Saving Lives With Multipurpose Prevention Technologies

Turning Ideas Into Solutions for Sexual and Reproductive Health

This brief was prepared by Bethany Young Holt from the Coalition Advancing Multipurpose Innovations (CAMI) of the Public Health Institute and UCBerkeley School of Public Health and Maggie Kilbourne-Brook, Jessica Cohen, and Michele Burns from PATH. It was developed on behalf of the Initiative for Multipurpose Prevention Technologies (IMPT) for Sexual and Reproductive Health, a coalition of domestic and international reproductive health researchers, health care providers, advocates, product developers, and funding agencies. The initiative advocates for the accelerated development, testing, and integration of multipurpose prevention technologies that improve sexual and reproductive health.

This document was made possible by the generous support of the American people through the United States Agency for International Development (USAID) under the terms of the HealthTech IV Cooperative Agreement #GPH-A-00-01-00005-00. The contents are the responsibility of PATH and do not necessarily reflect the views of USAID or the US Government. An electronic copy of the document is available online at www.path.org and www.cami-health.com and may be freely distributed to raise awareness of this work. Other organizations that support this initiative may post this document on their website as well.

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Suggested citation: PATH and the Coalition Advancing Multipurpose Innovations. *Saving Lives With Multipurpose Prevention Technologies: Turning Ideas Into Solutions for Sexual and Reproductive Health.* Seattle: PATH; 2010.

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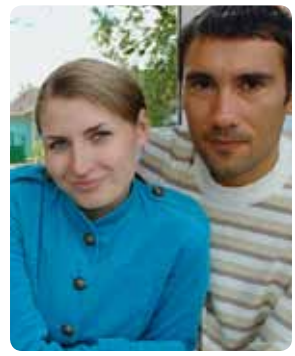
ALLIANCE FOR MICROBICIDE DEVELOPMENT

"Women's health is essential to the prosperity and opportunity of all, to the stability of families and communities, and the sustainability and development of nations. There is a direct line between women's reproductive health and their ability to lead a productive, fulfilling life. Investing in the potential of women and girls is the smartest investment we can make."

—**HILLARY CLINTON,** SECRETARY OF STATE
Remarks on the 15th Anniversary of the International Conference on Population and Development, January 10, 2010



Introduction

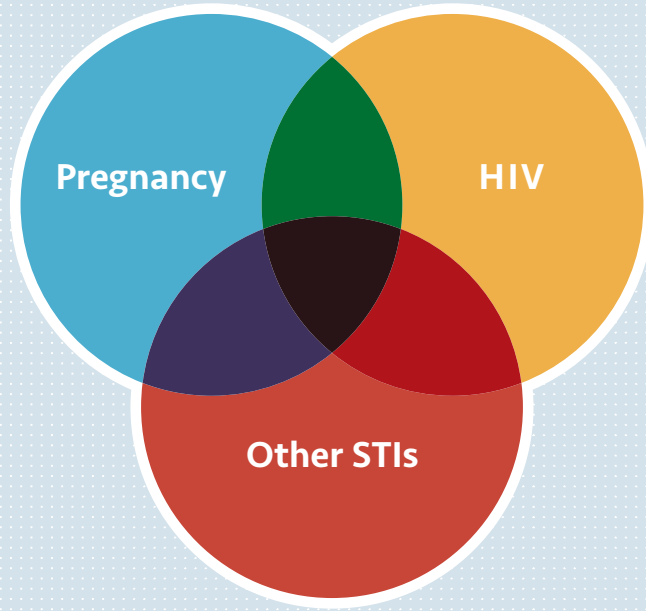
Over the past half-century, the global health community has made great progress in improving women's reproductive health. In particular, by increasing access to contraception, health care providers have helped millions of couples plan the number and timing of their births. Worldwide contraceptive use has increased dramatically during this time, from 10 percent of the population in the 1960s to nearly 60 percent today.

Despite these gains, however, too many women still have unrecognized and unmet reproductive health needs. Worldwide, an estimated 200 million couples continue to express an unmet need for contraception.[1] Persistent unmet need for family planning undermines progress toward all of the human development goals outlined in the Millennium Development Goals (MDGs)[2] as well as the recommendations that emerged from the 1994 International Conference on Population and Development.

