Developing a Strategy for Female Condom Parallel Programming

Proceedings of an Expert Meeting
23 - 24 November 2011
Durban, South Africa
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<td>Association Camerounaise pour le Marketing Sociale</td>
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<td>CONRAD</td>
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<td>Dahua</td>
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<td>Men who have Sex with Men</td>
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Male and female condoms are currently the only dual protection methods effective against unintended pregnancy and the transmission of infections (STIs) and HIV. In recent years, a number of initiatives including advocacy and support to female condom (FC) programmes and increased distribution have played a significant role in highlighting the need to ensure FCs are seen as an essential tool for prevention. Another important development has been the emergence of new FC products, differing in design and materials, that have the potential to lower cost and improve acceptability. There are challenges in developing new FC products, regulatory issues being by far the greatest hurdle, however several new designs are now available in different countries, some of which are progressing through the final stages of regulatory approvals, whereafter they will be more widely available. The availability of new designs of FCs, some of which may also be more affordable, will increase choice and options for couples who choose to use FCs as their prevention method.

The Universal Access to Female Condoms Joint Programme (UAFC) and MatCH (Maternal, Adolescent and Child Health) convened a meeting in Durban, South Africa in November 2011. The purpose of this meeting was to develop strategies, recommendations and guidelines for future female condom (FC) parallel programming. Existing FC programmes face a range of challenges and are rarely available outside the donor funded public sector. In recent years the development of new FC products has become a reality, and several FCs are in various stages of regulatory approval. Although this has the potential to widen choice and lower product costs, there are other considerations that need to be addressed. New products vary considerably in design, material and method of insertion and once available, providers and users will need to be trained on the use of new FCs. This meeting presented an update on FC product technology, shared experiences and plans for FC programming and reviewed current FC programmes and initiatives that will support FC programming more broadly.
Key Priority Areas for Female Condom Parallel Programming

In this section, we present “key priority areas” considered by the meeting participants to be essential to address the introduction of new FC products into existing and new markets.

Training, Guidelines and Policy

Ensure that comprehensive, product specific training and guidelines, supported by effective policy, are available for all those involved in provision of FCs as part of introduction of any new product.

❖ Conduct a stakeholder analysis to understand who will be involved in provision of FCs;
❖ Develop comprehensive training guidelines and curriculum for new FC products;
❖ Conduct skills building workshops with those who will be directly dealing with users;
❖ Integrate new information into existing barrier method/other appropriate training packages. FC training can be incorporated into broader prevention training, however specific training should always be ensured;
❖ Ensure training information is disseminated to all sectors who may be involved in FC distribution;
❖ Ensure training plan and training is conducted prior to introduction;
❖ Ensure teaching method/approach covers a variety of female condoms with no bias;
❖ Ensure service providers/managers are trained on use of correct products, instructions and specifications for each product;
❖ Ensure there is an ample supply of FC products for trainers and models that can be used to correctly demonstrate each product;
❖ Maintain a database of who has been trained.

Information, Education and Communication (IEC) and Promotional Materials

Ensure locally relevant and product specific IEC and promotional material are available and backed up by accessible centralized sources of information.

❖ Ensure centralised sources of information are available at local and global level for users and providers. Linkage from local level to global level for information is critical so countries know what is available globally and can adapt to their local circumstances;
❖ Inform and disseminate availability of the UNFPA website “allaboutcondoms.org” which maintains up-to-date and comprehensive information on both male condoms (MCs) and FCs;
❖ Consider in-country hotline/helpline for condom advice and information. Link to “allaboutcondoms.org website;
❖ Disseminate information on new products to all levels of health care, public sector, non-governmental organisations (NGOs), private sector and social marketing organisations;
❖ Build relationships with manufacturers and stakeholders to ensure they continually provide up to date information on FC products;
❖ Ensure IEC material gives correct information on specific brands with detailed instructions to avoid confusion. If generic information is developed it needs to be easily understandable;
❖ Develop/review/adapt IEC materials in local languages with locally relevant pictures and drawings of insertion techniques.

Marketing, Branding and Product Positioning

Develop and budget for a marketing strategy including FC branding for all sectors (public, private, social marketing) that targets identified user groups with attractive products.

