





Opinion

Advancing Health Solutions: Practical Considerations for Multipurpose Prevention Technologies in Sub-Saharan Africa's Fight Against HIV, Sexually Transmitted Infections, and Unintended Pregnancies

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Abstract: Sub-Saharan African (SSA) women experience a high prevalence of HIV, sexually transmitted infections (STIs), and unintended pregnancies, necessitating effective, integrated prevention strategies. Multipurpose prevention technologies (MPTs) offer a promising approach to address these overlapping health concerns by providing single products that simultaneously prevent HIV, other STIs, and/or unintended pregnancies. Given the persistent sexual and reproductive health (SRH) challenges faced by women in SSA, in this opinion piece, we explore practical considerations for MPT adoption and scale-up within the region. With this opinion article, we discuss the data on MPT development and identify key factors for successful MPT implementation in SSA. We examine the current MPT pipeline, product features, regulatory challenges, and structural, individual, and community barriers that impact MPT acceptance and usage among SSA women. Successful MPT uptake hinges on designing discreet, user-controlled products and engaging end-users, healthcare providers, and communities in product development and promotion. Structural factors such as robust supply chains, regulatory clarity, and financial support are also essential. Addressing socio-cultural norms, especially partner consent, and strengthening demand creation through community-driven, culturally sensitive strategies are critical for scaling MPTs. In conclusion, MPTs represent a transformative opportunity to reduce the burden of HIV, STIs, and unintended pregnancies in SSA. Strategic, culturally attuned approaches are essential to ensure the acceptability and accessibility of MPTs. Expedited pathways for regulatory approval, collaborative partnerships, and community-centered demand creation will be vital to realize the full potential of MPTs in advancing women's SRH in SSA.



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1. Introduction

African women bear a disproportionate burden of human immunodeficiency virus (HIV), other non-HIV sexually transmitted infections (STIs), and an unmet need for contraception. Of the 39 million people currently living with HIV globally, 20 million are women aged 15–49 years, and the majority reside in sub-Saharan Africa (SSA), where they constitute almost 60% of the burden [1]. Although there have been significant advances in HIV prevention, about 3200 new HIV infections are reported daily, of which about half are in SSA, and of those, almost 46% are in women [2].

STIs significantly increase the risk of HIV acquisition [3]. The World Health Organization (WHO) estimates a daily global incidence of one million STIs, of which 40% are in SSA [4,5]. Again, the 15–49 years age group is at the most substantial risk of acquiring an STI. In this age group, there were an estimated 374 million infections in 2020, with one of the curable STIs, namely chlamydia, gonorrhoea, trichomoniasis, and syphilis. Herpes simplex and human papillomavirus are also transmitted at significantly high numbers [6,7]. Approximately 30% of STIs among women are asymptomatic [8] and may lead to long-term sequelae, including increased incidence of subfertility, ectopic pregnancies, congenital birth defects, stillbirths, chronic pelvic pain, and cervical cancer without the knowledge that they ever had STIs [9]. Besides the physical clinical complications, STIs also have marked psychological and social impacts on the lives of women [10].

SSA women are also at a higher risk of unintended pregnancies compared to their peers from other parts of the world. The region bears the highest proportion of women with an unmet need for contraception, where nearly 25% (about 47 million) of reproductive-age women fall into this category [11]. This results in approximately 14 million unintended pregnancies [12], which may lead to unsafe abortions, as several LMICs have prohibitive laws regarding medical pregnancy terminations [13]. Additionally, HIV incidence and STI prevalence are alarmingly high in young African women seeking effective contraception [14].

In this paper, we provide an overview of multipurpose prevention technologies (MPTs) development and highlight the potential challenges that may arise during their scale-up in sub-Saharan Africa (SSA). Drawing from our experiences, we propose possible strategies to address these challenges. We examine successful approaches to introducing and scaling up sexual and reproductive health (SRH) products in SSA, as well as recent advancements in involving end-users as co-designers of SRH interventions. Additionally, we propose strategies that are likely to succeed in this context. We emphasize the importance of iterative and collaborative engagement among multiple stakeholders, including product developers, healthcare providers, end-users, government health departments, researchers, and regulatory authorities (see Figure 1). The paper concludes with a call to action.

