

Commentary

Paving the Way for Multi-Purpose Technologies: Programming for Choice and Strengthening Integrated HIV and Sexual and Reproductive Health Services

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Addressing multiple health needs with a single product, Multipurpose Technologies (MPTs) have generated significant interest given their potential impact in countries and among populations that face concurrent epidemics with high HIV burden and incidence of Sexually Transmitted Infections (STIs), alongside a high unmet need for voluntary Family Planning (FP). Ensuring the successful roll out of MPTs will require a conducive enabling environment along the continuum of discovery to delivery, from establishing pathways for regulatory approval to demand creation and distribution at the point of

care. Yet, investments in strengthening platforms to deliver promising biomedical products are often an afterthought, occurring late, if at all, in introduction planning. Maximizing the potential of MPTs will demand that: 1) product developers anticipate and address complexities of delivery in the research stage and incorporate potential user needs, preferences, and lifestyles in product design; and 2) donors, governments, community leaders, and potential MPT users collaborate to allocate sufficient resources to integrate health services and prepare for a reality when MPTs are available. Growing momentum and political will for strengthening primary health care offers a unique opportunity to maximize the use of health and development funds to support integrated care, and by extension, facilitate the roll-out of MPTs [1,2].

The current portfolio of MPTs in development include prevention methods for HIV, STIs, and contraception through diverse modalities, such as pills, rings, injections, implants, films, and inserts, all of which could benefit and appeal to various populations [3,4]. These products could be of particular benefit to Adolescent Girls And Young Women (AGYW), who are often at highest risk for HIV, STIs, and unintended pregnancy and, in countries with overlapping epidemics, and high rates of gender-based violence [5]. With Africa projected to account for half of the world's population growth through 2050, there will be greater numbers of young people in the region who could potentially benefit from MPTs [6,7]. Adolescent girls and young women in Sub-Saharan Africa (SSA) are disproportionately affected by HIV with nearly two-thirds of new infections occurring in this age group [8]. In addition, approximately 10 million unintended pregnancies occur each year among 15-19 year olds in SSA [9, 10]. Based on a pooled analysis of Demographic and Health Survey data in a subset of 30 countries in SSA, unmet need for FP is 27% among youth aged 15-24 [11]. In SSA, high HIV incidence and burden overlaps with high unintended pregnancy and adolescent birth rates and STI prevalence [12-14]. Clinical trials on HIV biomedical prevention in East and Southern Africa also report high HIV incidence among AGYW [15-17]. Similarly, recent Pre-Exposure Prophylaxis (PrEP) trials to prevent HIV have reported high STI incidence with chlamydia incidence ranging from 27% to 53% per 100-person years and gonorrhea incidence from 11% to 20% per 100-person years among study participants [18]. Growing rates of multi-drug resistant gonorrhea in low- and middle-income countries also underscores the potential benefit of an MPT with an indication for the prevention of gonorrhea [18-20].

These trends underscore the need for products and integrated services that can meet multiple health needs. Integration of HIV and Sexual And Reproductive Health (SRH) services provide women of reproductive age access to a range of services that typically encompass HIV testing, prevention and treatment, maternal health, and contraception and include condoms, STI screening and treatment, GBV screening, and post-violence care. These services can be implemented through a one-stop shop model by the same provider in the same room, or through referrals to different providers within or across facilities. While HIV and SRH integration spans both prevention and treatment services, the majority of MPTs in development focus on pregnancy and HIV prevention, therefore this commentary places a stronger

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emphasis on integrating HIV prevention within SRH services. Providing cohesive care across facility, community, and online platforms could help to more comprehensively address multiple health needs and improve the quality of person-centered care and cost-effectiveness. Strengthening HIV and SRH integration may accelerate the roll-out of an MPT, once available, and could improve access to related services and health outcomes.

While the epidemiological need for an MPT is clear, the typical path from product development to licensure and access, to delivery is on average 12-15 years long; [21] therefore, a suite of viable, scalable, acceptable, and affordable options may only be available in the distant future. Investment in Research and Development (R&D) for MPTs remains limited, although there is evidence of growth in the last three years. In 2020, funding for MPTs was estimated to be \$48M and primarily focused on drug development [22]. In addition, the National Institutes of Health recently released a call for proposals for MPT development, and private foundations have committed funds to MPT research [23,24]. However, of the 24 products in development, 20 are in the preclinical stage, [25] suggesting that the majority of these options will be available on average 10-20 years from now, assuming key milestones, including regulatory approvals, are met. While MPTs have the potential to shape the future of biotechnology for prevention, these products are many years away from making a difference in the lives of young people, many of whom face barriers to accessing existing services and products. Although many MPTs (excluding the dual prevention pill) may not be available in the near future, advancing HIV and SRH integration now would help to lay the groundwork for an era when MPTs are widely available. This includes developing more integrated guidance, investing in provider training and education, measuring the effectiveness of different integrated models, engaging users in product and program design, integrating data, and supply chain systems, all of which could improve access to integrated care in the near-term.