❖ Conduct in-country market research for both existing and new FC products to understand target groups and existing user profiles;
❖ Develop marketing techniques and a demand generation framework in all sectors (public, private, social marketing) including creative briefs for service providers to use in different scenarios depending on target group;
❖ Donor supported countries need to advocate for a portion of the commodity budget (at least 10%) to be set aside for developing a marketing strategy and associated activities;
❖ Primary funders of FC commodities need to create a generic marketing strategy tool that can be adapted in-country;
❖ Manufacturers should be lobbied by global and local organisations and tasked with developing attractive and appealing designs for the market;
❖ Consider rebranding if FC is less popular or where FC is available at no cost and there are concerns of quality as no value is attached to the product;
❖ Country programmes should consider developing their own brand even if there is only funding to have one brand;
❖ Investigate strategies for sustainability of FC programmes post donor funding;
❖ Evaluate cost of introduction, including different packaging.

[Red Box] Research, Monitoring and Evaluation
Support continued research on FCs, in particular new FC products to ensure that evidence for pregnancy, HIV and STI prevention efficacy is available for the product.

[Red Box] Global level:
❖ Efficacy studies for pregnancy, HIV and STI prevention are urgently required. There is a need to advocate for global funding for studies to build the evidence base for prevention using FCs, so existing and new products have solid prevention data as a basis for advocating for more widespread use;
❖ Conduct studies which examine the increase in protected sex acts with both FC and MC use. Investigate the concept of greater choice leading to more protection to counteract concerns about the migration from MC to FC;
❖ Develop simple indicators on FC use at a global level that countries can select according to their capacity and needs.

[Red Box] Country level:
❖ Ensure local research is conducted before (baseline) and after introduction (also see market strategy);
❖ Document user profiles of current and new condom products;
❖ Closely monitor uptake of different products to ensure demand for each is met;
❖ Select simple indicators (developed globally) and include indicators that can track FC use by type of product.

[Red Box] Advocacy and Awareness
Advocacy efforts are urgently needed to raise the profile of FCs as an essential component of prevention efforts. The emergence of new FC products presents an opportunity to promote new and existing products and address user issues.

[Red Box] Global level:
❖ Advocate for funding for global FC research. Pregnancy, HIV and STI efficacy and studies looking at protected sex acts are expensive and cannot be conducted in all countries;
❖ Advocate for WHO to disaggregate condom type in its Essential Medicines list to include both MC and FC;
❖ Convene an International Condom Conference to present research, new technologies, programmatic activities and advocacy initiatives;
❖ Promote awareness at global and country level about new FC products so that countries know there is a choice and are knowledgeable about the different products before they order.

[Red Box] Country level:
❖ Advocate for choice in FC products not just a single product/cheaper product;
❖ Advocate for political commitment and buy-in for FCs;
❖ Ensure media reports are unbiased;
❖ Advocacy to promote inclusion of FCs in country Essential Drug List (EDL)/Essential Medicine List (EML);
❖ Ensure awareness of new products in-country.

[Red Box] FC Introduction
Develop an in-country introductory strategy for new FC products.

[Red Box] Country level:
❖ Review and adapt WHO contraceptive document “Strategic approach to contraceptive introduction at country level” for FC product introduction;
❖ Develop and implement a phased introduction with post introduction evaluation to monitor progress and uptake of introduction;
❖ If another FC product is going to be phased out, a phase out strategy should be planned, implemented and monitored.
Session 1

Introductory Session – Female Condom Technology and Programme Update

The participants were welcomed and the purpose of the two day meeting was outlined. This session reviewed new female condom technology and gave an update on progress in development and availability of new products. UNFPA and UAFC initiatives in supporting female condom programmes and development were presented. Full presentations can be found in Appendix 2.

More Than One Female Condom? What Female Condoms, and When Will They be Available: Update on Development and Approvals

Mags Beksinska, MatCH

This presentation reviewed the history, development and major milestones of female condoms since the 1980s. New devices have been developed to increase choice and reduce costs. The presentation reviewed all the latest designs and where they were reached in the development and regulatory approvals pathway. New products are made of latex, polyurethane and polyethylene with different types of retention features used internally and externally. Reuse research has not been conducted on any of the new FC products, however, as new FC designs move into the market further reuse research will potentially be conducted on new products.