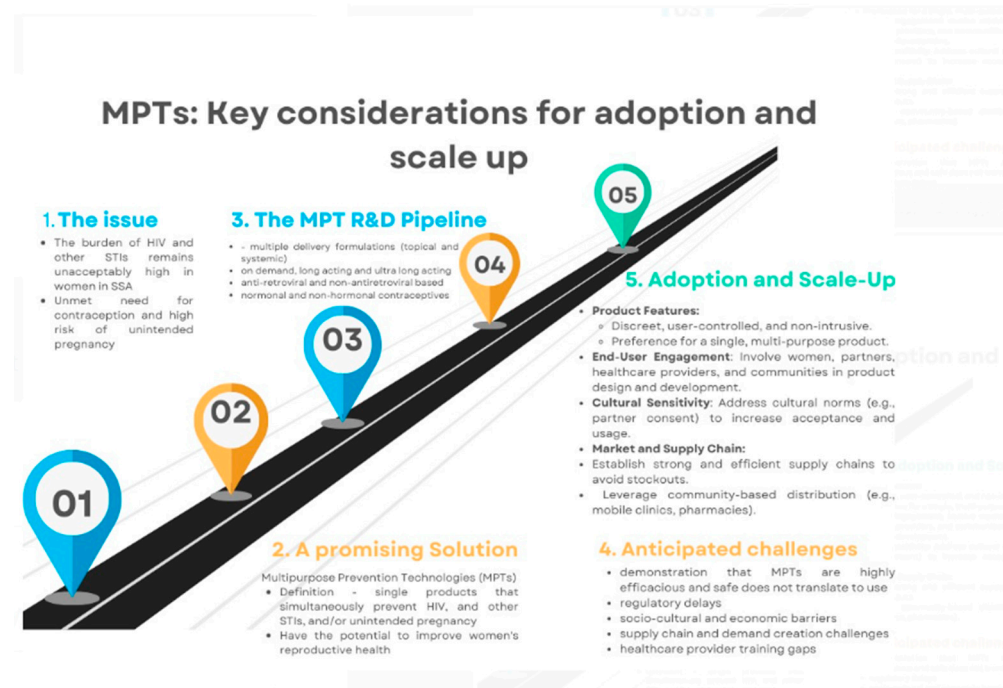


Figure 1. MPTs: key considerations for adoption and scale-up. Designed by the authors.

2. The Need for a Combination of Sexual and Reproductive Health Interventions

Family planning is often African women's primary concern, and contraception is more acceptable than HIV/STI prevention in many of their communities. Hence, most women are more interested in using HIV-prevention methods that also prevent pregnancy [15]. Ninety-six percent of women in the Tablets, Ring, Injections as Options (TRIO) study conducted in Kenya and South Africa and 64% of women in the Dual Prevention Pill (DPP) acceptability study conducted in Zimbabwe expressed a preference for a 2-in-1 product that prevents both pregnancy and HIV versus two separate products [16,17]. Also, 82% of women in the *Share.Learn.Shape* online survey preferred an HIV/STI prevention product with contraception versus disease prevention alone [18]. They cited the appeal of increased simplicity and ease of use of one instead of two separate products, autonomy, reduced clinic visits, discreteness, convenience, and improved sex [16–18]. Women desire single products that simultaneously prevent HIV, other non-HIV STIs, and/or unintended pregnancy—multipurpose prevention technologies (MPTs) [19]. The condom is currently the only effective MPT but has some limitations; African women may not always be able to negotiate for correct and consistent condom use. While the use of the male condom was reported to range from 30% to 41% in Cameroon, Nigeria, and Zimbabwe, the use of the female condom was negligible at rates ranging from 0.1 to 0.3% [20]. Women must, therefore, be provided with a wide array of women-controlled, safe, acceptable, and affordable MPTs.

