

Time to Put Women-Controlled Multipurpose Prevention Technologies for Their Protection in Full Gear

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Abstract

In this concise communication, we shed some light on the urgent need to support and fund women's sexual and reproductive health research in the area of STIs/HIV/unintended pregnancy prevention that is largely underserved. We stress the need for developing affordable safe and effective innovative vaginal products under the control of women to protect themselves against unintended pregnancy and sexually transmitted infections (STIs). We highlight the importance of complete and homogenous coverage of the vaginal and cervical mucosae of women by the vaginal product for optimal protection, especially against biofilm vaginal infections. Finally, we focus on the necessity of equity for women and the ease of access to such woman-controlled products for the benefit of the whole society.

Keywords: Women's health, Unintended pregnancy, Non-hormonal vaginal contraceptives, Sexually transmitted infections (STIs)/HIV, Multipurpose prevention technologies (MPTs), Health equity

The Need for Affordable Woman-controlled Protection

Women's sexual and reproductive health has been marginalized for many years, and it worsened during the COVID-19 pandemic. The majority of government funds were directed to the development of vaccines and treatments against SARS-CoV-2. Of the 37 U.S. FDA-approved drugs in 2022, only 2 were for women-specific health conditions [1]. This article focuses on women-controlled protection with vaginally self-administered products for women to protect themselves against unintended pregnancy and STIs. Hence, it is not about hormonal or other birth control methods that do not protect against STIs. Male and female condoms are examples of preventing both unintended pregnancy and STIs, but difficulties with consistent use is well recognized [2]. In our opinion, many large pharmaceutical companies and investors are shying away from this area (women-controlled protection) thinking that it gives low return on investment needed for

research and clinical development of such woman-controlled products. However, it is estimated that a \$300 million investment into research focused on women could yield a \$13 billion economic return [3]. Yet, women's health research area for protection against HIV/STIs and unintended pregnancy with women-controlled products is still underfunded, under researched, and underserved.

Earth population just hit 8 billion people on the 15th of November 2022. Overpopulation is continuing to worsen environmental degradation, overexploitation and depletion of natural resources, and it also exacerbates climate change. Population control through family planning might therefore help humankind live a more pleasant future. In its official report of the State of world population- Seeing the unseen- The case for action in the neglected crisis of unintended pregnancy of 2022, the United Nations Population Fund (UNFPA) stated that nearly half of all pregnancies, totalling 121 million each year worldwide, are unintended and also stated that it represents

a global crisis [4]. Therefore, educating and empowering women and girls with more affordable and accessible choices that are safe, effective, and under their control to prevent unintended pregnancy and to prevent sexually transmitted infections (STIs) including HIV will give them confidence to avoid a risky sexual encounter (unprotected sex, sex with an infected person, sex with a person who has multiple partners, etc.), premature sexual debut, and early or unintended pregnancy [5]. Such women-controlled and women-initiated products act as microbicides (to protect women against HIV/STIs) and spermicides (to protect women against unintended pregnancy) that are also called multipurpose prevention technologies (MPTs) [6]. Many women have contraindications to use or do not want to use hormonal contraceptives. Affordable non-hormonal contraceptive choices are hence needed to protect women around the world in all economic settings. Women need choices, access, and control regarding their sexual and reproductive health. The price of a single use (on-demand) vaginal product (pre-filled vaginal applicator) should be less than 5\$ per each protected vaginal intercourse, not costing more than 20\$ as the price for the first FDA-approved vaginal contraceptive. Every woman deserves to be protected, and every child deserves to be wanted and loved.

