

Advancing Female Condoms

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Consultation on Female Condoms: selected recommendations

- Expand product choice; reduce product cost.
- Define process to assure quality for non-U.S procurement (for products w/o FDA approval).
- Expand effective FC programming (integrate in HIV/ AIDS prevention and treatment programs).
- Build supportive environment through advocacy.

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- Despite the benefits that female condoms offer, they are still not readily accessible in most countries.



Product Status: FC1[®] and FC2[®]

- Female Health Company (FHC).
- FC1: polyurethane. USFDA approved. Available in 100+ countries.
- FC2: nitrile. Introduced in 2005 with CE approval.
- WHO technical review in 2006 cleared the way for UNFPA procurement.
- Approved in India and Brazil.
- USFDA approved FC2 March 2009 based on comparison to FC1.
- Lower costs means more FCs can be procured and programmed.



Product Status: VA w.o.w



- Medtech Industries, India.
- Latex condom pouch, attached to v-shaped outer frame, with polyurethane sponge.
- CE mark and country approvals.
- Sold primarily through the private sector in Brazil, Argentina, Indonesia, southern African region, and some EU countries.



Product Status: Panty® Condom

- Natural Sensation, Colombia.
- Polyethylene condom pouch. Reusable cotton or nylon panty.
- CE Mark and some country approvals.
- Sold through private sector in Colombia, Panama, Venezuela, Dominican Republic, Costa Rica; also in UK and Spain.



Product Status: Woman's Condom (WC)



- Developed by PATH, with CONRAD and USAID.
- Phase I comparative clinical trial completed with good results.*
- Production transferred to China in 2008.
- Clinical trial for product registration in China anticipated 2010.

*Schwartz, et al. 2008 Contraception.



Regulatory Issues: approval strategies

- USFDA approval: requires contraceptive effectiveness study.
- Other countries accept short-term failure-mode study (similar to male condom approval).
- CE Mark: affirms confirmation to established production standards.



Regulatory Issues: ensuring FC quality

- WHO technical committee convened; reviewed dossiers of clinical and safety data for new products.
- Consensus definition of clinically significant failure modes defined.
- ISO developing Female Condom standard; testing guideline for new developers.



Contraceptive effectiveness study: challenge of obtaining good data

- Difficult and expensive to recruit and retain study population.
- Assumes consistent product use (not realistic given how couples use barrier methods).
- Potential solution: alternative study – slippage/breakage study and use biomarker of semen.*

*Mauck CK, Weaver MS, Schwartz, JL, et al. Critical Next Steps for Female Condom Research: Report from a Workshop. *Contraception*. (In Press)



Expanding FC Programming into HIV/AIDS programs*

- Fewer than half of respondents (48%) felt that the AIDS community promoted FCs.
- 13% reported neither FP nor HIV/AIDS community embraced FCs.
- 55% reported that dual protection promotion increased use and acceptability.
- VCT and ART programs seen as easiest entry points.
- Need coordinated institutional support to integrate FCs into existing programming.

*PATH, 2008 (>200 respondents from 44 countries).



Smarter FC Programming: assessing cost effectiveness*

Key Findings:

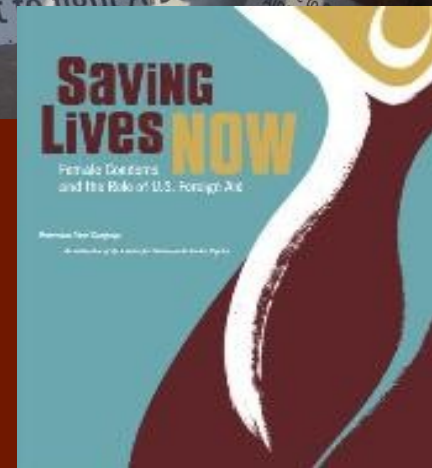
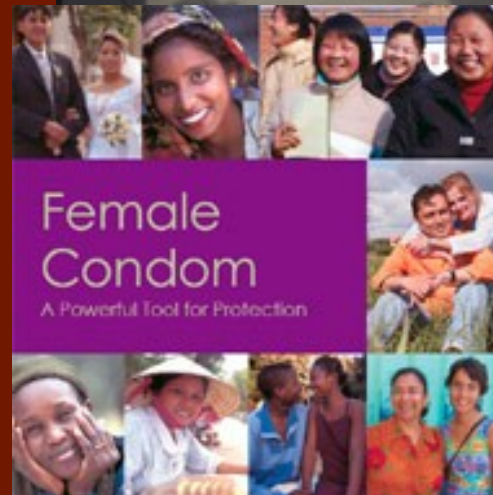
- Female condoms lack consistent definition of success.
- Female condoms less cost effective than MC; therefore, target programming to those who need it most.
- FCs necessary when MC cannot/will not be used.
- However, report acknowledges that it's difficult to quantify impact of FC on women's empowerment, which is seen as integral to HIV prevention.

*Smarter Programming of the FC, FSG Social Impact Advisors, 2008.



Advocacy Updates

- Uptake by broad coalition of groups/ organizations.
- Advocacy materials developed/distributed
- International meetings and conversations organized.



Advocacy Updates

- UNFPA Advocacy Task Force: strengthens advocacy at country level, bridges international efforts.
- Advocacy needed in PEPFAR and CCP countries to urge National AIDS Councils, MOH and USAID missions to expand commitment to FC supplies, education and promotion.



Critical Role of Positioning

- A product always has a “position”; even if very little promotion.
- A “position” can be either good or bad.
- Appropriate strategic promotion can influence how the market perceives, or “positions”, a new product.



Critical Role of FC Positioning

- Positioning: both a situation and a process—a perception in the minds of the target market (users, buyers, providers).
- *“How the market perceives a new product in relation to current products or services.”*
- The most important step in choosing a promotion strategy.



Implications: lessons for other SRH technologies

- Range of prevention options needed.
- Cost matters; product and supply costs influence introduction & scale up.
- Define success. Set realistic targets for uptake/impact.
- Long-term planning required to establish sustainable demand/supply.



Priority Actions

- Relaunch of the FC in the US: opportunity for education and outreach to HIV/AIDS programs.
- Country-level advocacy for expanded commitment to FCs in PEPFAR and CCP countries.
- Messaging around consistent and correct use—does this set up couples for failure?
- Establish measures of program success. Strengthen monitoring and evaluation to build evidence.
- Next generation FC products: 2nd product in a market. How to program for best health benefit?



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