As of August 2024, there were 21 MPTs in different stages of development, as shown in Table 1 [3,21]. These products include injectables, oral tablets, implants, vaginal rings, gels, inserts, and films. Over 70% of products are still in preclinical development; 57% are indicated for HIV and pregnancy prevention, 19% for HIV, pregnancy, and non-HIV STIs, 19% are for HIV and non-HIV STIs, and 5% are for pregnancy and non-HIV STIs [21].

Table 1. The research and development pipeline for multipurpose prevention technologies (MPTs).

| | Product Name Delivery Method/Duration | Product Developer | Indications | Phase of Development and Comments |
|----|---|--|--------------------|---|
| 1. | Cabotegravir + Levonorgestrel Implantable pellet | CONRAD | HIV and Pregnancy | Early Preclinical Trial: An implantable pellet for delivery of cabotegravir, an integrase strand transfer inhibitor for prevention of HIV [pre-exposure prophylaxis (PrEP)], and levonorgestrel for contraception. |
| 2. | Cabotegravir + Levonorgestrel Long-acting injectable | CONRAD | HIV and Pregnancy | Advanced Preclinical Trial: This is a silica hydrogel-based long-acting injectable delivering cabotegravir for HIV prevention and the contraceptive levonorgestrel for a duration of 3–6 months. |
| 3. | Dapivirine + Levonorgestrel Extended-release monthly intra vaginal film | Magee-Women’s Research Inst. and Fndn., University of Pittsburgh | HIV and Pregnancy | Early Preclinical Trial: This is a monthly vaginal film designed to release dapivirine, a non-nucleoside reverse transcriptase inhibitor, for HIV prevention and the contraceptive levonorgestrel. |
| 4. | Islatravir prodrug (EFdA-P) + progestin (levonorgestrel or etonogestrel) Intra vaginal film | Magee-Women’s Research Inst. and Fndn., University of Pittsburgh | HIV and Pregnancy | Early Preclinical Trial: Islatravir (EFdA) is a nucleoside reverse transcriptase translocation inhibitor of HIV. The progestins–levonorgestrel and etonogestrel are licensed contraceptive agents. |
| 5. | Islatravir (EFdA) + etonogestrel/ethinyl estradiol Intra vaginal ring | University of North Carolina, Chapel Hill | HIV and Pregnancy | Early Preclinical Trial: The intra vaginal ring is manufactured through a novel three-dimensional (3D) printing process that allows customization of the delivery platform to facilitate sustained drug delivery intra vaginally. The progestins–etonogestrel/ethinyl estradiol are licensed contraceptive agents. |
| 6. | Islatravir (EFdA) or lenacapavir + etonogestrel Long-acting refillable nanofluidic implant (NanoMPI) Sub-cutaneous implant | University of Washington Methodist Hospital Research Institute (HMRI) | HIV and Pregnancy | Early Preclinical Trial: The goal is to develop a long-acting delivery implant of etonogestrel and islatravir/lenacapavir with a 2-year release duration for pregnancy and HIV prevention. Anticipated to have good adherence. Lenacapavir is an HIV capsid inhibitor and viral entry inhibitor. |
| 7. | Low-profile copper IUD Intra uterine device | University of Washington | HIV and Pregnancy | Early Preclinical Trial: Copper intra uterine device with antiretroviral drug for pregnancy and HIV prevention. |
| 8. | Etonogestrel/ethinyl estradiol/Qgriffithsin (EEQ) Intra vaginal ring (IVR) | Population Council, Oak Crest Institute of Science | HIV and Pregnancy | Early Preclinical Trial: 90-day pod-type IVR. The pod design (multiple polymer-coated drug cores) allows for the sustained vaginal delivery of multiple drugs or agents with varying physicochemical properties. Griffithsin is a plant-based non-antiretroviral HIV entry inhibitor that binds to the HIV envelope glycoproteins and blocks virus entry into target cells. Anticipated to help decrease the emergence of ARV-resistant HIV, reduce the risk of HIV transmission, and address common issues of irregular uterine bleeding associated with the use of progestin-only products. |
| 9. | Monoclonal antibody (mAb) + enofovir disoproxil fumarate (TDF) Intra vaginal ring (IVR) | Oak Crest Institute of Science, Univ. of North Carolina, Chapel Hill | HIV and Pregnancy | Early Preclinical Trial: The nonhormonal monoclonal antibody inhibits sperm motility through mucus, preventing fertilization of the ovum. TDF is a nucleotide reverse transcriptase inhibitor used for HIV prevention. |