Women have large (~80 cm²) unprotected vaginal and cervical mucosal surface. Because of their anatomy, women are at higher risk of contracting STIs including HIV compared to men [5]. In addition, according to the World Health Organization (WHO), there are more than one million STIs acquired every day worldwide, the majority of which are in young women and are asymptomatic [5]. Women have about 75% of all Chlamydia infections. It is mostly silent infection (asymptomatic) and can cause important consequences including pelvic inflammatory disease and infertility. Furthermore, human papillomavirus (HPV) infection is associated with over 311,000 women's deaths of cervical cancer each year [5]. In the 2019 STDs surveillance report of the United States Centers for Disease Control and Prevention (U.S. CDC), STIs hit record high for fifth year between 2015 and 2019 with 2.5 million cases of curable STIs. Only one-third of men in the U.S. who are aged 15-44 used condoms in their last sexual intercourse in the previous 12 months, hence putting women at risk [7]. Therefore, it is important to give women control of their own protection and access to innovative affordable on-demand vaginal products to protect themselves against HIV/STIs and unintended pregnancy.

The Importance of Vaginal and Cervical Mucosal Complete Coverage for Optimal Protection

The rather few medical researchers and pharmaceutical companies working on the development of non-hormonal vaginal contraceptive products that also protect against HIV/STIs should realize that the tool for effectively delivering such products intravaginally is as important as the pharmaceutical

product itself. Using conventional vaginal applicator with a single apical hole will deliver the vaginal product to cover only the cervix area offering contraceptive protection only, leaving the large vaginal mucosal surface unprotected against HIV/STIs. This (using conventional applicator) can lead to failure of potential products in very costly Phase III clinical studies that already showed promising protection against HIV/STIs in laboratory studies. In addition, vaginal biofilm infections cover most vaginal and cervical mucosae that is more difficult to treat. Hence, it is important to spread the protective treating vaginal product homogeneously and sufficiently over all vaginal and cervical mucosae for optimal efficacy and protection. Furthermore, up to one-third of women have recurrent bacterial vaginosis that need optimal vaginal protection to reduce that rate. As such, an innovative vaginal applicator with multiple apical and lateral holes to deliver content uniformly covering the whole vaginal and cervical mucosae of women would ensure optimal mucosal coverage and protection against both STIs and unintended pregnancy [8]. Such unique vaginal applicator design has already proven its superior performance (compared to conventional vaginal applicator) in clinical trials and was already used by women in more than 30,000 vaginal applications [8,9].

Equity and Ease of Access to Woman-controlled Products

Men have easy and non-medicalised access to over the counter (OTC) male condoms that protect against HIV/STIs and unintended pregnancy. Yet, women need appointment, doctor's visit, and a prescription to get a vaginal product that offers similar protection against unintended pregnancy and STIs. Such health inequity makes it difficult for women to access those essential protective products, especially those women in need who are vulnerable and unable to negotiate condom use with their male sexual partners. Those vaginal products would have a huge impact on the whole society. It is time for regulatory authorities to reconsider making such woman-controlled products freely available over the counter (OTC), or at least behind pharmacy counter (controlled by pharmacist, but not needing doctor's visit and prescription) to give women easier access and enable them control their own protection as men do. In support of our suggestion, in May 2023, the FDA advisors unanimously (in a vote of 17 to 0) endorsed making birth control pill (progestin only) available without a prescription [10]. This is a landmark in women's sexual and reproductive health that will make the contraceptive pill more available and accessible to women seeking to prevent unwanted pregnancy, especially those who have difficulty obtaining doctor's appointment and women from marginalized minorities. Two-months later, on 13th of July 2023, the US-FDA approved FIRST non-prescription (OTC) daily oral hormonal contraceptive. Finally, the committee on health care for underserved women of the American College of Obstetricians and Gynecologists reviewed and identified

the multiple barriers that prevent women from obtaining contraceptives or using them effectively and consistently. They discussed such barriers, offered strategies, and made recommendations to improve access [11].

In conclusion, women deserve no less than men, a universal protection under their control to protect themselves against unintended pregnancy and all STIs that is safe, effective, affordable, and accessible. It is time to empower women!

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Author contribution

RFO- Writing—original draft, Conceptualization, Investigation, Validation, Writing—review & editing.

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MGB- Writing—review & editing.

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