The process of getting new FCs approved is complex and there are currently generic specifications for FCs being developed by UNFPA/WHO. These will guide manufacturers who aim to apply for prequalification and approval. The WHO Female Condom Technical Review process and how current female condoms are evaluated was outlined. Manufacturer’s Dossiers are reviewed and on completion of this process an independent factory visit is conducted before final approval is given. A number of new FC products are currently being evaluated and it is anticipated that several new products may be approved in 2012.

The UAFC Programme – Future Plans?

Monique Dememint, UAFC

The Universal Access to Female Condoms Joint Programme (UAFC) was launched in 2008 and is composed of several partner organisations including OXFAM Novib, Rutgers World Population Foundation (WPF), The Dutch Foreign Ministry, and I+ Solutions. The overall goal of the UAFC is to make FCs available, accessible and affordable. The UAFC programme has a number of focus areas including programmatic and technical support and advocacy. UAFC is supporting FC country programmes in Nigeria and Cameroon with additional advocacy, linking and learning support to Mozambique. Technical support is also given to FC manufacturers to develop and improve technologies.

An international advocacy platform was established, bringing together a wide range of representatives from many organisations including donor agencies. One of these meetings was held at the recent and very successful Female Condom Conference in The Hague “Prevention, Pleasure and Protection” International Conference on the Female Condom held on the 17th and 18th of November 2011. Advocacy activities aim to ensure that FCs are included in policy papers and budgets, and to increase donor funding for FC activities.

As the end of the first three year phase of the UAFC draws to a close, major achievements include, making FCs more visible on the international agenda, increasing demand for FCs in country programmes and negotiating for a reduction of the public sector price of FCs which has been to date a major inhibiting factor for programmes. If funding is made available, the UAFC will continue its existing partnerships. Future plans include an expansion of FC programme support to more countries, an increase in FC distribution, and continued support to manufacturers to encourage innovation and increase competition in the FC market. There are also plans to combine international and local advocacy groups to encourage governments to pay more attention to FCs.

UNFPA Global Initiative – Successes in Programming

Bidia Deperthes, UNFPA

The condom is a critical component of prevention and there are currently no alternatives. As new interventions are made available such as treatment for prevention and medical male circumcision (MMC), which are partially efficacious, there will still be a need for condoms. Women in Africa are at high risk of HIV infection, in particular those engaging in sex with older men. In these situations, young women find it difficult to negotiate safe sex. UNFPA is involved in male and female condom specifications; guidelines; training; procuring and defining regulations for countries; fund raising for commodities and their programming at country level; and play a lead role in male and female condom programming.

There is a clear understanding by all donors that condom commodities are important. However few have historically supported programmes. Following the landmark 2005 FC global consultation in Baltimore, UNFPA committed to support FC programmes and increase distribution and launched the Global
Condom Initiative in 2006. With additional support from USAID, FC distribution increased from 13 million in 2005 to 38 million FCs at the end of the fourth year of support. This showed the development communities and governments that there was a demand for FCs. However funding has not been consistent and after many years of increased FC distribution, 2010 levels of distribution dropped to 35 million. Donors significantly reduced their support to $18 million in 2010 as compared to $38 million in 2009.

In 2011, UNFPA mobilized $17 million to re-intensify male and female condom programming, especially in Africa. This support should allow a boost that will increase access to the commodities, create demand for safer sex including more condom utilization and support programme managers to provide adequate and quality services to governments and users.

Session 1: Discussion Points

Discussion followed presentations and comments included:

✦ The FC is not included specifically in the WHO EML, only the term “condom”, and because of this, most countries follow this lead and do not include the FC in their own EML;

✦ The FC has been subject to the MC specifications because there was nothing else, however it is now accepted that the FC requires its own standard and specifications and these are currently in finalisation stage by the ISO (International Standards Organisation);

✦ A number of manufacturers are in the final stages of compiling their dossiers for evaluation and these are under review for pre-qualification. It is anticipated that some will be approved in the first half of 2012;

✦ There are two documents which will be made available in 2012 regarding the WHO technical review committee meeting in 2011:
  - Review of submissions by manufacturers of female condoms to initiate the prequalification process for bulk procurements;
  - Scientific and technical requirements to formulate a female condom generic specification and prequalification scheme;

✦ The challenges of collecting distribution information were raised, procurement figures are usually shown, but there is a need to capture accurate data on the end-user and the various distribution points on the way to the end-user;