Table 1. Cont.

| | Product Name Delivery Method/Duration | Product Developer | Indications | Phase of Development and Comments |
|-----|--|--|--|---|
| 10. | Dolutegravir/cabotegravir and etonogestrel/medroxyprogesterone acetate Injectable in situ forming implant | University of North Carolina, Chapel Hill | HIV and Pregnancy | Early Preclinical Trial: Dolutegravir (DTG) and cabotegravir (CAB) are antiretroviral drugs, and medroxyprogesterone acetate (MPA) is a contraceptive. First-in-line, ultra-long-acting MPT that offers durable and sustained protection from HIV transmission, high efficacy of contraception, increased user compliance, and the ability to be removed. It consists of a liquid MPT formulation utilizing excipients that form a biodegradable depot after subcutaneous injection (in situ forming implant (ISFI)). |
| 11. | Griffithsin (GRFT) Fast-dissolving Insert (FDI) vaginal insert | Population Council | HIV, Herpes Simplex Virus-2 (HSV-2), and Human Papilloma Virus (HPV) | Pre-formulation stage: The Griffithsin (GRFT) fast-dissolving insert (FDI) is an on-demand HIV prevention product designed for women and girls, including pregnant and breastfeeding women. This insert is safe, discreet, user-controlled, and portable. It can be manufactured in low- and middle-income countries and offers protection against HIV, HSV-2, and HPV, making it suitable for widespread, over-the-counter use. |
| 12. | Monoclonal antibody 2C7 + tenofovir disoproxil fumarate Intravaginal ring (IVR) | MassBiologics, Oak Crest Institute of Science, Planet Biotechnology, Inc., University of Massachusetts | HIV and Gonorrhea | Advanced Preclinical Trial: The C27 monoclonal antibody targets a lipooligosaccharide epitope common in clinical gonococcal isolates, exhibiting complement-dependent bactericidal activity and aiding in the clearance of vaginal gonococcal colonization in mice. This epitope is being studied as a potential candidate for an antibody-based vaccine. Tenofovir Disoproxil Fumarate is a nucleotide reverse transcriptase inhibitor. |
| 13. | Dapivirine + pritelivir + levonorgestrel Intravaginal ring (IVR) | University of North Carolina, Chapel Hill | HIV, Pregnancy, and HSV-2 | Early Preclinical Trial: Pritelivir is a novel viral helicase-primase inhibitor active against HSV. The IVR utilizes the novel 3-D printing process. |
| 14. | Anti-viral peptide + Soluble adenylate cyclase inhibitor Intravaginal ring (IVR) | Oak Crest Institute of Science | HIV, Pregnancy, HSV-1, HSV-2, and HPV | Advanced Preclinical Trial: Non-antiretroviral/non-hormonal ring. Made from soft, flexible silicone elastomer and has two lobes for releasing two novel active ingredients—an antiviral peptide targeting HIV, HSV, and HPV, and a hormone-free contraceptive, soluble adenylate cyclase inhibitor, that prevents sperm movement and its ability to fertilize eggs. |
| 15. | Organic acids + Q-Griffithsin (QGRFT) Fast dissolving vaginal insert | Population Council | HIV, Pregnancy, HSV-2, Bacterial Vaginosis (BV), Chlamydia, and Gonorrhea | Non-hormonal contraceptive MPT containing organic acids + Q-Griffithsin (QGRFT): The candidate organic acids reduce vaginal pH in the presence of semen, resulting in the deactivation of sperm and bacteria. QGRFT is a strong non-antiretroviral HIV inhibitor. |
| 16. | Copper, Zinc, and Lactide Intravaginal ring (IVR) | Population Council, Queen's University Belfast, Weill Cornell Medical College | HIV, Pregnancy, HSV-2, BV, Chlamydia, and Gonorrhea | Early Preclinical Trial: Contains non-hormonal contraceptives and non-antiretroviral HIV inhibitors. Copper, zinc, and lactide possess spermicidal properties and exhibit broad antibacterial and antiviral activity against various viruses and bacteria. Additionally, the release of lactic acid may enhance vaginal health by maintaining an acidic pH and alleviating symptoms related to bacterial vaginosis. |

