



INTERNATIONAL
PARTNERSHIP FOR
MICROBICIDES



**NEW TECHNOLOGIES
FOR WOMEN'S
HIV PREVENTION**

THE PAYOFF FOR SUSTAINABLE
DEVELOPMENT



HEALTHY WOMEN, **HEALTHY PLANET**



THE CENTURY OF WOMEN

The world is in the midst of an exciting conversation about human development: What kind of future do we want for our planet, and what would it take to achieve this vision? As endorsed by the United Nations (UN), the bold new Sustainable Development Goals (SDGs) provide a shared statement of what must happen to advance human development by 2030.

Gender equality and the empowerment of all women and girls will be critical to achieving the aspirations set forth in the SDGs. This sentiment is reflected in UN Secretary-General Ban Ki-moon's call to action: "Let the 21st century be the century of women. ... The empowerment and rights of girls and women must be at the heart of everything we do."¹ That imperative begins with ensuring the health and well-being of women and girls, which must be prioritized in any effort to encourage sustainable growth.



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According to the UN's Every Woman Every Child Initiative, women's health remains one of the core pieces of unfinished business of the Millennium Development Goals, the predecessor to the SDGs, and must be prioritized in the post-2015 development agenda.² Indeed, evidence shows that when women are both empowered and healthy, they are more likely to have healthy families, educate their children, and make positive social and economic contributions to society.

Realizing this reality for women and girls everywhere will require decisive coordination, investment and perseverance on multiple fronts. That effort must include giving women the tools they need to address two of the greatest risks to their sexual and reproductive health: HIV, which disproportionately strikes women in the prime of their lives, and unintended pregnancy, a leading contributor to maternal mortality, which is magnified in women with HIV.

INNOVATION FOR IMPACT

Scientific discoveries and biomedical innovations have delivered solutions that have transformed women's health. However, one of the greatest challenges remains: preventing HIV/AIDS in women.

Despite global progress against HIV/AIDS, it is still the leading cause of death worldwide for women ages 15-44.³ Nearly 2,400 women are infected with HIV every day.⁴ While the exciting promise of an HIV vaccine is on the long-term horizon, women need practical new tools that meet their needs in the near term.

Current products in the HIV prevention toolkit include male and female condoms, and, more recently, daily oral antiretroviral pills (known as pre-exposure prophylaxis or PrEP). But ending the epidemic will require a range of self-initiated tools women can choose from that fit within the context of their daily lives. The next big breakthrough in HIV prevention could be products called microbicides, which are based on the same types of antiretroviral (ARV) drugs used successfully to treat and prevent HIV. Recently, a monthly vaginal ring was shown to safely help reduce a woman's HIV risk. Long-acting products designed specifically for women such as vaginal ARV rings and ARV-contraceptive rings could one day soon put discreet and convenient new solutions in women's hands. Other microbicides such as on-demand vaginal films and rectal gels are earlier in development and also show promise.

HIV PREVENTION FOR WOMEN: A SMART INVESTMENT

Although there have been marked improvements in HIV treatment, the rate of new HIV infections is not falling fast enough,⁵ and it remains unacceptably high among young women, especially in sub-Saharan Africa. Continued and increased investment in women-centered HIV prevention promises to yield significant economic benefits in two important ways: prevention will bring down the global cost of HIV treatment through infections averted, and it will drive economic growth by helping to ensure women are healthy enough to participate in the labor force and invest in the well-being of their children.

Scientific innovation is key to delivering solutions that will transform women's health. The payoff will be enormous: a future free of AIDS, where women and girls thrive, and their communities and nations prosper as a result.

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*Improving the health of women and children is not only the right thing to do, it's also one of the smartest investments we can make to reduce poverty and improve well-being.*⁶

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*World Bank President
Jim Yong Kim*

¹ Ki-moon, Ban. Secretary-General's address to the United Nations General Assembly. New York, Sept. 24, 2013. <http://www.un.org/sg/STATEMENTS/index.asp?nid=7119>, accessed Aug. 25, 2015.