Even for couples who have access to contraception and related services, the available options seldom address the full spectrum of risks that can be associated with sexual activity. Women at risk of pregnancy, for example, may also be at risk for reproductive tract infections (RTIs) and sexually transmitted infections (STIs), such as HIV.[3,4]

Safe, acceptable, and affordable technologies that could address these simultaneous sexual and reproductive health needs would improve individual, family, and community health and well being. For this reason, many global health professionals—including researchers, policymakers, product developers, and donors—have begun to intensify their commitment to a new generation of technologies that address multiple prevention objectives.

FIGURE 1. The intersection of prevention needs.



The challenge

To develop combination products that are acceptable, affordable, easy-to-use, and prevent:

- ■ Pregnancy + HIV
- ● Pregnancy + other STIs
- ▲ HIV + other STIs, STI + STI
- ✱ HIV + pregnancy + other STIs

"Women in both the global north and the global south want contraceptive methods that protect against both pregnancy and disease without unpleasant side effects, that do not interfere with sex, require little or no medical supervision, and are effective when used postcoitally."

—**SHARON CAMP,** PRESIDENT AND CEO, GUTTMACHER INSTITUTE

What are multipurpose prevention technologies?

Multipurpose prevention technologies are designed to address these multiple needs, including prevention of unintended pregnancy; prevention of STIs, including HIV; and/or prevention of other RTIs, such as bacterial vaginosis (Figure 1). Often referred to as "multipurpose," "combination," or "dual" technologies, these products will help alleviate the heavy health and economic toll that unintended pregnancy and RTIs/STIs can cause.

Multipurpose products that are acceptable, affordable, and widely available would greatly improve health and save resources. Health care providers and commercial outlets would be able to stock, supply, and advise women on a compact range of products, and women, in turn, could have the option to purchase, understand, store, and use fewer products. In addition, women would be protected against multiple risks, even if their intention was to address just one perceived health need.

The tools we have today

The multipurpose tools available to health programs today are:

- **Male condoms.** Male condoms are effective at both pregnancy and STI prevention when used consistently and correctly. Despite substantial promotion efforts during the past 30 years, however, male condoms are not always used consistently. Regular, ongoing use is particularly low in relationships between primary partners, where issues of trust and power make it difficult for women to negotiate condom use.
- **Female condoms.** Female condoms also protect against pregnancy and STIs. Unfortunately, their high product cost (relative to male condoms) and mixed acceptability have limited their promotion and use. Lack of support for introduction, an inconsistent supply, and insufficient monitoring and evaluation have made it difficult to build sustainable programs.
- **Behavior change.** Interventions based on behavior-change strategies—for example, strategies that encourage delaying sexual activity, promoting abstinence, reducing the number of partners, and practicing mutual monogamy—have been successful in some settings. Like condom negotiation, however, these approaches are not useful or sustainable for all relationships.

Reproductive health programs need support to expand access and program capacity for these technologies and interventions. Expanding access to existing tools through strategic investments in supplies and programming are essential if women's prevention options are to be improved and expanded.

Multiple risks, multiple needs

GLOBALLY, UNSAFE SEX IS THE SECOND-LARGEST CAUSE OF DISABILITY-ADJUSTED LIFE YEARS (DALYs), exceeded only by underweight status among children.[5] The costs of unintended pregnancy and STIs typically fall hardest on the most disadvantaged groups—especially young women, adolescents, and the poor.[6]

The challenges are universal. Condom negotiation, access to health care services, and the burden of child care affect millions of women, no matter where they live. Women who experience unplanned pregnancy or illness from repeated STIs sometimes face dire social and economic consequences, chronic ill health, and shortened life spans (Table 1).

A critical investment

Poor sexual and reproductive health is a major impediment to global health and economic development. In addition to their immediate health effects, unplanned pregnancy, STIs, and RTIs affect quality of life and productivity. In turn, they have a profound impact on local and national economies throughout the world.