Table 1. Cont.

| | Product Name Delivery Method/Duration | Product Developer | Indications | Phase of Development and Comments |
|-----|---|--------------------|------------------------------------|--|
| 17. | Dapivirine + Levonorgestrel Intravaginal ring (IVR) | Population Council | HIV and Pregnancy | Phase 1 Clinical Trial: The ethylene vinyl acetate core-sheath vaginal ring slowly releases the antiretroviral drug dapivirine and the contraceptive hormone levonorgestrel. Women insert the ring themselves and replace it every three months, providing a user-controlled, long-acting dual prevention method. Phase I trials showed no safety concerns and high plasma levels of the combination. A Phase Ib trial is currently ongoing with the National Institute of Child Health and Human Development. This dapivirine–levonorgestrel ring is a natural extension of the dapivirine vaginal ring and should have a relatively quick path to regulatory approval. |
| 18. | Tenofovir disoproxil fumarate + emtricitabine + levonorgestrel + ethinyl estradiol Dual prevention pill (DPP) TELE Oral Tablet | Viartis | HIV and Pregnancy | Viartis Bioequivalence Clinical Study: Combination of two already-approved products—Tenofovir Disoproxil Fumarate and Emtricitabine for oral PrEP and ethinyl estradiol and levonorgestrel for contraception. Emtricitabine is a nucleoside reverse transcriptase inhibitor. No efficacy trials are required; only bioequivalence studies are necessary. Anticipated to have an expeditious regulatory approval pathway. |
| 19. | Tenofovir alafenamide (TAF) + elvitegravir (EVG) Topical vaginal and rectal insert | CONRAD | HIV and HSV-2 | Phase 1 Clinical Trial: TAF is a nucleoside reverse transcriptase inhibitor with a lower risk of bone and renal toxicity compared to TDF. EVG is an integrase strand transfer inhibitor. The TAF/EVG insert is a solid, tablet-like dosage form for on-demand vaginal or rectal use, offering dual protection against HIV and potentially HSV-2. Studies in non-human primates showed strong protection against SHIV exposure when dosed vaginally or rectally. Phase I trials in 2019 and 2021 demonstrated the insert’s safety, pharmacokinetics (PK), and pharmacodynamics (PD), with promising results. It was also tested for acceptability in international studies. Phase I studies (MATRIX-001, RITE-PrEP) are exploring its safety, PK, and multiple dosings. MATRIX-004 is planned to start in early 2025. A new insert generation with antibacterial properties is in preclinical development. |
| 20. | VivaGel® Vaginal gel | Starpharma Ltd. | HIV, HSV-2, HPV, and BV | Phase 3 Clinical Trial (US): Registered internationally. VivaGel (SPL7013 or astodimer sodium), a mucoadhesive gel that prevents bacteria from attaching to the vaginal lining and is also antiviral, is designed to treat and prevent bacterial vaginosis (BV) and sexually transmitted infections. |
| 21. | Yaso-Gel Vaginal gel | Yaso Therapeutics | Pregnancy, HSV-2, and Gonorrhea | Phase 0 Clinical Trial: The gel contains polyphenylene carboxymethylene (PPCM), a condensation polymer that demonstrates both contraceptive and antimicrobial properties. It has shown activity against several sexually transmitted viruses, including HIV and herpes simplex virus, and exhibits potent antimicrobial activity against <i>Neisseria gonorrhoeae</i> in murine models. |

This table was designed by the authors gathering and checking information pieces delivered in the references included in the review (in particular, MPT 1010).