² Every Woman Every Child. "Investing in every woman, child and adolescent to survive and thrive by 2030." <http://www.everywomaneverychild.org/news-events/events/25-old-site/past-events/1109-financing-for-development-conference>, accessed Aug. 25, 2015.

³ UNAIDS. "Fact Sheet: World AIDS Day 2014." 2014.

⁴ UNAIDS. July 2015 Core Epidemiology Slides. 2015.

⁵ Piot, Peter et al. "Defeating AIDS—advancing global health." *The Lancet* 2015 July 11; 386(9989): 171-218.

⁶ Kim, Jim Yong. "Global Financing Facility in Support of Every Woman Every Child." Speech, Third International Conference on Financing For Development. Addis Ababa, July 13, 2015. <http://www.worldbank.org/en/news/speech/2015/07/13/global-financing-facility-woman-child>, accessed Aug. 25, 2015.



PREVENTING HIV IN WOMEN AND PROMOTING SEXUAL AND REPRODUCTIVE HEALTH: **URGENT CHALLENGES**

In the last decade, global efforts have brought about important declines in preventable deaths, including those from HIV/AIDS in developing countries. But progress has not reached everyone evenly, particularly women and girls. Women's HIV prevention, maternal health and other essential health needs have largely been left behind.



WHERE WE ARE TODAY – AND WHY WOMEN BEAR THE BURDEN OF THE GLOBAL HIV EPIDEMIC

Women are particularly vulnerable to HIV because a combination of biology and gender inequities renders them more susceptible to infection than men. In some parts of sub-Saharan Africa, HIV is as much as eight times more prevalent in young women and adolescent girls than in young men,⁷ partly because they lack effective and discreet tools they can use on their own, without partner negotiation, to protect themselves.

Women and girls continue to be infected at an alarming rate. In Africa, girls account for nearly three of every four new infections in adolescents.⁸ Given recent advances in HIV prevention science, we can, and must, do better.

Investing in research and development (R&D) for safe, effective and extremely promising HIV prevention technologies like microbicides for women could help save millions of lives and slow the global epidemic among women.

WOMEN'S SEXUAL AND REPRODUCTIVE HEALTH NEEDS: A SNAPSHOT

Women in areas with high rates of HIV often also face an unmet need for family planning. An estimated 225 million women of reproductive age in developing countries lack modern contraceptive methods that would allow them to space their pregnancies.⁹ This is a serious public health issue because complications due to unintended pregnancy are a leading cause of maternal mortality.

In fact, the intersection of HIV and reproductive health poses one of the greatest threats to women's health. HIV/AIDS is a leading cause of death and disability among pregnant women and mothers. Nearly one-quarter of all pregnancy-related deaths in sub-Saharan Africa can be linked to HIV,¹⁰ and more than 52 percent of maternal deaths in Botswana from 2000-2015 were due to AIDS-related causes.¹¹ Women who have HIV and are pregnant or recently gave birth are eight times more likely to die than those who are HIV-negative.¹² The consequences for children are also enormous: Observational studies in sub-Saharan Africa show that children are up to four times more likely to die during the year before or after their mothers died.^{13,14,15}

Expanding the range of HIV prevention options for women would also help give mothers and their newborns a greater chance at healthy futures. New long-acting, multipurpose innovations are being developed that combine an ARV with a contraceptive hormone to protect against HIV and unintended pregnancy simultaneously.

By addressing sexual and reproductive health challenges together, women and their families can benefit from better health outcomes and take advantage of educational and economic opportunities.

⁷ Human Sciences Research Council. *South African HIV Prevalence, Incidence and Behaviour Survey, 2012*. Cape Town, 2014.

⁸ UNAIDS & the African Union. *Empower Young Women and Adolescent Girls: Fast Tracking the End of the AIDS Epidemic in Africa*. 2015.

⁹ Guttmacher Institute. *Adding It Up: The Costs and Benefits of Investing in Sexual and Reproductive Health 2014*. 2014.