✦ Lack of investment in condom programming can only lead to poor utilization. Providers are key for distribution but unless they are trained, negative attitudes and lack of information will hamper condom programming;

✦ There is a need to step back and refocus on men, making them a key target for promotion and education;

✦ There was considerable discussion on how to turn around the recent reduction in FC procurement. It was felt that countries need to ensure that they request FCs and that they are included in their budget lines;

✦ It was highlighted that as new FCs become available costing and budgets will need to be set aside for re-education on a new product or there will be confusion which may lead to negative repercussions;

✦ In South Africa, the medical device directorate has been established and will take responsibility for both male and female condoms.
Session 2
Experiences and Plans for Dual FC Programming

This session reviewed some examples of country programmes that are planning for dual programming in the near future. Full presentations can be found in Appendix 2.

Introducing New FCs in UAFC Supported Countries

Caitriona Rush, UAFC

UAFC is currently supporting FC programmes in Cameroon, Nigeria and Mozambique. One of the objectives of this support was to consider the introduction of a second FC. Although this has not happened in this first phase of the programme, there are future plans to do this. If further funding is secured, the UAFC programme will continue to support its existing programmes and aim to expand further to between seven and ten countries.

To help bring more manufacturers into the market, one of the main activities UAFC supported in the first phase was a functionality study which will provide the clinical evidence that several manufacturers are lacking to complete their product dossiers. This information is crucial for the pre-qualification process required by UNFPA/WHO. It is anticipated that two further FCs will be pre-qualified in 2012. A second functionality study is in the planning stage and will offer an opportunity for more recently developed FC products to compile their clinical data for pre-qualification purposes. Each country has its own regulatory process and testing requirements for condoms brought into the country. UAFC have provided technical support to countries who want to test FCs and this will continue in the next phase.

Social Marketing in Cameroon – Preparing for FC2 and Reddy

Lilly Claire Ekobika, Association Camerounaise pour le Marketing Sociale (ACMS)

Unmet need for contraception is 44% in Cameroon, condom use is low and women are more affected by HIV than men. The FC distribution programme commenced in 2002 and was positioned as a Family Planning (FP) tool targeting both men and women. Currently both UNFPA and UAFC support the FC programme and this has allowed for strengthening of the distribution network with more community based organizations (CBOs) and the introduction of FCs to hair-dressers. This has been backed by high level advocacy and mass media campaigns.

Cameroon has considered introduction of a second FC to the FC2. In adopting an evidence-based approach, focus group discussions were conducted with women, of whom 64% expressed the need for product choice. Targeting different groups with the different products has also been discussed. Discussions are on-going with the Ministry of Health regarding local testing of new FCs. Other considerations discussed were the need to develop specific marketing mix strategies for different products and availability of pelvic models to demonstrate all products.

The Condom Programme in South Africa

Eva Marumo, National Department of Health, South Africa

South Africa has one of the largest and most established Government funded public sector male and female condom programmes. The current financial year aims to procure 1 billion MCs and 11 million FCs. Condoms are promoted and distributed for dual protection with at least one FC distribution site in all sub-districts, totalling more than 400. Initially the focus of FC distribution was from primary health care or clinical sites, but more NGOs and other non-traditional outlets have been trained to distribute FCs. Public, Private Partnerships (PPP) distribute MCs through channels such as taverns and diverse private companies have been encouraged to participate and maintain condo-cans. Both PPP and social marketing will be expanded to include FCs in the future.

Condom training is essential, in particular for FCs, in order to counsel clients and promote continued use. IEC leaflets are made available to all sites along with pelvic models for demonstration. Demand creation, promotion and education around FCs will expand uptake and increase access. Quality assurance of condoms is the responsibility of the National Department of Health and all batches of MCs and FCs coming into SA are tested, including donations. Future local medical device regulation will potentially allow new FC products to be made available.