This diverse portfolio of MPTs in development will potentially revolutionize the health of African women in the future and is well-aligned with the WHO’s public health priority of the triple elimination initiative to address mother-to-child transmission of HIV, syphilis, and hepatitis B [22].

When MPTs are eventually rolled out at the population level, it will be important for all stakeholders involved in implementation to consider these challenges and recommendations to ensure that they timeously reach the populations where they are most needed.

For expeditious MPT delivery at scale, individual, community, and structural barriers; product- and market-related factors; regulatory approval pathways; intellectual property rights; service delivery mechanisms; and supply chains must be considered early in the research and development (R&D) process [3].

3. Challenges and Considerations for Scale-Up

3.1. Individual Factors and Engagement of Product End-Users

SSA women are heterogeneous regarding culture, religion, social norms, and literacy rates. Polygamous marriages, partners with multiple sexual partners, and socio-economic disparities place some women at a differentially high risk of the acquisition of HIV/STIs and unintended pregnancy. Some women need first to seek permission from male partners before they can use a sexual reproductive health (SRH) product [18]. A study conducted among pregnant and breastfeeding women in Zambia found that the majority of women would not use HIV prevention methods, such as HIV pre-exposure prophylaxis (PrEP), if their partners did not approve [23]. MPTs must meet the varied needs of women. Discrete products do not require partner approval or involvement, do not require partner approval or involvement, and have no impact on sexual intercourse or menstruation are more likely to be preferred, accepted, and consistently used. While these positive product attributes are important, they will not automatically lead to widespread adoption and sustained use of MPTs in SSA. Implementation research will be crucial for scaling up MPTs. Marketing strategies in the region must consider patriarchal and cultural norms and should be designed to engage women, men, and significant others. Input from women, their sexual partners, key informants, and healthcare providers (HCPs) should be solicited throughout the MPT R&D process as much as possible.

Fear of side effects, unfamiliarity with product dosage forms (e.g., vaginal rings and films), unfavorable product packaging and size, as well as myths and misconceptions, may be barriers to the uptake of MPTs in SSA [16]. Product developers should address product-specific concerns early, and this, together with de-medicalization and innovative packaging, will likely improve the acceptability and uptake of MPTs [2]. Recent findings from the DPP pilot/formative acceptability studies showed that young women did not like the bulky packaging of the large, co-encapsulated DPP, which resembled a box of condoms and was apt to result in social harm or intimate partner violence. Additionally, though they preferred a DPP vs. two separate products, they recommended that the size be smaller [24,25].

Under MATRIX, researchers from the University of Pittsburgh and Magee-Womens Research Institute (MWRI) are developing two first-ever monthly vaginal films—one containing dapivirine for the prevention of HIV and the other containing both dapivirine and evonorgestrel, a contraceptive hormone [26]. Feedback from the QUATRO Study, which examined end-user preferences for and choices among four vaginally delivered HIV prevention methods among young women in South Africa and Zimbabwe [27] and in-person stakeholder consultations, was the basis for conducting MATRIX-002, a trial to assess acceptability and safety of two placebo prototype vaginal films, to determine whether film shape (rounded corners versus square corners) mattered to women who actually use the film [26,28]. Preliminary results from MATRIX-002 show that women found both films easy and comfortable to use, and partners reported no interference with sexual intercourse. Findings from MATRIX-002 will inform the film to be evaluated in a first-in-human study of the dapivirine film and continued development of the dual-purpose film and the MPT field at large [28].

As part of its development of a dual-purpose intravaginal ring delivering an antiviral peptide targeting HIV and a hormone-free contraceptive (item #14, Table 1), the Oak Crest Institute of Science, through the MATRIX Program's Rapid Response Network, has queried potential end-users on the preferred color and durometer of the ring [26].