¹⁰ Zaba, Basia et al. "Effect of HIV infection on pregnancy-related mortality in sub-Saharan Africa: secondary analyses of pooled community-based data from the network for Analysing Longitudinal Population-based HIV/AIDS data on Africa (ALPHA)." *The Lancet* 2013 May 18; 381(9879): 1763-71.

¹¹ Alkema, Leontine et al. "Global, regional, and national levels and trends in maternal mortality between 1990 and 2015, with scenario-based projections to 2030: a systematic analysis by the UN Maternal Mortality Estimation Inter-Agency Group." *Lancet* 2015 Nov 12 epub.

¹² Guttmacher Institute. "HIV linked to many pregnancy-related deaths in sub-Saharan Africa." *International Perspectives on Sexual and Reproductive Health* 2013; 39(2).

¹³ Nakijjingi, Jessica et al. "Child survival in relation to mother's HIV infection and survival: evidence from a Uganda cohort study." *AIDS* 2003 August 15; 17(12): 1827-34.

¹⁴ Zaba, Basia et al. "HIV and mortality of mothers and children: evidence from cohort studies in Uganda, Tanzania, and Malawi." *Epidemiology* 2005; 16(3): 275-80.

¹⁵ Newell, Marie-Louise. "Mortality of infected and uninfected infants born to HIV-infected mothers in Africa: a pooled analysis." *The Lancet* 2004 October 2; 364(9441): 1236-43.

ANSWERING THE CALL: **OFFERING HOPE WITH NEW TECHNOLOGIES FOR WOMEN**



THE PROMISE OF NEW TECHNOLOGIES

New practical, female-initiated prevention tools could slow the disproportionately high rates of infection among women and help bring the epidemic to an end. But any product, no matter how effective, will prevent HIV only if women will use it in their daily lives.

No one product will suit all women or end the epidemic. Some women will want to take a daily ARV pill, while others will prefer a longer-acting ARV ring — with or without contraception. That is why we must expand the prevention toolkit with multiple product options.

At the International Partnership for Microbicides (IPM), a nonprofit product developer, women are at the heart of our mission to develop the tools they can and will use to prevent HIV and protect their sexual and reproductive health. Our robust pipeline includes three innovations with significant potential to offer women powerful new prevention tools:

- Long-acting HIV prevention vaginal rings
- Multipurpose products to protect against HIV and unintended pregnancy
- Combination products for next-generation HIV prevention

LONG-ACTING VAGINAL RINGS FOR HIV PREVENTION

A monthly ring would address a critical gap in current prevention strategies by offering women a long-acting, easy-to-use and self-initiated way to protect themselves from HIV.

OVERVIEW

- Easy-to-use monthly dapivirine vaginal ring developed by IPM
- Only long-acting product shown to safely help prevent HIV
- Flexible ring slowly releases the ARV dapivirine

IPM's dapivirine ring is designed to remain in place for a month to provide sustained protection against HIV. The ring is made of a flexible silicone material with the ARV drug dapivirine dispersed uniformly throughout. The ring delivers the drug locally with low systemic absorption, which helps minimize side effects.

Promising results from two recent Phase III clinical studies show that IPM's monthly dapivirine ring safely prevented HIV in about one in three women ages 18-45 overall. One study showed that the ring cut HIV risk by more than half among women older than 21, who used the product more consistently. This finding suggests that greater protection can

be achieved with more consistent ring use, or adherence. Next steps include two open-label studies designed to provide the ring to women who participated in the Phase III trials, and to understand how women will use the ring now that the product's safety and efficacy are known. Another study will focus on young women and adolescent females in Africa, assessing the ring's safety and adherence among this high-risk group. Findings from all these studies will provide insights into how to best support ring use. Given the ring's promise for many women at high risk, IPM is also seeking to license the ring for use in developing countries and to make it available at the lowest possible cost.

In the face of difficult challenges to women's health, new technologies hold promise.

MULTIPURPOSE PREVENTION TECHNOLOGIES

Discreet, long-acting multipurpose prevention products are being developed to simultaneously protect women from two of the leading threats to their sexual and reproductive health in low-resource settings: HIV and the life-threatening complications posed by unintended pregnancy. Integrated solutions could result in significant health gains for women by addressing overlapping needs.