Prudent investments in multipurpose prevention technologies would help address many of the world's health priorities identified in the Millennium Development Goals,[7] including:

- Improving maternal health (MDG 5) through access to technologies and interventions that meet the complex range of women's reproductive health needs.
- Combating HIV/AIDS and other diseases (MDG 6) through technologies that target STIs.
- Improving child health (MDG 4) by improving their mothers' health. Healthy mothers are better able to care for their families.

Research has shown that multipurpose prevention technologies save time and resources. Technologies that allow clients to address multiple health issues, for example, are likely to be cost-effective over time.[8,9] Combined vaccines for childhood diseases serve as one well-documented example, as they have been proven to offer cost savings, diminish the frequency of injections, and increase overall health benefits.[10,11,12,13,14]

By reducing the direct and indirect costs associated with unintended pregnancy and STIs, multipurpose prevention technologies could lead to substantial health care savings. In the United States, for example, the direct medical costs of unintended pregnancy were estimated to be $5 billion in 2002.[15,16] Estimates for direct medical costs

TABLE 1. Health impact from unplanned pregnancy and STIs

	PREGNANCY AND BIRTH	STIs (INCLUDING HIV)
Global context	Each year, an estimated 210 million women have life-threatening complications of pregnancy, often leading to serious disability.[6] Annually, 80 million women have unwanted or unintended pregnancies; of these, 45 million pregnancies end in abortion.[6] Unsafe abortion causes an estimated 70,000 deaths each year. An additional 5 million women are treated annually for complications from unsafe abortion.[17] Each year, 343,000 to 500,000 women die from complications associated with pregnancy, childbirth, and the postpartum period.[18,19]	Nearly 1 million people acquire an STI (including HIV) each day.[20] The risk of HIV infection is increased in the presence of STIs, especially syphilis, chancroid ulcers, and genital herpes. Each year, 340 million people acquire new treatable infections from gonorrhea, syphilis, chlamydia, or trichomonas.[21] Untreated gonorrheal and chlamydial infections are the main preventable causes of infertility.[21,22,23] More than 23 million people become infected with chronic infections from herpes simplex virus (HSV) each year.[24]
Developing-country burden	Approximately 200 million women in developing counties have an unmet need for contraception—that is, they wish to space or limit births but lack access to contraception.[25] More than one-third of pregnancies in developing countries are unintended.[26] Countries with high fertility also have high maternal mortality rates. Sub-Saharan Africa and South Asia are regions of particular concern. In Africa, 26 of 30 countries have contraceptive prevalence rates below 30% and fertility rates above 5%.[27]	In developing countries, STIs and their complications are among the top five disease categories for which adults seek health care.[21] In women of childbearing age, STIs (excluding HIV) are second only to maternal factors as causes of disease, death, and healthy life lost.[21] Human papillomavirus (HPV) causes about 500,000 cases of cervical cancer annually with 240,000 deaths, mainly in resource-poor countries.[20] In many sub-Saharan African countries, more than 25% of adults are living with HIV. Of these, 61% are women.[28,29]
US burden	In the United States, nearly 750,000 women 15 to 19 years old become pregnant each year.[30] Nearly half of all pregnancies are unintended; among teens, more than 82% are unplanned.[15] Four in ten unplanned pregnancies are terminated by abortion.[15]	18.9 million new cases of STIs occur each year; nearly half of these cases occur among 15- to 24-year-olds.[31] In the United States, racial and ethnic minorities are disproportionately affected by STIs, including HIV. Although African-Americans represent 12% of the US population, they account for 46% of HIV prevalence and 45% of HIV incidence.[28]

HANH

Caring for women in rural Vietnam

An hour and a half outside of Vietnam's Ho Chi Minh City, nurse Hanh Nguyen provides health care for rural rice farmers, merchants, and their families. Many clients walk for more than half a day to visit her. Each week, Hanh sees at least a dozen women who seek a way to prevent or space pregnancies or treat an STI. These women often need all of these services in a single visit.

Hanh knows that her clients take on a lot to visit the clinic: the time and expense of the trip, as well as the burden the trip places on their domestic responsibilities, field work, and children. This makes it even more frustrating when a specific product is out of stock or when an assistant fails to provide information on all of a woman's health concerns. This means her client will have to wait even longer and work even harder to protect herself and stay healthy.