HCPs who do not have adequate knowledge about an intervention or service are less likely to recommend it to clients. In contraceptive provision, it has been shown that access provides diversification. Still, robust engagement in shared decision-making coupled with HCP capacitation/skills training allows the client's preferences and autonomy to guide the choice and improve continuation rates [29]. To reduce provider bias, HCPs in SSA will need training on all aspects of MPTs, including use, effectiveness, administration, and side effects.

MPTs may burden HCPs more due to the added product-specific training and extra procedures to be conducted. However, in some areas, community health workers already provide contraception and, if adequately trained, could provide some forms of MPTs. More complex MPTs, such as injections and implants, which require laboratory tests and special training for administration, will still require clinic visits and consultation with HCPs. We recommend decentralization and diversification of service provision, e.g., at sexual reproductive health facilities, pharmacies, private practitioners, and outreach/mobile clinics, coupled with self- or point-of-care testing.

3.2. Community Involvement and Demand Creation

Community involvement reflects special cultural practices, diversities, and norms, which are vital in translational research. Engaging target communities as product co-designers and co-implementers will help with counseling messages and programs that are culturally acceptable and appropriate. Robust community involvement, education, and buy-in are pivotal in successfully scaling new technologies.

There is a need to leverage best practices and effective demand-creation strategies from family planning and HIV prevention roll-out programs to avoid unnecessary delays in availing MPTs to women who need them the most. Comprehensive MPT demand creation strategies are beyond the scope of this narrative. However, SSA needs to review strategies that worked well for other SRH interventions to inform the marketing of MPTs. Sustainable demand-creation activities should be tailored to the different geographical locations and be specific and sensitive to the needs of different communities. Programs should be community-led through partnering with civil society to develop appropriate, culturally sensitive information, education, and communication materials. Messaging should normalize the narrative on HIV, STI and pregnancy prevention and shift from risk reduction to empowerment, taking responsibility for one's health and safe, pleasurable sex. This will create awareness, increase knowledge on MPTs, and address attitudes, beliefs, perceptions, and misperceptions that might adversely affect scale-up.

3.3. Supply Chain Management

Stockouts and other logistical challenges are common with health commodities in SSA [2]. To successfully scale up MPTs, supply chain systems must be established first and put in place to minimize stockouts. Staff will need to be trained in logistics and supply chain management. Different MPT distribution facilities, such as private pharmacies, primary healthcare clinics, and mobile units, should be utilized to reduce travel costs and time commitments for users of MPTs. A study conducted in South Africa revealed that community-based mobile health clinics for the provision of PrEP were acceptable among young women and could potentially increase uptake and continuation [30]. Faith-based organizations and non-governmental organizations will need to be engaged, and where possible, public-private partnerships will be established to ensure hard-to-reach areas receive adequate supplies.

3.4. Regulatory Pathways

The MPT regulatory pathways are not clearly defined yet. This unclear process and the complexity of MPTs with combinations of different drug substances and/or drug delivery devices contribute to the challenges of the regulatory review process, which might delay the registration and availability of MPTs [2,19,31]. There is a need for harmonized regulatory review in SSA, where many national medicines regulatory authorities have limited capacities to review new medicines [2]. ZAZIBONA is a successful collaborative medicines registration initiative in Southern Africa, and the recently established African Medicines Agency (AMA) aims to harmonize Africa's regulatory standards. Applying for registration to national regulatory authorities affiliated with these agencies should simultaneously result in efficient review processes for several countries.

Our past experience shows that involving drug regulatory authorities and providing them with information through the clinical trial phases enables them to review registration applications more expeditiously, as was previously performed in Zimbabwe with the dapivirine vaginal ring (DVR) and long-acting injectable carbogravir (CAB-LA) [26]. Product developers can also leverage obtaining WHO pre-qualification and approval from stringent regulatory authorities such as the US Food and Drug Administration, which are used as reference authorities by some national authorities in SSA, resulting in a more efficient review process. This regulatory pathway also enabled Zimbabwe to register the DVR and CAB-LA timeously, ahead of other countries [32].