OVERVIEW

- 90-day HIV prevention-contraceptive vaginal ring developed by IPM
- Long-acting duration could help encourage consistent use
- Expected to enter Phase 1 trial in mid-2016

These products may also help promote increased efficiency in health care delivery, encourage healthy behaviors, minimize clinic visits by addressing related issues in fewer appointments and reduce the stigma associated with receiving HIV-related services.

IPM is applying its expertise in ring development to create a multipurpose prevention technology that combines dapivirine with a contraceptive hormone (levonorgestrel). This 90-day MPT ring is expected to enter a Phase 1 trial in mid-2016.



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PLANNING FOR ACCESS

Health products are effective only if people can and will use them. By partnering with women around the world to understand their needs and testing products for ease-of-use, researchers can develop tools that are acceptable and appropriate for women's lives. Planning for product access also includes developing supply chain partnerships that ensure product availability and affordability. IPM engages in access-focused partnerships from the earliest stages of product development to ensure that its products, once found effective, offer practical HIV prevention options for women in developing countries and around the world.

COMBINATION MICROBICIDE PRODUCTS FOR INCREASED PROTECTION

Combination microbicide products use multiple ARVs in a single product, such as a ring, tablet, film or gel, to help increase effectiveness and prevent HIV over time.

OVERVIEW

- Combination products use two or more ARVs to target HIV
 - Multiple ARVs could offer greater protection than a single drug alone and outsmart the ever-evolving virus
 - First combination microbicide tested was safe and well-tolerated
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IPM is pioneering the development of combination products, including the first combination microbicide to reach clinical trials: a vaginal ring that leverages two ARVs with different mechanisms of action, dapivirine and maraviroc. The ring was found to be safe, well-tolerated and acceptable in a Phase 1 clinical trial. By deploying multiple ARVs that target the virus at different points in its life cycle, combination products may offer greater protection against HIV than a single drug alone.

Continuing this cutting-edge science, IPM is exploring new combination products that use potent new ARVs such as DS003, which acts early in the virus's life cycle to help outsmart the ever-evolving HIV virus in the long term.



WOMEN'S HIV PREVENTION
AND SEXUAL AND
REPRODUCTIVE HEALTH:
**THE CENTERPIECE
OF SUSTAINABLE
DEVELOPMENT**



Investing in new tools women can use to prevent HIV and protect their sexual and reproductive health will be critical to achieving the SDGs.

Goal 1.

End poverty in all its forms everywhere

Households affected by HIV are more vulnerable to poverty. By reducing the number of HIV infections, we can reduce illness-related poverty, keep families strong and grow communities.

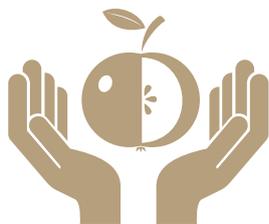


end poverty

THE ECONOMIC IMPACT OF HIV/AIDS

HIV robs countries of workers in the prime of their life, which contributes to slower economic growth. Scaling up investments to end HIV/AIDS in countries with the highest prevalence could generate US\$124-612 billion of income growth and economic benefits from increased life expectancy by 2030.¹⁶





food security



healthy lives

Goal 2.

End hunger, achieve food security and improved nutrition and promote sustainable agriculture

Women make up more than 40 percent of sub-Saharan Africa's agricultural workforce.¹⁷ Keeping women healthy can help ensure food security for all.

Goal 3.

Ensure healthy lives and promote well-being for all at all ages

Microbicides would reduce the burden of HIV/AIDS and improve the health and well-being of women and their children.

Goal 4.

Ensure inclusive and equitable quality education and promote life-long learning opportunities for all

New and practical HIV prevention options would help girls and young women stay in school and improve their chances for employment later.

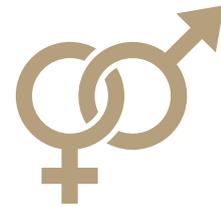


equitable education

Goal 5.