If Hanh could provide her clients with a microbicide or vaccine that could prevent both pregnancy and STIs, she could help her clients meet their sexual and reproductive health needs.

associated with STIs are even greater: $14.7 billion in 2006.[32,33,34] Additional indirect costs, such as lost wages and productivity, as well as the lifelong costs for infants infected with STIs at birth, add to this burden.

Beyond their benefits to individual, family, and community health, technologies that prevent unintended pregnancy, STIs, and their associated costs would bring significant savings to constrained health care and system budgets. Technical innovation, scientific persistence, and significant resources will be needed to achieve this potential. Increased support and engagement can help improve access to existing technologies and accelerate the development, testing, and regulatory approval of promising emerging technologies.

A portfolio of possibilities

WITH EACH ADVANCE IN THE SEXUAL AND REPRODUCTIVE HEALTH FIELD, our understanding of scientific possibilities and their potential evolves. Current and emerging technologies for single-indication prevention provide a foundation for the development of new multipurpose prevention technologies. At the same time, new explorations in the multipurpose arena, together with advances in other fields, offer important insights and lessons.

Technologies for single indications

Advances with a number of single-indication technologies offer especially relevant approaches:

- **Pre-exposure oral prophylaxis with antiretroviral drugs and anti-HIV vaccines.** These approaches are being clinically evaluated to prevent HIV acquisition.
- **Microbicides for HIV prevention.** Although early microbicide candidates have so far proven ineffective,[35,36] researchers and advocates are hopeful that new microbicide candidates with different mechanisms of action will be shown to be effective.
- **New physical barriers, such as single-size diaphragms.** These devices are being developed to prevent unintended pregnancy and possibly STIs that infect the cervix. Using them in combination with even a partially effective microbicide could provide dual protection.
- **Vaginal ring technology.** Developed to deliver hormonal drugs, vaginal rings are now being adapted for long-term, controlled release of agents that protect against HIV and other STIs.
- **Experience with HPV and hepatitis B vaccine.** Emerging lessons can guide development and introduction of combination reproductive health vaccines.

Current explorations in multipurpose prevention

Multipurpose prevention strategies currently being explored include combinations of devices and drugs, combinations of drugs or vaccines, and entirely novel approaches. A number of nonprofit, academic, government, and biotechnology entities are leading these efforts. Many of the approaches are in preclinical feasibility testing.

Prevention of unwanted pregnancy and HIV or other STIs

- Several efforts are under way to combine contraceptive intravaginal rings with drugs that could prevent HIV and/or STIs. For example, controlled release of a progestin and an antiretroviral compound from a vaginal ring could protect women against pregnancy and sexual acquisition of HIV. Such a system might provide other benefits, such as reducing the incidence of menorrhagia, anemia, or

KADJIATA

A mother, and co-wife, in West Africa

Twenty-nine year-old Kadjiata Ba is a married mother of five young children. Like many women in Mauritania, Kadjiata was married at the age of 15, has several co-wives, and attended school for only a few years. Her husband, a merchant, often travels throughout West Africa. She has never been unfaithful to him, but she knows that he has sexual encounters with women other than her and her co-wives.

Kadjiata desperately feels that her five children are all that she wants and can care for. She is afraid of getting pregnant again, but her husband does not approve of sterilization. She also fears she may have gotten a sexually transmitted infection (STI) from her husband.

Kadjiata is determined to reach the clinic—a two-hour trip over dirt roads—to get some type of long-acting birth control method, and if she's lucky, medicine for the symptoms she fears are caused by an STI. If she could obtain a product that would protect her from pregnancy and STIs—a product her husband would approve of—Kadjiata would be much more likely to remain healthy and able to care for herself and her family like she does today.

endometriosis. Significant challenges remain, however, as the contraceptive ring was designed for hormone delivery. Compatibility of the current ring with new agents intended to prevent HIV requires considerable retooling.