Demand for FCs is growing and in the next five years there are plans to expand access by supporting provinces to ensure that FCs are widely available through public, private and NGO outlets. The National Condom Policy and Guidelines are being finalised and there are plans to strengthen FC recording and monitoring. Although much research has been conducted in South Africa more is needed on user issues.
Social Marketing Perspectives of Dual FC
Social Marketing in Mozambique: Preparing for Cupid

Raquiana Mafuca and Dorien Rhebergen,
PSI Mozambique

In Mozambique, contraceptive uptake is very low and is coupled with high maternal and infant mortality rates (408/100,000 and 141/1,000 respectively). These are some of the critical issues that are being addressed as part of the PSI reproductive health programme in Mozambique where PSI is responsible for social marketing and community mobilization. The FC1 was introduced by the government in 1999 followed by FC2 in 2009 but there has been limited IEC available. Furthermore, stock outs and distribution problems have hampered availability. From 2010, PSI and its consortium partners, Pathfinder International and Fórum Mulher are implementing a programme that aims at increasing the demand for the FC. Promotion of the public sector FC2 is primarily done in the context of FP and dual protection, to avoid the FC being stigmatized as an HIV prevention method.

The potential for introducing a second condom (Cupid) through the UAFc programme, created an ideal opportunity for providing the FC programme with a private sector component. Market research was conducted to better understand women's perception of sex in general and their sexual needs and, most importantly, their perception of the female condom. The “Jeitosa” brand name for the new FC was created, represented by an archetype; a 25 year old woman living in an urban/peri-urban area, who has just finished school and started her first job. She alludes to both younger and more mature women who are not afraid to try new things, are comfortable with their own bodies, speak openly about sex and feel good about being different from others. Jeitosa will be pink and vanilla scented and the launch is expected in the first half of 2012.

The FC2 will be for public distribution only and Jeitosa will be the first FC in the private market in Mozambique. The FC2 will continue to be distributed and managed by the Ministry of Health and the National AIDS Council while Jeitosa will be distributed and managed by PSI Mozambique. The two FCs will be positioned to reinforce each other’s promotion. A communication and distribution plan is currently being finalized that will focus on below the line promotion and sales through Jeitosa FC sales representatives, starting in Maputo province and gradually expanding into others areas.

Session 2: Discussion Points

✦ A discussion was held on the issue of in-country testing of FCs. Different countries have different policies and some test the FCs as they arrive in countries while others do not. UNFPA noted that they did not recommend testing of donated FCs as not all laboratories had been accredited by international regulatory bodies. There was concern from some countries that, post shipping and storage, the quality of condoms did require testing and this was a national regulation. This issue was noted as an important point to consider as new FCs are introduced and equipment and testing may potentially have to be adapted;

✦ Not all countries require WHO/UNFPA prequalification to introduce a new FC. If a national laboratory is able to do their own testing this may be possible without other approvals;

✦ The name “female condom” was debated as to whether this language was correct when it may be used by men who have sex with men (MSM) and the term “internal condom” was put forward as another possible name that could be used;

✦ Sustainability of FC programmes was discussed amidst fluctuating donor funds. PSI reported on how they were trying to build local markets and get private companies to take over male condom brands. For the FC this would also need to be done in the future and demand generation activities would be critical;

✦ Rebranding of the FC2 to suit target populations was put forward as important when introducing new FCs. If a new FC enters the market, branding should always be considered even if for the public sector.
Developing a Marketing Strategy for FCs – Donor’s Perspectives and Requests

Bidia Deperthes, UNFPA

It is critical to create a market for FCs. Historically FC funding has been around commodities, with limited attention to the associated programming costs. This can result in a number of problems including poor distribution leaving stock to expire in warehouses, misunderstanding of the product and lack of demand.

A demand generation initiative launched by UNFPA has focused on the need to treat the FC as a private sector product in order to succeed and make it sustainable and this would require a marketing strategy with a target audience identified based on the four “Ps”: Population, Product, Place strategy and Price. The focus Population needs to be clearly identified followed by one of the Products, which will be specifically targeted to that population. The Place strategy identifies where the target audience is comfortable to go and get FCs. Finally Price is important, the target population will advise on an acceptable price of a condom – either free, subsidized or market price.

Policy makers need to decide on who to target, however in some countries there are sensitivities around young people under 18 as a focus of distribution. Partnerships are critical and need to go beyond government and the UN. A total market approach is needed with condom programming. By targeting all sectors including the NGO sectors and community women’s groups will feel comfortable to say where to go to get condoms.

The Global FC Demand Generation Strategy has selected six countries (India, Brazil, South Africa, China, Swaziland and Ukraine). Every country will have a specific FC market strategy. These pilot countries will inform the development of the generic Demand Generation Document, enabling other countries to replicate programmes that are nearest to their own experiences.

