Prevention Options for Women

A Woman's Condom
Product Development

Women and health professionals alike have shown a significant interest in female-initiated barrier methods that prevent both pregnancy and sexually transmitted infections (STIs), including HIV. The female condom is a pioneering vaginal barrier device that achieves both of these goals. Since the first design was approved by the U.S. Food and Drug Administration (FDA) in 1994, the female condom has been introduced in 60 countries for both family planning and infection prevention.

Limitations of Current Designs

Despite the clear benefits of a female condom, only one type has been approved by the FDA and introduced globally. Acceptability studies show that many users of the female condom initially find the product acceptable. Data from long-term use are scarce, however. Women and couples often cite problems related to use (such as difficult insertion, discomfort, and concerns about stability) as well as design (including its unattractive appearance, high cost, and problems with slippage).

In response to these issues, product development teams around the world are working to design second-generation female condom products. As part of a Stage I feasibility analysis, PATH evaluated existing products and those in development to investigate whether they adequately address—or could be modified to address—user needs. Our research indicated that even with modifications, none of these products would satisfy the needs that users found most important.

Redesigning a Woman's Condom

PATH is working towards a refined female condom product, which we refer to as a woman's condom. PATH works with groups of users and potential users, representatives from donor agencies, and health care providers to establish design priorities that will enable a woman's condom to be:

- easier to insert and remove,
- easier to use (especially for first-time users),
- comfortable for both partners,
- stable during use,
- less expensive than current options.

Based on these criteria, our design team developed proof-of-concept prototype models in the PATH laboratories and evaluated the prototype designs for function and stability through bench testing. The most promising designs graduated to user evaluations—first in a controlled clinical setting and later with couples using them at home.

PATH is currently evaluating the prototype designs with couples in Mexico, South Africa, Thailand, and the United States. After each round of evaluation, we modify the design based on feedback from these users. Working with couples from diverse regions helps ensure that the design responds to cultural differences and incorporates the needs of women who represent a range of ages, body sizes, and parity status.

In addition, PATH is evaluating designs and materials that will allow the product to be priced much more competitively when produced in greater quantity. These activities help ensure that the final design will be comfortable, usable, and affordable for a wide range of users.

Partnering With a Manufacturer

Since PATH does not manufacture the products we develop, our long-term goal is to partner with an appropriate manufacturer who will take the final design to production and distribution. We are most interested in partners who can ensure:

- cost-effective production,
- wide-range distribution and marketing capabilities,
- ability to capitalize on a new manufacturing production design,
- the desire to include a woman's condom in their current lines.

To date, the PATH team has established contact with manufacturers of female condom designs, who offer unique capabilities and use production techniques and materials that ultimately could be compatible with the final PATH design. Other appropriate partners may include manufacturers producing synthetic and latex men's condoms.

Next Steps

PATH's woman's condom program is currently in the third stage of product development, which is focused on iterative development through design refinement and validation. By 2003, we plan to:

- evaluate new generations of prototype devices at field sites in four countries;
- refine prototypes based on user feedback;
- develop and implement parallel testing on additional design concepts to accelerate the development process;
- investigate a wider range of process and manufacturing options that may reduce production costs and, ultimately, the cost of a woman's condom.

Once PATH has completed, optimized, and validated the design, CONRAD will lead the development and implementation of clinical trials on acceptability and efficacy.

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