- Several product developers are working to advance a one-size-fits-most cervical barrier that would improve women's options for nonhormonal contraception. When used with a microbicide gel, the barrier device could prevent semen from accessing the cervix and directly inactivate HIV or other pathogens.
- Cervical barriers also have the potential to serve as controlled-release delivery systems that would slowly disperse a microbicide over a specified time period. Similar to the vaginal ring approaches described above, this method incorporates a microbicide compound into the rim of the cervical barrier. Unlike rings, however, controlled-release cervical barriers may require daily removal and washing.

▲ Protection from HIV and other STIs

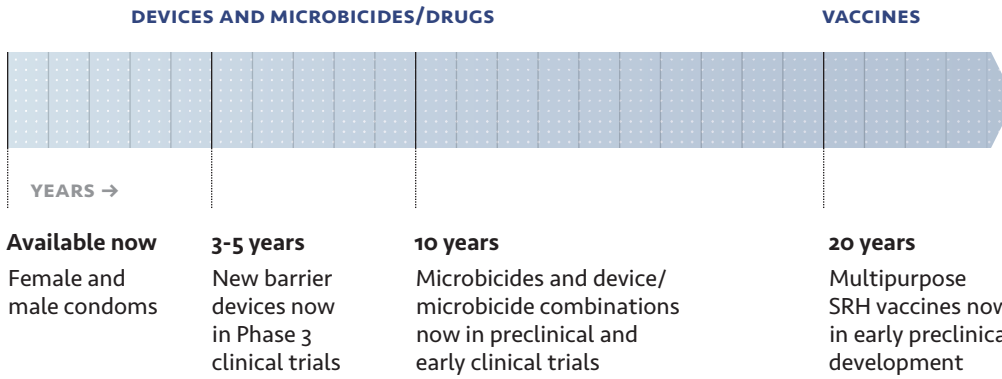
- The vaginal ring technology is also being applied to the simultaneous prevention of HIV and herpes simplex virus (HSV). Acyclovir suppressive therapy, which reduces the risk of herpes recurrence, requires daily dosing regimens. These are a challenge in many settings. To improve adherence and acceptability, developers are working on a vaginal ring that will deliver antiretroviral compounds along with anti-herpes analogs. This product could be especially appealing to women at risk of HIV and HSV who want to have children.

▲ Combination vaccines for sexual and reproductive health

- Some commercially available children's vaccines target more than six pathogens. Experience with these vaccines indicates that health care providers find combined approaches convenient and that children and parents like the convenience and the requirement for fewer injections. In addition, the combined vaccines have led to higher immunization rates. The development of combination vaccines has involved a host of technical, clinical, regulatory, manufacturing, and marketing challenges. It also has produced lessons that can be applied to developing new combination vaccines for sexual and reproductive health.
- Vaccines have been developed for protection against HPV and the hepatitis B virus. At least one company manufactures both vaccines. It may be feasible for the vaccines to be combined, as they are manufactured through similar processes, delivered on similar immunization schedules, and approved for co-administration. Currently, the vaccines' cost (several hundred dollars per vaccine) limits global distribution. Alternative manufacturing systems and novel immunization strategies are being developed to lower costs. A lower-cost combination vaccine could increase uptake and acceptability.

■ Pregnancy + HIV ● Pregnancy + other STIs ▲ HIV + other STIs, STI + STI ✱ HIV + pregnancy + other STIs

FIGURE 2. Pipeline for multipurpose SRH prevention technologies.



- There is also great interest in a combined HPV and HSV vaccine, since both HPV and HSV infections are prevalent globally and are often acquired early after sexual activity begins. While the HSV vaccine is still experimental, its delivery schedule will be similar to that for HPV. A combination vaccine designed to protect adolescents from the two infections is plausible.

✱ Novel delivery systems

- Researchers are investigating new delivery systems for microbicides. These systems include nanoparticles—ultrafine particles that can pass through mucosal membranes—and bioresponsive gels that can release microbicides under specific physiological conditions.[37] For example, a low-viscous polymer gel under development reacts at a molecular level when exposed to semen, forming a tight mesh that blocks particle movement. Although still in early development, this approach could eventually be combined with antimicrobial agents to provide a dual defense against pathogens.
- Oral and vaginal administration of probiotics may be useful in preventing and treating bacterial vaginosis, urinary tract infections, HIV, and other infections. For example, a natural vaginal strain of *Lactobacillus jensenii* has been genetically engineered to deliver a potent HIV-inhibitor within the vaginal mucosa. The use of bioengineered bacteria as a drug-delivery system could protect women against HIV transmission.[38,39] It could be used as a stand-alone product or possibly combined with contraceptive agents and other preventive drugs. Obstacles facing these protein-based microbicides are cost and production/volume requirements. Efforts are under way to base production on genes inserted into plants, yeast, or bacteria.[37]