Achieve gender equality and empower all women and girls

New female-initiated HIV prevention products are a crucial part of a rights-based toolkit that will empower women and girls to protect their own well-being.



gender equality

Goal 8.

Promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all

New HIV prevention tools for women would lower HIV infection rates, allow healthy women to pursue employment, and help sustain strong and productive workforces.



productive employment

Goal 9.

Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation

Research to develop effective HIV prevention options is a major contribution to the global community's scientific knowledge base and helps build research capacity and infrastructure in the areas most affected by the epidemic.

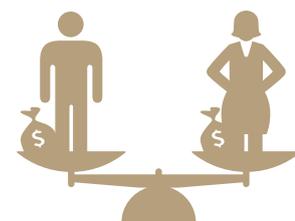


infrastructure & innovation

Goal 10.

Reduce inequality within and among countries

Gender discrimination, the root cause of many inequalities, is linked to higher HIV prevalence. New female-centered tools would help empower women and communities.



reduce inequality



resilient cities

Goal 11.

Make cities and human settlements inclusive, safe, resilient and sustainable

Cities are hardest hit by HIV and many are burdened by growing epidemics. New technologies are needed to ease the epidemic, and strengthen health and social systems overall.



global partnership

Goal 17.

Strengthen the means of implementation and revitalize the global partnership for sustainable development

Developing new HIV prevention technologies like microbicides requires global collaboration of public and private entities to bring the needed scientific ingenuity, political will and financial resources to bear on product development.

¹⁶ Piot et al., 2015.

¹⁷ Food and Agriculture Organization. "The State of Food and Agriculture: Women in Agriculture." 2010-2011.

PUBLIC-PRIVATE R&D PARTNERSHIPS FOR THE GLOBAL GOOD

Nonprofit product development partnerships (PDPs) like IPM aggregate resources from the public and private sectors to develop new products designed to address epidemics in the world's poorest countries, where the need is urgent but the market incentive is lacking. This effort coordinates intellectual and financial resources from governments, foundations, researchers, advocates and pharmaceutical companies. For example, through a public-private partnership with Janssen Sciences Ireland UC, IPM negotiated a royalty-free license for the ARV dapivirine that has since expanded to a worldwide rights agreement. This landmark partnership allows IPM to develop and market dapivirine products such as its monthly HIV prevention ring at an affordable cost in developing countries.





INVESTING FOR IMPACT: **THE PAYOFF OF R&D FOR WOMEN'S SEXUAL AND REPRODUCTIVE HEALTH**



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Investing in the health of women and girls has far-reaching ripple effects. Advancing new technologies for women's HIV prevention and sexual health will have significant payoff for sustainable development: improved health and well-being, thriving communities, inclusive economies, and resilient, sustainable societies.



IMPROVED HEALTH AND WELL-BEING



Toward an AIDS-Free Generation

Slowing, and ultimately stopping, the spread of HIV to women and girls must be a top priority if we are to achieve an AIDS-free generation. Investment in promising scientific innovations can drastically reduce the global health and economic burden the epidemic poses, especially for young women in sub-Saharan Africa. UNAIDS calls investments in female-controlled HIV prevention tools a potential “game-changer” for women everywhere.¹⁸

Extending the Power of HIV Treatment

For every person with HIV who gains access to treatment today, another person — who is more likely than not to be a woman — becomes infected. By reducing the number of new HIV infections, we will extend countries’ abilities to provide effective treatment to people living with the virus.

Saving Lives Through New Reproductive Health Options

New long-acting and female-initiated multipurpose technologies would give women easy-to-use tools to address overlapping health needs at the same time: preventing HIV and unintended pregnancy. Because women's perceived risk of HIV is low compared to their perceived risk of pregnancy, such products may be widely used.

EMPOWERED WOMEN, STRONG FAMILIES

Empowering Women

Protecting one's health is a right no one should have to compromise on. Yet gender inequalities continue to threaten that right for many women and girls, especially when it comes to HIV. Existing prevention strategies aren't doing enough to reduce the high rate of infections among women, particularly young women. Marriage does not necessarily offer protection from the virus. Abstinence is not a practical solution for women who want to have children. And, while many women may choose to discuss HIV prevention options with their partners, it is not a feasible option for others, including those at risk of sexual violence.