Demand, access, and delivery considerations for MPTs must be an integral part of the research and development phase as well as product introduction planning. Method efficacy often is the most salient criteria used to assess the potential public health impact of innovative biomedical prevention products. User preference for specific and composite product attributes and use-effectiveness which measures correct and consistent use over time also drive population benefit [7]. However, ease of delivery for potential users and providers is a product feature that has been less emphasized until recently. From a user perspective, where a product can be accessed (fixed or mobile clinic, pharmacy, private sector, peers) and who can administer it (self or provider-dependent) and resupply requirements (number of refills, prescription required, etc.) are key considerations. Given that fertility intentions and HIV risk are dynamic, it will also be critical that individuals receive appropriate counseling on stopping and restarting methods safely and switching methods due to adverse effects or changes in circumstances, lifestyle, and health needs. Identifying which providers would administer MPTs in a non-integrated health system also poses challenges related to training, provider workload, and client follow up. From the provider perspective, dual purpose implants that combine contraception and HIV prevention require providers trained in insertion and removal, thereby limiting which cadre can prescribe and dispense the method and restricts the settings where they can be administered. Removal could be complicated if an individual's risk for acquiring HIV or an STI remains the same, but their fertility desires change or vice versa. Making MPTs available at a

single entry point could undermine the value of an MPT by limiting its reach to clients only seeking either FP, STI, or HIV services. Conversely, training nurses at various entry points in a health facility would require significant investments in training and integrated data systems but would amplify the benefits and reach of integration.

Ease of delivery also refers to the barriers the intended user may face in adopting and sustaining use of a new method. A MPT may be less desirable if it requires routine or frequent attendance at a health clinic, waiting in long lines, and interacting with providers. Yet, there are tools and approaches learned from many years of successful HIV and SRH integration that can be applied widely to minimize barriers to efficient, integrated person-centered care. Addressing the historical and systemic barriers to integrated SRH care, namely, verticalized funding streams as well as supply chain and data systems, health workforce planning and training, and inadequate infrastructure [26,27] are essential to maximize the impact of existing and future HIV/STI prevention and contraceptive options, and to realize the promise of MPTs. Providing a range of options and expanding indications for use are critical first steps in the MPT equation; building systems and platforms to maximize access to and use of MPTs is equally essential, but also complex and under-funded. Strengthening and scaling integrated SRH services prior to MPT introduction may accelerate access once these promising products receive regulatory approval and is vital to meeting the prescient health needs of millions of young people, particularly AGYW. Integrated SRH services align with user preferences and may also improve health outcomes. A recent systematic review of integrated HIV services reported improved HIV outcomes as well as higher use of non-HIV services in integrated models of care [28]. Ensuring that public and private sector HIV and SRH services address young people's needs for comprehensive and tailored care does not need to wait for the era of MPTs.

Global guidance around adolescent-responsive health systems also underscores the importance of offering HIV, SRH, and Maternal, Newborn and Child Health (MNCH) services together as an integrated package of care, which helps to address the needs of adolescent couples and parents [29]. Primary health care and SRH services have the potential to be a gateway for greater access to HIV prevention, especially for AGYW, who may use contraception to avoid unintended pregnancy, but are unclear of their risks for acquiring STIs and HIV and opportunities to access integrated care [30]. Several studies show that AGYW desire integrated, comprehensive, and flexible SRH services that are centered to their preferences and life situations [31,32]. Additional studies show that initiation of oral PrEP is higher when integrated with FP services, and integrated delivery can also increase contraceptive prevalence and reach new contraceptive users as observed in South Africa [33,34]. A recent qualitative study in Zambia documented that AGYW prefer one-stop shop clinics where they can access HIV and pregnancy testing, along with a range of HIV prevention and contraceptive methods [35]. Similarly, one-stop shop service delivery models in Zimbabwe found that AGYW clients received double the number of SRH services (FP, STI screening and treatment, HIV prevention), including PrEP initiation and referrals for HIV care and treatment, than clients who received vertical FP, STI, and HIV services before the intervention [36].

