospital in Kenya subsequently initiated use;[59] in Thailand, only 13 percent of trans women younger than 25 accepted oral PrEP through key population-led services.[26] The intervention in Thailand included access to gender-affirming services and saw higher uptake among trans women 25 years and older compared to younger trans women, with 44 percent initiating oral PrEP across all age groups.[60] Studies have found that the number of trans AGYW who initiate oral PrEP is far below that of those who could potentially benefit from it,[11–13] although continuation is relatively high among this group.[11]

Newer forms of HIV prevention have proved highly effective among transgender individuals. CAB PrEP has been shown effective in trans women who have sex with men.[66] However, research on young trans people and HIV prevention is limited. Reviews of their participation in studies have identified a desire not to disclose one's gender identity to clinic staff as a reason not to participate.[157]

Annex G. Crosscutting issues affecting AGYW access to and use of PrEP

Spotlight on parents and caregivers

Parents and caregivers[xv] can play an important role in the use or nonuse of pre-exposure prophylaxis (PrEP) by adolescent girls and young women (AGYW). This is particularly true when young women live with their parents.[147] Although whether to use PrEP is an individual's choice, many young women decide to disclose their use to their parents for reasons such as fear of inadvertent disclosure or simply because they want their parents to be informed.[147,148] Young women's reasons for telling their parents about their PrEP use include wanting to ask their parents for permission, which is generally in keeping with social norms related to respect for elders, and wanting to explain trips to a clinic or the presence of PrEP products in the home.[147] In some locations, parental consent is required for PrEP use by individuals younger than 18.[158]

When parents do not understand the purpose of PrEP, they may reject it because they believe it is an HIV treatment or that it would lead to HIV acquisition.[75,147] Yet, many parents are interested in and supportive of PrEP for their children once they understand what it is.[159,160] Parents of AGYW PrEP users reported feelings of relief that their daughters were protected and pride that their children were grown up enough to make such good decisions.[147] Some AGYW reported feeling happy that they could alleviate their parents' fears about their daughters' health by disclosing their PrEP use. In many places — especially those with a high HIV prevalence — parental acceptance of PrEP was the rule and not the exception.[147,161] However, parents in each setting will have different opinions.[147,162] In some settings, parents raised concerns that their daughters would be perceived as promiscuous because they used PrEP, but most were still willing to support PrEP use.[161] The parents most likely to support AGYW PrEP use were those who knew that their daughters were sexually active or those who were living with HIV themselves.[147]

Young women who tell their parents about their PrEP use report that this disclosure can be a positive and meaningful experience.[75] It can also be supportive logistically; for example, young women who have disclosed oral PrEP use to their parents report relying on parents for reminders to take it. Mothers' support strategies may differ from those of fathers. Mothers were more likely to note that they would create a supportive environment for their daughters' PrEP use — for example, by ensuring a good diet — while fathers expressed shame and embarrassment about talking to their daughters about sex but said they could provide logistical and material support, such as driving their daughters to health centers.[161] When parents are not told about PrEP use, AGYW report, adherence is more difficult, and they need to go to great lengths to hide their PrEP. Many AGYW who felt they could not disclose their PrEP use said they struggled with taking oral PrEP or had discontinued use.[147]

If parents do accept or support their daughter's PrEP use, it is important that they have the skills to vocalize this support.[147] Young women decide whom to tell, or not tell, based in part on perceptions of acceptance. They may also ask a trusted parent or other adult to help them disclose their PrEP use to additional family members, if necessary. In some cases, parents may not be against PrEP use and may even be more supportive of PrEP use

[xv] We use "parents" to refer to parents and caregivers (generally understood to be the persons responsible for the care and well-being of children within the home) in this annex.

than their adolescents perceive them to be.[69] But the perception that a parent is unsupportive is associated with lower PrEP interest and can lead PrEP users to hide or discontinue their PrEP use.[69,75]

Parents are also an important component of AGYW trial participation. Community engagement that focuses on parents could help them decide whether to allow their child's participation in a clinical trial. Parents are likely to look to members of their community whom they trust, so broader community engagement will also be necessary. Until parents understand what their children are getting into, it is unlikely that they will support the inclusion of adolescents in HIV prevention clinical trials.[163] Among transgender youth, the extent to which their parents accepted their gender identity was predictive of whether they would approach their parents about joining a clinical trial.[157]