Additional prevention options will allow women to choose one that makes sense in the context of their lives. Convenient, discreet and long-acting tools that do not require partner negotiation would give women the freedom to protect themselves — and stay protected — for a month or more at a time. New tools that women could use on their own, whether they choose a daily ARV pill or a monthly ARV ring, would empower them to protect their own health.

Promoting Strong Families

Healthy women are the backbone of strong families. They are often primary caregivers, redirecting the vast majority of any earned income back to their families. Children's future success in life depends on mothers who are healthy — and empowered to protect their own health.



THRIVING COMMUNITIES



Ensuring Food Security

Women play vital roles in food production — from crop production and animal tending to food processing, preparation and marketing. Because women are crucial to the agricultural workforce, when they are sick and cannot work, the security of sustainable food sources is jeopardized. Effective HIV prevention products that keep women healthy benefit national food security.



Expanding Equitable Education

Education empowers girls to pursue jobs and to care for themselves and their families in the future. However, as one study found, in some countries, up to two-thirds of children caring for parents living with HIV/AIDS are girls.¹⁹ This caregiving role makes them less likely to stay in school. Introducing effective HIV prevention products for women is critical to enabling girls and young women to pursue an education.



Building Research Capacity

Conducting HIV prevention clinical trials in developing countries hardest hit by the epidemic utilizes the research capacity and expertise of scientists, providers and countries, who are intimately involved in finding solutions to health issues their communities face. In turn, that investment adds to a crucial knowledge base that has opened doors to innovation for all. For many communities, active research centers can increase HIV awareness, improve access to health services, and offer employment and skills development.

INCLUSIVE, RESILIENT SOCIETIES

Eliminating Extreme Poverty

The high cost of addressing HIV/AIDS and other serious illnesses can drive families to financial ruin, trapping them in a cycle of poverty and weakening economies. Preventing HIV in women and girls is a big step toward eliminating extreme poverty for generations to come.

Building a Vibrant Workforce

Women are a crucial part of the formal economy, and they shoulder the majority of unpaid care and other informal work.²⁰ HIV robs countries of workers in the prime of their lives, thwarting economic growth. By developing tools that stop the spread of HIV, countries can better sustain a healthy workforce and a productive economy.



productive employment



end poverty

UNLEASHING POTENTIAL TO MEET 21ST CENTURY CHALLENGES

Big challenges for the 21st century loom. Investments in women's well-being are vital to unleashing the full potential of half the population to contribute to big solutions for the planet.

¹⁸ UNAIDS. *How AIDS Changed Everything*. 2015.

¹⁹ VSO. "Challenges of Care: VSO-RAISA Regional Conference 2007 Report Back." 2007.

²⁰ UN Women. "Facts and Figures: Economic Empowerment." <http://www.unwomen.org/en/what-we-do/economic-empowerment/facts-and-figures>, accessed Aug. 25, 2015.



AN HIV-FREE FUTURE STARTS WITH WOMEN



Scientific advances have helped the global community make great strides against the HIV epidemic, but women have largely been left behind. Through the new Sustainable Development Goals, the world is recognizing that improving women's health – particularly by addressing HIV and unintended pregnancy – is a moral and economic imperative, and is paramount to achieving sustainable development. By investing in R&D for innovative technologies that women can and will use to protect their health, we can bring about the end of the AIDS epidemic, save and improve millions of lives, and move closer to a more sustainable world.



ABOUT IPM





For 14 years, the International Partnership for Microbicides (IPM) has advanced its mission to create products that women in developing countries can use to prevent HIV, and to protect their sexual and reproductive health. Today, we are as optimistic as we have ever been that the possibility of putting new life-saving products into women's hands is within reach.

IPM extends its deepest thanks to our partners around the world and to our generous donors. By continuing to unite scientific discovery with political will and financial commitment, together we will find solutions to meet women's urgent HIV prevention needs and improve their sexual and reproductive health.

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