Regional Training Experiences in Change from FC1 to FC2

Maya Gokul, Support Worldwide

Support Worldwide trains all categories of providers in the public, private and NGO sector in both male and female condoms. Training focuses on values, beliefs and attitudes, in order to achieve a change in mind-set in relation to sexual and reproductive health (SRH). An important strategy is to shift the demand to clients, motivating them to ask for condoms, rather than providers asking if clients want condoms. A key part of the training also focuses on pleasure and condoms, challenging the negative stereotypes of condom use. Training has had an important effect on changing attitudes towards the perception of condoms among providers and contributed to the increase in sites providing FC2.

Training on the transition for FC1 to FC2 was straightforward as both products are similar in size, shape, inner ring, lubrication and packaging. Providers have accepted the FC2 and indicate it is a better product, with a softer outer ring and less noise reported in use. Ensuring a consistent supply is important and providers are trained on record keeping of condoms to avoid stock-outs. Training has been expanded to include men who have shown interest in using the FC.

The Condom Project

Joy Lynn Alagabres & Franck de Rose, The Condom Project

The Condom Project works internationally in three main areas of condom programming: destigmatization, distribution models and education. These programmes work together as a global condom awareness strategy, aiming to find a way to get condoms into the hands of the end-user. Partnering with grassroots organisations that are already working with condoms in their own communities enables development of culturally specific initiatives that strengthen existing outreach models.

The anchor component of condom destigmatization initiatives is an arts-based programme that brings people together to create Condom Art Pins. The process allows people to handle condoms outside the sexual context and encourages dialogue about sexual health, myths, HIV transmission and condom use. The FC is being included in these sessions as a way of introducing them into the communities in a non-threatening way.

In some countries, a youth-driven programme called 30 Seconds: A Visual Voice uses simple video and editing equipment to create 30-second silent videos about condoms (where the subject can include anything but sex or religion) in order to stimulate dialogue about condoms in their communities.

Community feedback is used to inform educational initiatives; one of these was to create an educational 3D animation disc in 8 languages on how to use FCs and MCs, and a workshop on using condoms and lubricant. These videos are available on the “All About Condoms” website and distributed on discs in conferences and in the community. Designed for an end-user or educator these discs were made available in condom cases that also contain an indestructible, waterproof insert on how to use the FC and MC.
Conferences are used to amplify awareness about condoms. The “CONDOMIZE Zones” use the principle of attraction rather than promotion: colourful condoms are unrolled and inflated on PVC pipes, so participants can see the different types of condoms from around the world. Activities and education are also available, and lubricants can be sampled and tasted. Condoms are distributed in innovative ways, including putting condoms on the sleeve of the CONDOMIZE! “What’s YOUR Slogan?” t-shirts, giving people a voice and a place to write their own CONDOMIZE slogans.

The CONDOMIZE Campaign and the “All About Condoms” website is an initiative of UNFPA in partnership with The Condom Project and the Condom Interagency Task Team.

The Condom Project:
http://www.thecondomproject.org/

All About Condoms Use:
http://allaboutcondoms.org/allabout/use.htm

The CONDOMIZE Campaign:
http://www.thecondomizecampaign.org/

CONDOMIZE Facebook:
http://on.fb.me/CONDOMIZE

CONDOMIZE Twitter:
http://twitter.com/#!/CONDOMIZE

CONDOMIZE MySpace:
http://mysp.ac/y27dy7

Preparing for Introduction: Research and Regulatory Progress achieved for the Woman’s Condom

Kim Whipkey, PATH

The Woman’s Condom was developed by PATH through a user-driven approach to ensure women and men found a design that was acceptable, comfortable, and easy to use. The final design was verified through an evaluation study in South Africa, Mexico, and Thailand. After evaluating more than 10 manufacturers, PATH signed an agreement with the Dahua Medical Apparatus Company (Dahua), based in Shanghai, China, to manufacture and distribute the Woman’s Condom.

Research on the safety and performance of the Woman’s Condom has been extensive with studies completed in the US, China, and South Africa. Additional on-going studies include a comparative performance and failure mode study using prostate-specific antigen (PSA) as a biomarker for semen exposure and a contraceptive effectiveness study – both in the US – and a functionality study in China and South Africa. Chinese regulatory approval has been granted, and the Woman’s Condom is currently under review by the WHO Female Condom Technical Review Committee. US FDA approval will be sought in 2013-2014. In 2011, with funding from the Netherlands Ministry of Foreign Affairs, the Protective Options for Women (POW) Product Development Partnership (PDP) was launched among PATH, Dahua, CONRAD, and the Eunice Kennedy Shriver National Institute for Child Health and Human Development (NICHD). The goal of the POW PDP is to create sustainable markets for the Woman’s Condom in China and sub-Saharan Africa using a total market approach.