Spotlight on male partners

Although men are not a population of focus for MOSAIC, research and experience shows that they have a significant impact on the ability of cisgender and transgender women — especially AGYW — to access and effectively use HIV prevention methods. We recognize that partner influence and relationships are important for all people regardless of sex assigned at birth and gender identity. This document focuses on the engagement of cisgender men due to their extensive influence on the sexual and reproductive health choices made by their female partners and women more broadly.[164]

Male partners, for example, play a role in the ability of women of all ages to effectively use oral PrEP or access family planning services.[132,165] AGYW may also be exposed to HIV through sex with older male partners, who often have a longer and more networked sexual history than adolescent boys and young men.[166] More broadly, gender norms impede HIV prevention by limiting the ability of women — especially AGYW and trans women — to negotiate decisions about sex with their male partners, including decisions about PrEP uptake and use.[132,167,168] However, male partners have also been shown to play an important positive role in uptake and continuation of sexual and reproductive health services, acting as primary sources of information and providing financial, emotional, and logistical support.[21,76,164,169,170] Finally, gender-based violence (GBV), which is most commonly perpetrated against women by cisgender male partners, has been shown to both increase the likelihood a survivor will acquire HIV and constrain her ability to adhere to PrEP.[133,171,172]

Spotlight on health care workers

Health care workers are key players in the provision of biomedical HIV prevention provision. As trusted sources of credible information, they are highly influential in user decisions about new HIV prevention methods.[173,174] However, stigma and discrimination by health care workers also continues to be a critical barrier to reaching AGYW with HIV prevention services. AGYW often understand the likelihood of exposure to HIV and want to access health care services but are reluctant to do so due to poor treatment — or the anticipation of poor treatment — by clinic staff.[80,84] Studies of health care workers' attitudes and perceptions across countries have found that moral stances on sexual activity, especially for young unmarried women, often influence their willingness to offer PrEP.[80–82] Many health care workers have concerns about risk compensation — the idea that people adjust their behavior in response to perceived levels of risk — despite lack of evidence from oral PrEP implementation.[83] The result has been that many women and AGYW who do seek services are reluctant to ask for oral PrEP or are not offered oral PrEP, while others are deterred from seeking it.[84–86]

In one qualitative study with AGYW in Kenya, South Africa, and Zimbabwe, many health care workers said girls engaged in sexual activity at an earlier age than they thought was appropriate. The majority preferred that girls wait until they are 18. Some health care workers also shared concerns about adherence, especially among AGYW clients whose partners or parents disapproved of PrEP use.[175]

In a mixed methods study with both AGYW and clinic staff in South Africa, many clinical and nonclinical staff worried that providing PrEP to AGYW would encourage them to become more sexually active and discourage them from using condoms to protect themselves from pregnancy and sexually transmitted infections.[80] AGYW reported both anticipated and experienced stigma, including judgmental lecturing and intrusive questioning that was seen as medically unnecessary, when seeking PrEP and other sexual and reproductive health services. They also reported lack of privacy and confidentiality, largely due to the physical layout of clinics and how services were delivered.

Spotlight on gender-based violence

Experience of GBV, including physical, sexual, emotional, and economic violence committed by partners and non-partners, is highly prevalent among cisgender AGYW in sub-Saharan Africa. Intimate partner violence (IPV) is the most common form of violence against women and girls.[176] According to the 2018 Violence Against Women estimates, 28 percent of cisgender AGYW 15–24 years old in the region had experienced physical and/or sexual IPV in the past year.[138]

In the countries where MOSAIC operates, estimates of past year IPV among cisgender AGYW ages 15–24 range from 13 percent in Nigeria to 30 percent in Zambia,[177] and prevalence increases substantially during the transition from adolescence to young adulthood. Young cisgender women ages 20–24 in those countries have the highest prevalence of past year physical and/or sexual IPV compared to other age groups.[178–180] During this stage of life, AGYW are particularly vulnerable to violence because they may continue to experience some forms of violence against children, such as violent discipline and sexual abuse in their families, and begin to experience common forms of violence against adults, such as IPV and non-partner sexual assault.[181] These forms of violence and HIV have common drivers, including gender inequality, unequal gender norms, and acceptance of violence.[171,181,182]

Transgender women and gender nonconforming people experience even higher levels of GBV. In a cross-sectional study in nine African countries, 44.6 percent of trans women and 36.8 percent of gender nonconforming individuals reported experiencing physical or sexual violence in the past year.[183] Younger sexual and/or gender minority people (18–24 years old) faced the highest prevalence of past year violence (30.2 percent) compared to their older counterparts.