■ Pregnancy + HIV ● Pregnancy + other STIs ▲ HIV + other STIs, STI + STI ✱ HIV + pregnancy + other STIs

The way forward

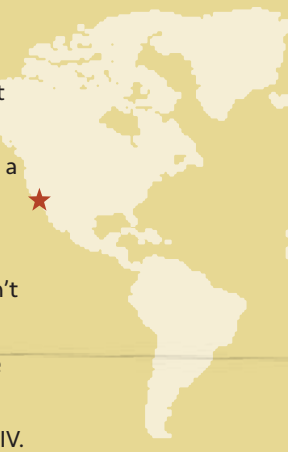
BRINGING THESE PROMISING IDEAS TO LIFE will require an integrated development framework. The approach must move technologies from basic research to widespread use—in other words, from bench to clinic to market to bedside. Many partners—including governments, product developers, providers, researchers, and advocates—must join in this effort.

ALICIA

A young, single mother in the United States

Alicia, 21, lives in Richmond, California. She was born to Mexican immigrants who were farm workers. She worked hard in school, but she found it challenging to navigate between her traditional Mexican upbringing and the modern adolescent culture in the United States.

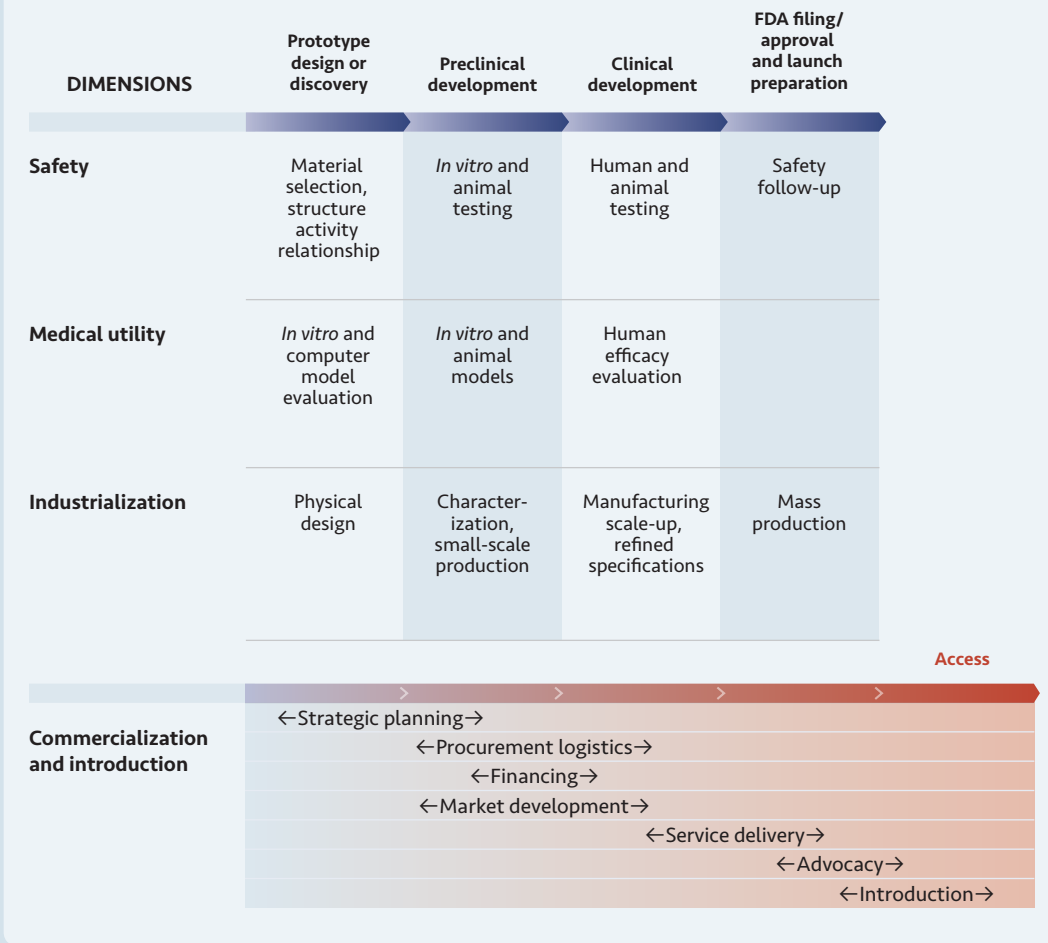
Despite her parents' expectations to delay sex until marriage, Alicia started having sex when she was 15. She became pregnant at 17 and now raises her son as a single parent while working and taking classes at a community college.