PATH and Dahua plan to use the total market approach strategy in China, with initial product introduction in the private-sector followed by the public-sector. The Woman’s Condom is branded as “O’lavie” in the Chinese market meaning “happy woman,” and is meant to convey a sense of vitality. The target market for O’lavie for private-sector sales is fashionable and educated young people with some disposable income. In addition, PATH and Dahua have assessed ten countries in Africa as potential market introduction sites. PATH and Dahua ultimately aim to create partnerships in the private and public sectors to ensure sustainability of the Woman’s Condom in the long term.

Session 3:
Discussion Points

✦ There was a discussion on how the FC should be positioned with existing prevention activities such as MMC and in the future, microbicides. There is a need for combination interventions where products do not compete;

✦ Funding has been extensive for other prevention methods yet even now the FC lacks efficacy data from high quality trials, in particular as the only FC with efficacy data has been phased out. This is a marketing problem as FCs will not be able to make the same claims of prevention as other methods which have had investment in conducting trials to show efficacy. The Woman’s Condom was noted as the exception and the current pregnancy efficacy study in the US will provide important data for the product;

✦ Avoiding confusion in the market place was stressed again and the importance of how to introduce a second female condom was emphasized.
### Appendix 1: Programme

**Female Condom Parallel Programming Meeting**  
**Venue:** MatCH, Durban  
**Date:** 23 - 24 November 2011

#### Day One – Wednesday 23rd November 2011

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<thead>
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<tr>
<td>9:15</td>
<td>Welcome &amp; Purpose of the Meeting</td>
<td>Jenni Smit, MatCH</td>
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<td>9:20</td>
<td>Introductions</td>
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<tr>
<td>9:50</td>
<td>More than one female condom? What FCs, and when will they be available: Update on developments and approvals</td>
<td>Mags Beksinska, MatCH</td>
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<tr>
<td>10:05</td>
<td>The UAFC programme – future plans?</td>
<td>Monique Demenint, UAFC</td>
</tr>
<tr>
<td>10:20</td>
<td>UNFPA Global FC initiative – successes in programming</td>
<td>Bidia Deperthes, UNFPA</td>
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<tr>
<td>10:40</td>
<td>Questions and Discussion</td>
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#### Session 2: Experiences and plans for dual FC programming

**Session Chair:** Zonke Mabude

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<tr>
<td>11:10</td>
<td>Introducing new FCs in UAFC supported countries</td>
<td>Caitriona Rush; Monique Demenint, UAFC</td>
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<td>11:30</td>
<td>ACMS social marketing in Cameroon-preparing for FC2 &amp; Reddy</td>
<td>Lilly Claire Ekobika, ACMS</td>
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<td>11:50</td>
<td>FC programme in South Africa</td>
<td>Eva Marumo, National DoH, SA</td>
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<tr>
<td>12:10</td>
<td>Social Marketing perspectives of dual FC social marketing in Mozambique: preparing for Cupid</td>
<td>Raquiana Mafuca, PSI Mozambique</td>
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<tr>
<td>12:30</td>
<td>Discussion</td>
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<td>13:00</td>
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#### Session 3: Training, education and Marketing

**Session Chair:** Jenni Smit

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<tr>
<td>14:00</td>
<td>Developing a marketing strategy for FCs – donors perspectives &amp; requests</td>
<td>Bidia Deperthes, UNFPA</td>
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<td>14:20</td>
<td>Regional Training experiences in change from FC1 to FC2</td>
<td>Maya Gokul, Support Worldwide</td>
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<tr>
<td>14:40</td>
<td>The condom project</td>
<td>Joy Lynn Alegabres; Franck de Rose, Condom Project</td>
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<td>15:10</td>
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<tr>
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<td>Preparing for introduction: Research and regulatory progress achieved for the Women's Condom</td>
<td>Kim Whipkey, PATH</td>
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<tr>
<td>15:45</td>
<td>Discussion and Closure – Day One</td>
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#### Day Two – Thursday, 24th November 2011