Experiencing GBV can increase the likelihood of acquiring HIV directly through unwanted or forced sex and indirectly through poor mental health, harmful alcohol and substance use, and limited agency regarding the timing and circumstances of sex.[23,171,182] A small body of research also shows a link between behaviors that increase the chances of exposure to HIV and other forms of violence, such as emotional and economic IPV, among young cisgender women.[184,185] For example, a cross-sectional study in South Africa found that emotional violence, including verbal abuse and threats, was associated with condomless sex, transactional sex, and frequent alcohol use among young women who participated in the HIV Prevention Trials Network (HPTN) 068 trial.[185] A review of Demographic and Health Survey data from 10 countries in sub-Saharan Africa also found a strong association between male controlling behavior and the likelihood of exposure to HIV.[186]

GBV affects cisgender women's interest and willingness to use PrEP and their ability to initiate and continue using different methods of PrEP; in some cases GBV acts as a barrier to PrEP use, while in others it acts as motivator for PrEP use.[92,133,187–189] Evidence from oral PrEP trials and demonstration studies shows an association between physical, sexual, and/or economic IPV and lower uptake, increased interruptions,[187] and lower adherence to oral PrEP among adult cisgender women.[133] Conversely, a PrEP feasibility and acceptability study in Lesotho found that having a friend who experienced IPV was associated with increased willingness to use PrEP.[190] The association between IPV and oral PrEP adherence is also affected by age: a secondary analysis of HPTN 082 data found that past year IPV was associated with lower adherence among younger AGYW (16–20 years) and higher adherence among older AGYW (21–25 years).[191]

Qualitative interviews with participants from the Partners PrEP Study found that IPV resulted in women forgetting to take pills and leaving pills at home when escaping a violent episode and in partners threatening to take or throw away pills.[133] Similarly, qualitative interviews with women who were pregnant or planning a pregnancy revealed that some women did not initiate oral PrEP due to fear of IPV. Among women who did initiate oral PrEP, nondisclosure contributed to suspicions of infidelity and violence by their male partners, driving women to leave their homes and miss pills.[192]

Partner-related social harms, including IPV, were also associated with lower adherence to the dapivirine ring (PrEP ring) among women in the MTN-020/ASPIRE study.[188] Common triggers of social harms included discovery of the ring and partner suspicion that the ring was associated with promiscuity. Common consequences included male partners removing and destroying or discarding rings, physical and verbal violence, and dissolution of relationships.[188] Qualitative interviews with former participants in the MTN-020/ASPIRE study revealed that study participation and PrEP ring use triggered IPV in their homes and was used as a reason for further abuse.[193] For some, fear of anticipated IPV led to discontinuing PrEP ring use.[193]

Finally, it is important to acknowledge the link between PrEP and HIV post-exposure prophylaxis (PEP). PEP should be offered, as appropriate, to children and adolescents who have been raped if the rape involves oral, vaginal, or anal penetration with a penis and if they present within 72 hours of the incident. When taken correctly, PEP is an effective tool to prevent HIV acquisition among people who experience sexual assault; however, very few survivors even initiate PEP. Data on rates of completion of the full course of PEP are limited. Current evidence suggests that as few as 40 percent of sexual assault survivors globally complete the full 28-day course, with completion rates as low as 36 percent among adolescents.[194,195] In some studies, fewer than one in three survivors completed PEP.[196]

Spotlight on transactional sex

Transactional sex, defined as "non-commercial, non-marital sexual relationships motivated by an implicit assumption that sex will be exchanged for materials goods or other benefits," [108,197,198] is prevalent among AGYW in many sub-Saharan African countries: estimates range from 5 percent in Cameroon to 85 percent in Uganda.[199]

On average, women who have engaged in transactional sex are 50 percent more likely to be living with HIV compared to women who have not; studies suggest that AGYW who have practiced transactional sex are about two to three times more likely to be living with HIV.[200] Many pathways connect transactional sex and HIV, including alcohol use, multiple and concurrent sexual partners, age-disparate sex, nonuse of condoms, low power in sexual relationships, and a history of IPV.[108,200]

Transactional sex and sex work: What's the difference?

"Transactional sex is not sex work but refers to non-marital, non-commercial sexual relationships motivated by an implicit assumption that sex will be exchanged for material support or other benefits. Most women and men involved in transactional sex relationships consider themselves as partners or lovers rather than sellers or buyers. Conflating transactional sex and sex work in intervention design and funding may be counterproductive, as interventions designed for sex workers will not reach people engaged in transactional sex."