Alicia uses birth control pills to avoid pregnancy, but her current boyfriend doesn't like to wear condoms. Alicia has already been treated for a chlamydia infection. She worries about getting other STIs, including HIV. Her partner refuses to get tested for HIV.

Seeing a doctor is difficult for Alicia, given the logistics of child care, work, and public transportation. Alicia wishes there was a way to protect herself from pregnancy and STIs—a simple, inexpensive method like the vaccine her son received to avoid multiple childhood diseases.

FIGURE 3. The product-development pathway.



Adapted from the US Food and Drug Administration, 2004,[40] and PATH, 2007.[41]

"Developing safe and effective prevention products for sexual and reproductive health can be very challenging and as with the development of any new drug, some of our efforts may not work at first. But we cannot give up or else we will never make progress."

—**GUSTAVO DONCEL,** DEPUTY DIRECTOR, PRECLINICAL RESEARCH, CONRAD

The pathway through product development and introduction

Development of any technology is difficult and expensive, and the risks of failure are plentiful. Even the most promising drugs and health devices must advance through a complex product-development and introduction pathway. As shown in Figure 3, multiple regulatory and licensure activities are required to assess safety, efficacy, usability, and production. At the same time, steps to ensure supply and manufacturability must also be taken.

The inherent challenges

The development of technologies for multiple indications will face particularly complex challenges. In addition to standard acceptability and commercialization challenges, researchers will need to ensure the compatibility of the combined products or strategies. Collaboration, resources, and persistence will be critical.

The global health community must acknowledge that with a new, more ambitious goal—developing, testing, and commercializing multipurpose prevention technologies—comes the need for a new paradigm. We will need to think differently about the connections between disciplines. We will need to work with new partners—especially in the private sector—to leverage expertise and resources for product development, research, and commercialization. We will need to create new tools (such as more relevant evaluation tools), incorporate translational research, and emphasize user acceptability.

Multiple and coordinated product-development tracks could accelerate and streamline movement through this product-development pathway. This portfolio approach requires coordinated financial commitments, a willingness to share scientific expertise across disciplines, early engagement and planning, and strong advocacy efforts. The following section of this document describes these elements in more detail.

Recommendations

THE CALL FOR MULTIPURPOSE PREVENTION TECHNOLOGIES IS GAINING MOMENTUM. It is critical to build on this sense of possibility and encourage new perspectives among donors, researchers, product developers, providers, health advocates, policymakers, and others committed to women's health.

The following recommendations will help the global health community accelerate access to the benefits that these technologies can bring to women and communities around the world (see Figure 4).

1. Increase collaboration and resources across disciplines.

Substantial collaboration, particularly across disciplines, will be needed to bring this new class of products forward. Scientists, developers, and advocates will need to draw on relevant research findings from across disciplines. Researchers will need to work with end users and health providers to ensure that emerging products truly reflect stakeholders' needs. Nongovernmental organizations, funders, industry groups, and regulatory authorities will need to work together to address regulatory approvals, manufacturability, supply, and plans for market access. Such cross-discipline collaboration is emerging in similar efforts as well, such as the US Government's Global Health Initiative, which also seeks to create integrated solutions for women's reproductive health.[42]

Furthermore, collaboration across scientific disciplines *and* health and funding sectors will be essential. Product developers and funders will need to work together to move promising ideas forward, from concept to broad, widespread use.