The prior approval of individual medicines or medical devices that make up an MPT by regulatory authorities provides valuable evidence supporting the safety and efficacy of the combination product, thereby streamlining its evaluation process. One such product of interest is the dual prevention pill, which combines approved tenofovir/emtricitabine (TDF/FTC) for HIV prevention and levonorgestrel/ethinyl estradiol for combined oral contraception. Given that these components are already registered, the DPP is expected to follow a streamlined regulatory pathway, requiring only bioequivalence testing rather than full efficacy trials. Additionally, WHO/CDC guidelines already recommend the concurrent use of PrEP and combined oral contraceptives, further supporting the DPP's potential.

Collaborating with the Population Council, we recently completed pilot acceptability studies of the over-capsulated DPP. Although this over-capsulated pill is not the final product that will go to market, results from the acceptability studies share important end-user insights that will be useful in future research and DPP rollouts. Lessons learned from the pilot study will be instrumental in the conduct of the planned HPTN 104, a study evaluating daily adherence to a single DPP compared with daily adherence to two separate pills of FTC/TDF + combined oral contraception for pre-exposure prophylaxis and pregnancy prevention in people of childbearing potential [33].

We reiterate the urgent need to scale up MPT programs and strengthen markets across SSA. Overcoming the region's challenges and accelerating product delivery will require coordinated short-term and long-term actions from multiple stakeholders. A central strategy in this effort is our active participation in The DPP Project, which seeks to accelerate the development and introduction of MPTs, and in The DPP Consortium, which acts as a collaborative platform, bringing together donors, governments, implementing partners, and civil society to shape priorities and guide the planning for the DPP rollout.

3.5. Financial Support

Before 2009, the development of MPTs for resource-limited settings (RLSs) like SSA had been slow and underfunded. There was no major investment in MPT research by large pharmaceutical companies because MPTs are targeted mainly for RLSs as low-cost products. Hence, the minimal financial returns may not warrant huge investments poured

into R&D. Iterative MPT design to support basic research, discovery, and development research, and post-marketing surveillance must be employed to ensure that MPTs not only reach the market but are also affordable, acceptable, safe, and accessible [21,31].

4. Conclusions

The current triple burden of HIV, other STIs, and unintended pregnancies in SSA women remains unacceptably high. MPTs have numerous benefits and have the potential to impact women's sexual reproductive health positively. A reduction in unintended pregnancies will result in fewer unsafe abortions and associated complications. Child health will also benefit from increased birth spacing, resulting in lower rates of preterm births, low birth weight, and under-5 mortality. The reduction in HIV and STI infections will enhance women's overall health and decrease the likelihood of mother-to-child transmission. Healthier women and children will contribute to economic benefits, including lower healthcare costs and fewer missed workdays for women. Moreover, with MPTs, women will be empowered, enabling young women to remain in school longer and contribute more significantly to the economy.

Seamless delivery at scale requires soliciting input from end users, the community, and regulators at every stage of product development. The MPT R&D process must utilize public-private partnerships and employ an iterative design to ensure the timely availability of products to populations that need them the most.

5. Call to Action

The time for setting targets without achieving them is over. African women continue to suffer the devastating impacts of HIV, other STIs, and unintended pregnancies. In sub-Saharan Africa alone, in the hour it takes to read this article, approximately 18 new HIV infections will occur among adolescent girls and young women, 43,000 curable STIs will be acquired by adults aged 15–49, and 1600 unintended pregnancies will occur among women of reproductive age. The need for preventive action to address this triple burden is urgent and cannot be delayed any longer.

When MPTs have been proven safe, acceptable, and efficacious, it is critical that they are also accessible, deliverable, and affordable to those who need them most. The time to act is now. We must ensure these products are swiftly and equitably distributed to the women who will benefit most from them. It is time to turn the commitments of policymakers, product developers, regulatory authorities, health departments, and all other stakeholders into concrete actions. Together, we can make a lasting difference and address this critical health crisis without further delay.

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