Prevention Options for Women

Topical Microbicides

Product Development

The international health community is facing an urgent need for health products that will help people—particularly women in developing countries—reduce the transmission of sexually transmitted infections (STIs) and HIV. Researchers have been working to develop topical microbicides, substances that will one day reduce STI transmission when applied in the vagina.[1] After more than 10 years of research and development, approximately 60 microbicide products are in some stage of development, and more than half are in pre-clinical stages.[2]

A Challenging Goal

The benefits of a microbicide are clear, but the development process is wrought with challenges. A lack of efficacy data has hampered the advancement of a viable microbicide candidate and, in turn, discouraged commercial investment.[3] In addition, because a successful microbicide will need to meet a range of performance requirements, developers face numerous technical challenges.

To be effective and appropriate, a microbicide candidate will need to:

- be active against HIV *in vivo*;
- be safe;
- preferably have broad-spectrum anti-microbial and contraceptive properties;
- be formulated into a product that is acceptable to the user;
- be stable, even at high temperatures or in uncertain storage conditions;
- remain in the vagina for prolonged periods of time through vaginal adhesion;
- be easy to manufacture in bulk quantities;
- be produced cost-effectively.

These are complex criteria. Many compounds that could serve as potential active ingredients have been identified, but very few fulfill all of these requirements.

Advancing the Promise of Microbicides

The goal of PATH's microbicide development program is to accelerate the development of new products by determining if any of the vaginal products currently marketed in developing countries can be used to prevent viral and microbial infections. Because it allows developers to build on progress made in formulation development, production, commercialization, and appropriate use, this approach streamlines many of the challenges related to product introduction. The time and resources saved in these areas can then be devoted to proof of clinical safety and efficacy.

PATH's work on microbicide development consists of three phases: selection, product development, and introduction. The scope of our current work plan is focused on the selection phase, which will last up to 18 months. The primary objective of this phase is to evaluate currently marketed vaginal products in India and identify the most promising products and partners for microbicide development.

PATH has chosen to conduct this work in India for a number of reasons. With nearly 4 million Indians living with HIV/AIDS, India has the highest HIV incidence of any country in the world after South Africa.[4] India also has a well-developed pharmaceutical industry that meets international standards for good manufacturing practices. This industry not only has access to its own Indian markets, but to a number of other developing-country markets, such as those in Africa.

Next Steps

The selection phase is integral to the product development and introduction activities that will follow it. The PATH team will survey vaginal products that are already marketed in India, including therapeutic and cosmetic/hygiene products. These will be evaluated for their anti-HIV properties as well as other criteria such as toxicity, acceptability, and formulation.

As with all of PATH's technology development projects, we will collaborate with representative user groups, technical development and testing agencies, pre-clinical trials and clinical product development experts, and private manufacturers. PATH is collaborating with the Indian National Institute of Pharmaceutical Education and Research (NIPER) and a U.S. organization, the Program for the Topical Prevention of Conception and Disease (TOPCAD).

By using already marketed vaginal products, identifying user preferences, and fostering formulation development, we plan to move potential microbicide compounds or formulations further along the product-development pipeline. Our hope is that our work will help protect, maintain, and improve the health of women, especially women in developing countries.

This work is made possible with funding from the Bill & Melinda Gates Foundation and the Andrew W. Mellon Foundation.

References

1. Alliance for Microbicide Development. What in the world is a microbicide? http://microbicide.org/ (Accessed March 2002).
2. Alliance for Microbicide Development. *Microbicide Research and Development—Progress Report.* (January 2002). Available online at http://www.microbicide.org/micro.research.progress.report.jan02.pdf.
3. Population Council and International Family Health. *The Case for Microbicides: A Global Priority*. New York, London: Population Council and International Family Health (2000).
4. Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO). *AIDS Epidemic Update*. (December 2001). Available online at http://www.unaids.org/epidemic_update/report_dec01/index.html.

1455 NW Leary Way ~ Seattle, WA 98107 USA ~ Tel: (206) 285-3500 ~ Fax: (206) 285-6619 ~ www.path.org