2. Plan deliberately and early.

To ensure efficient and effective research and development, researchers and developers must use systematic evaluation and rigorous product-development planning and implementation processes. For example, proponents of multipurpose technologies should develop:

- Early-stage assessments to clarify a product's potential role and ensure that it will be appropriate for the intended context.
- Reviews of feasibility, sources of supply, and manufacturability to identify issues that will affect product specifications.
- Clear go/no-go decisions for safety, efficacy, acceptability, and cost-effectiveness parameters.

FIGURE 4. Recommendations.

1

Increase collaboration and resources across disciplines

2

Plan deliberately and early

3

Increase awareness and support for multipurpose prevention technologies

"There is a need for increased funding and commitment to produce multipurpose prevention technologies that are effective, affordable, easy to provide and use and give women everywhere, from Baltimore to Burundi, a measure of security against a variety of reproductive health concerns."

—**JUDY MANNING,** OFFICE OF POPULATION AND REPRODUCTIVE HEALTH, U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT

- User evaluations to ensure that the needs of end users, health care providers, and other stakeholders are incorporated throughout the development process.
- Market research and business and financial analysis plans for sustainability.
- Public-private partnerships to ensure product supply and financing.

As the product-development cycle progresses, the level of analysis in these areas should increase, and development plans should be refined to incorporate emerging information.

3. Increase awareness and support for multipurpose prevention technologies.

Stakeholders must raise awareness, build support, and mainstream the concept of multipurpose prevention. By building a cadre of stakeholders across disciplines, for example, the global health community can foster a new generation of researchers, developers, advocates, providers, and policymakers who will incorporate multipurpose prevention options into health programs. Stakeholders can also strengthen programming for the technologies we have today.

Central to this effort is the urgent need to mobilize resources. Proponents must secure the resources, skills, and support required for every phase of product development and introduction, from discovery and clinical trials to regulatory approvals and commercialization. To build momentum, it will be critical to communicate progress, which will likely include strengthened collaboration across sectors, new multidisciplinary approaches, greater cost efficiencies, and accelerated impact.

Now is the time to stimulate discussion, debate, and action on multipurpose prevention technologies. We encourage stakeholders to join in this effort to accelerate development and access to multipurpose prevention technologies for sexual and reproductive health. Women around the world deserve our commitment to their health and well being.

ACKNOWLEDGMENTS

The authors are grateful to the following reviewers for their comments and support of this brief:

- Mags Beksinska, Reproductive Health & HIV Research Unit, University of the Witwatersrand
- Heather Boonstra, Guttmacher Institute
- Martha Brady, Population Council
- Marianne Callahan, CONRAD
- Ward Cates, Family Health International
- Meredith Clark, CONRAD
- Patricia Coffey, PATH
- Polly Harrison, Alliance for Microbicide Development
- Anke Hemmerling, University of California, San Francisco
- Susan Ivey, Health Research for Action, University of California, Berkeley
- Peter P. Lee, Osel, Inc.
- Joan Lichterman, Health Research for Action, University of California, Berkeley
- Judy Manning, US Agency for International Development (USAID)
- Lanre Onigbogi, University College Hospital, Nigeria
- Wayne Shields, Association of Reproductive Health Professionals
- Jeff Spieler, USAID
- Alan Stone, Medsa Ltd.
- Jim Turpin, National Institutes of Health, National Institute of Allergy and Infectious Disease
- Kevin Whaley, Mapp Biopharmaceutical
- Rachel Wilson, PATH

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Advancing Prevention Technologies for Sexual and Reproductive Health

This document draws from an international symposium on multipurpose prevention technologies held in Berkeley, California, in March 2009. "Advancing Prevention Technologies for Sexual and Reproductive Health" brought together more than 150 reproductive health researchers and advocates to discuss and debate opportunities and challenges for advancing technologies that address multiple reproductive health indications. Readers may access the symposium presentations and a report of the symposium proceedings at www.cami-health.com/symposiums.html.[43]

To learn more about the Initiative for Multipurpose Prevention Technologies, visit our website at www.cami-health.com.

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