Sex work	Transactional sex
• Self-identifies as sex worker • Exchange of money or goods linked explicitly to sex • Often little shared emotional intimacy	• Does not self-identify as sex worker • Exchange of money or goods implicit in relationship (including sex) • Often some shared emotional intimacy

(UNAIDS. Transactional Sex and HIV Risk: From Analysis to Action, 2018)[108]

Gender inequality in sexual and romantic relationships, including gender norms that men should provide for and control their partners and that women must reciprocate with sex, drives transactional sex.[108,200] In a formative study in Brazil, Tanzania, and Uganda, key norms that influenced AGYW to participate in transactional sex included: (1) AGYW are expected to receive money, gifts, or other benefits from their sexual partners; (2) AGYW are expected to gain social status through ownership of material items; and (3) AGYW who receive money, gifts, or other benefits from men are implicitly expected by the men to reciprocate with sex.[201] For men, key norms that influenced their participation included: (1) men are expected to have heightened sexuality and sexual prowess and (2) men are expected to provide economically in sexual relationships.[201]

Transactional sex can take place in a range of economic contexts, from uniform poverty to high inequality, and with women who have varying levels of agency in their relationships.[108] Depending on their contexts, AGYW have multiple, interrelated motivations for engaging in transactional sex, such as meeting their basic needs, improving their social status, and receiving material expressions of love.[108,201] For example, in Tanzania, AGYW engaged in transactional sex in pursuit of short-term aspirations, such as gaining social status by having trendy clothes or smartphones.[202] For many AGYW who engage in transactional sex, the perceived benefits outweigh possible negative consequences such as HIV.[201] Men have their own set of motivations and costs: they seek out younger women, considering them more agreeable and compliant, and they face financial pressures, reputational damage, and HIV risk.[148,201] For example, in Uganda and Eswatini, men believed that providing money and gifts was the main way to build and maintain relationships with young women and worried about losing relationships if they could no longer provide them.[203]

Providing a full range of HIV prevention tools, including PrEP products, may reduce the likelihood of acquiring HIV among AGYW who engage in transactional sex.[108] In a qualitative study embedded in the SEARCH study in Kenya and Uganda, young women in transactional sex relationships saw oral PrEP as a potential option for reasserting their control over the chances of exposure to HIV and preventing HIV, particularly when they had limited agency to negotiate condom use and were uncertain about their partners' HIV status.[148]

Spotlight on mental health

Globally, 10 to 20 percent of adolescents experience depression,[104] and AGYW are twice as likely to be affected by depression compared to their male peers. Evidence also suggests that AGYW in lower- and middle-income countries are particularly susceptible to depression.[101,105] AGYW often face imbalanced power dynamics with older male partners, and lack of control in sexual decision-making has been associated with depression among African women.[102]

PrEP efficacy depends on adherence and retention, and unmet mental health needs are associated with nonadherence to drug regimens. In addition, unmet mental health needs increase the odds of engaging in behaviors more likely to expose an individual to HIV.[204–206] Social support can help reduce the likelihood of engaging in such behaviors, but research shows that this is not the case for women when their mental health needs increase.[103] Studies among AGYW in Kenya,[97] Uganda,[98]and South Africa[99,100] found that the frequency of multiple factors associated with greater likelihood of HIV exposure was higher among AGYW with depression. Although examples of integrating mental health services into HIV prevention programs are limited, the evidence suggests that addressing the unmet mental health needs of AGYW may help increase PrEP adherence and reduce their chances of being exposed to HIV.

Annex H. What do we know about engaging young people in research?

Young people, especially those younger than 18, are underrepresented in biomedical HIV prevention research. This lack of representation remains a significant challenge to integrating biomedical strategies, such as pre-exposure prophylaxis (PrEP), into effective combination prevention packages for young people.[207]

Meaningful youth engagement (MYE) means MOSAIC will take into account where young people are developmentally, emotionally, educationally, economically, and as members of their families and communities (just to name a few characteristics).

Meaningfully engaging young people in biomedical prevention product research is critical to improving the understanding of the safety and efficacy of new HIV prevention technologies among young people seeking to prevent HIV. Engaging young people provides an opportunity to learn more about their understanding of and reactions to prevention products, including a product's acceptability, use of the product, and the degree of adherence to different dosing regimens.[208]

As researchers continue to discover, develop, and implement HIV prevention strategies — including new PrEP formulations and dosage (e.g., long-acting injectable PrEP, vaginal microbicides, and vaginal rings) and preventive HIV vaccines — studies must be inclusive of the needs of adolescents and young adults.[209] Closson et al. (2021) demonstrate that young men and women are interested in participating in biomedical HIV prevention research, but research programs need to be designed with their daily social realities in mind.[209] Gender and power inequities affect youth's willingness to participate in such research on individual, interpersonal, community, and structural levels. For young women, those decisions were based largely on external factors, including intimate partners', parents', and societal perceptions of what participating in HIV prevention research would say about their sexuality and sexual behaviors. For young men, decisions were based more on individual factors or peer-to-peer perceptions — specifically, what other young men in their communities would think about them.