The use of MPTs may also benefit women attending Antenatal Care (ANC) or Postnatal Care (PNC) who face higher risk of HIV/STI acquisition and/or are intending to use contraception. In many high HIV burden settings, ANC coverage is high, and in East and

Southern Africa, 20% of vertical HIV transmission cases are due to incident HIV infections during pregnancy or breastfeeding [37]. Family planning services, and increasingly HIV prevention and treatment, are routinely offered through MNCH platforms and have generated important lessons on effective HIV and SRH integration which can be leveraged to administer MPTs. Prenatal consultations offer an opportunity to reach millions of women living with or at risk of acquiring HIV with education as well as HIV testing to increase prevention. A recent study in Zambia showed that providing information about HIV prevention in ANC waiting rooms increased clients' interest and awareness of PrEP [38]. STI screening and linkage to treatment are also routinely provided in ANC, presenting a critical opportunity to prevent vertical transmission of both syphilis and HIV.

There are multiple opportunities to advance integrated service delivery to women of reproductive age as MPT R&D continues to be pursued. Specific strategies that have been implemented and can be scaled to streamline HIV services into FP include: 1) routinely offering HIV prevention education, testing, condoms, and where feasible, PrEP, within FP services in geographic areas with high HIV incidence; [39-41] 2) expanding and funding HIV self-care options (i.e., self-testing) in FP; [42] and 3) co-delivering contraception and PrEP during the same visit. Continuing to invest in these strategies will help to build a stronger foundation for the introduction of MPTs, help to ascertain user preferences and experiences, and ultimately, strengthen integrated care. While full integration of HIV and SRH services may require significant investment and time, these strategies are, in the short-term, feasible and cost-effective with some additional provider training and time, while reducing client burden [42]. Adding self-care options into the portfolio of MPTs in development can also enable women to discreetly use either or both contraception and HIV prevention methods. Self-care options for HIV and pregnancy testing and contraception (i.e., condoms, injectables, emergency contraception, over-the-counter oral pills) are feasible to deliver, acceptable and have become more widely available in the past five years, pointing to the potential to develop new products, including MPTs, that are provider- as well as self-administered [43-45]. Co-delivery of HIV testing and pregnancy tests, PrEP, contraceptive methods and STI screening could increase awareness of HIV status and dual method use. Bundling and packaging existing products for women's health at health facilities, pharmacies/drug shops and community outreach points would ease client burden, improve access and client satisfaction, and potentially reduce stigma. As programs shift to multi-month dispensing for antiretrovirals, synchronizing refills for HIV treatment or PrEP and contraception and coordinating follow up visits is another promising strategy to increase convenience and the likelihood of adherence and continuation.

Global efforts to ensure that clients have maximum choice in their health care decision-making are underway through national and donor supported programming, with particular attention being paid to person-centered care (including self-care approaches) and a wider method mix of contraception and HIV prevention options. MPTs will help to improve client choice by expanding clinical interventions and products and improving integrated SRH provider and self-care managed approaches and the platforms that are used to deliver them. USAID as well as other donors are investing in implementation science to better understand the uptake of oral, intravaginal (dapivirine ring), and injectable PrEP among different subpopulations including AGYW, pregnant and breastfeeding persons and female sex workers [46,47]. The findings from ongoing implementation research are

expected to add to the body of evidence on the impact of offering a range of methods within integrated care. Program strategies that emphasize strengthening primary health care are also an important avenue for facilitating and financing the integration of HIV and SRH services. Numerous donors and partners, including USAID, are developing recommendations and action plans to fortify health systems more broadly, while ensuring the quality of services like HIV and FP. This presents an opportunity to ensure that both HIV and SRH are intentionally and judiciously woven into the fabric of primary health care, where the majority of individuals access prevention services.

Conclusion

MPTs for HIV and STI prevention and contraception have the potential to substantially reduce new HIV and STI infections and unintended pregnancies, if these products are affordable, and can be accessed and effectively used. Alongside investment in MPT development, there is a pressing need to optimize existing solutions to provide more integrated care for women and young people, particularly AGYW. Historically, the introduction of novel HIV, STI, and contraceptive products has shown that one product alone, even an MPT, will not remove all barriers to access and acceptability. Health care systems and providers need to be equipped to provide clients with various options as their needs change throughout their life course. In the long-term, strategies that address gender norms and increase partner and community acceptance to create a more supportive environment for MPT use are equally critical.

With growing momentum to strengthen primary health care, there is an unprecedented opportunity to build on and integrate existing health platforms that will enhance the potential impact of MPTs. This includes the adaptation of service delivery models as well as infrastructure to ensure privacy and confidentiality, training for a wider range of providers and integrating supply chain and data systems. The multiple epidemics and unmet need for contraception affecting women and young people cannot afford to wait for a future when MPTs are available before services are designed and strengthened to meet their needs. Investing in integrated, holistic care today will help to realize the game-changing promise of MPTs tomorrow.

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Conflict of Interest

The authors have no conflict of interest to declare.

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