Understanding young women's and young men's perceived barriers and facilitators to participation in biomedical HIV prevention research is important for designing the adolescent-responsive services and acceptable technologies needed to reduce HIV incidence. Such barriers include (1) insufficient understanding of clinical prevention research, (2) self-presentation bias, (3) issues surrounding parental consent, (4) limited access to clinical trials, (5) mistrust of research, and (6) stigma associated with participation in clinical trials.[208]

Successful retention and support of participants was evident in the youth-engaged approach implemented in AYAZAZI (a Zulu word translated as 'knowing themselves'), an interdisciplinary longitudinal cohort study of HIV sociobehavioral patterns and clinical characteristics among youth ages 16–24 years living in Soweto, South Africa.[209] In AYAZAZI's approach, young people in this age group were recruited as research staff and received support and guidance from adults. Qualitative findings indicated that youth were generally interested in participating in biomedical HIV prevention research. However, research programs need to consider the social, lived realities of potential participants. Importantly, youth indicated a desire for youth-friendly sexual and reproductive health services and information as key facilitators of participation in research. Successes seen in AYAYAZI highlight the critical need to improve and build upon existing youth-engaged approaches to involving and retaining young people in HIV research.

Annex I. Monitoring, evaluation, and learning guidance for a user-centered approach

The MOSAIC Monitoring, Evaluation, and Learning (MEL) Plan describes the tools and approaches to track the progress and performance of the project against its goals and intended outcomes. Table 1 provides a list of performance indicators that will be used to document progress toward a user-centered approach where the needs and preferences of users and potential users of HIV prevention products are understood and addressed in product introduction and scale-up (Result 1). More information about these indicators can be found in the MEL Plan.

Table 1. User-centered approach performance indicators

Indicator	Level	Data collection method / source	Collection and reporting frequency	Anticipated targets
Percentage of MOSAIC research studies, knowledge products, journal articles, conference presentations, and PrEP Learning Network events developed with participation from youth or individuals from underrepresented populations	Process	Research and knowledge management trackers	Quarterly	50%
Number of youth (up to 29 years old) working for MOSAIC as NextGen Squad members, staff, interns/fellows, or other	Process	Human resources activity report	Semi-annually	24

In addition to these indicators, we collect data about end users who participate in MOSAIC activities such as assessments, trainings, and research studies. Program and research data should be disaggregated by gender and age, where relevant, to enhance the responsiveness and accountability of the project to an inclusive group of users and potential users. These data will be used to determine the users that MOSAIC benefits or excludes, address the gender- and age-related barriers they face, and leverage opportunities for improvement.

Gender-disaggregated data

We recommend collecting and reporting gender-disaggregated data by using a two-step method to ask about gender identity and sex assigned at birth, unless collecting these data would create undue stigma, discrimination, or other social harms. Using a two-step method is a best practice that has been used by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR)[210] and has become an increasingly validated way to accurately identify transgender and nonbinary individuals.[211,212] Table 2 lists recommended questions and response options using a two-step method; however, the response options may need to be adapted to be geographically and culturally specific. For example, in some settings, it may be appropriate to include intersex as a response option for sex assigned at birth.

Table 2. Recommended questions to ask about gender identity and sex assigned at birth using a two-step method

Question	Response options
1. What is your current gender identity? [Mark only one]	Female Male Transgender female Transgender male Genderqueer/nonbinary I use a different term Decline to answer
2. What was your sex assigned at birth? [Mark only one]	Male Female Decline to answer

Age-disaggregated data

Based on international research on stages of youth development, the U.S. Agency for International Development defines the different stages of youth as:[2]

- Early adolescence (10–14)
- Adolescence (15–19)
- Emerging adulthood (20–24)
- Transition to adulthood (25–29)

We recommend collecting and reporting age-disaggregated data using the age bands listed above with the addition of 30+ years old and unknown age.

Table 3. Recommended questions to ask about age

Question	Response options
1. What is your birthdate?	[__ __] / [__ __] / [__ __ __ __] *Day / Month / Year* I do not know
2. *If respondent does not know birth date exactly:* What is your age?	[____] Years I do not know

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