#### Session 4: Sustainability positioning and M&E

**Session Chair:** Zonke Mabude

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<td>Overview of Day One</td>
<td>Mags Beksinska, MatCH</td>
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<tr>
<td>08:45</td>
<td>More than one female condom product in country programmes: challenges and opportunities</td>
<td>All open discussion</td>
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<tr>
<td>10:30</td>
<td>Tea</td>
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<tr>
<td>11:00</td>
<td>Group work 2/3 small groups to discuss key issues for training, logistics, forecasting, research needs, tendering, M&amp;E, position with male condoms and other contraceptive methods etc.</td>
<td>Group work</td>
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<td>Developing a strategy, recommendations and guidelines for parallel programming</td>
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<td>15:30</td>
<td>Round up and way forward</td>
<td>Bidia Deperthes; Mags Beksinska</td>
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<tr>
<td>16:30</td>
<td>Closure</td>
<td>Jenni Smit, MatCH</td>
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More than one female condom? What FCs, and when will they be available: Update on developments and approvals

Mags Beksinska, MatCH (Maternal, Adolescent & Child Health)

TIMELINE FC DEVELOPMENT MILESTONES: 80’s – 90’s

- FDA approval of FC1 granted following completion of all required regulatory requirements.
- FC1 acceptability studies conducted globally.
- PATH start to develop Woman’s Condom.
- FC re-use research conducted with FC1.


TIMELINE FC DEVELOPMENT MILESTONES: 2000 -

- FHC begins to develop FC2.
- WHO clears FC2 for bulk procurement.
- FDA Approve FC2, FC1 production ceases.
- SFDA approve the Woman’s Condom.


FC product evolution

The FC has been around longer than you think! FC from 1937

Several patents filed for FC products pre 80s but few commercially developed or viable.

First FC design that went onto development was FC1, and was invented by a Hessel, a Danish doctor.
HISTORY-major milestones

- The FC approved by the USFDA in 1993 was welcomed as the first female-initiated method that could be used for both pregnancy and disease prevention.
- Enthusiasm was high and donor funding was made available for FC supplies and acceptability studies conducted in many countries.
- Was made available in over 90 countries (private, public, social marketing).
- 90s heralded the development of several new FCs.
- Distribution of FC1 increased globally to around 8 million in 2000.

What happened to female condom reuse?

Early reuse studies showed the polyurethane FC1 could be washed and reused. Limited research on synthetic latex (unpublished) and latex FCs cannot be reused.

What if some FCs could be reused and others not? Could cause confusion.

Recommended reuse protocol involved a bleach soak.

New lower cost materials, manufacturing and bulk purchase have been seen as the way forward to reduce FC costs.

Female Condom technology: what’s here and what’s in the pipeline

- Acceptability issues such as appearance, size, noise and insertion are being addressed in new designs.
- Latex and synthetic latex designs can keep material costs down.
- New designs are adopting large scale manufacturing to keep down costs.
- Several new designs are breaking into the market and several more are in development.

GLOBALLY FC2 REPLACES FC1

- FC1 discontinued at end of 2009.
- FC2 phased in from end of 2009.

NEWER DESIGNS

- VA WoW
- Woman’s Condom
- Cupid
- Phoenurse
- Panty
- Origami
- Belgian

FEMALE CONDOM DESIGNS
WOMAN’S CONDOM
- Inserts like tampon – cap made of PVA (polyvinyl alcohol) which dissolves after insertion
- Made of polyurethane
- Foam shapes cling lightly to vaginal wall to ensure stability
- Transferred to Chinese manufacturer in 2008 & SFDA approved in 2011. Under WHO review

REDDY FEMALE CONDOM V-amour/VA w.o.w
- Made by MedTech Health Products, India.
- Preformed latex pouch attached to a V-shaped Outer Frame encasing a sponge
- 90cm body length (previously 120cm)
- Sold in India and some African countries. Under review by WHO.

CUPID FEMALE CONDOM
- Made in India by Cupid Ltd, available in limited distribution outside India
- Latex material with insertion sponge and octagonal outer ring.
- Available in pink or natural latex colour.
- Under review by WHO

PHOENURSE FEMALE CONDOM
- Produced and distributed in China (SFDA approved)
- Made of polyurethane
- Distinctive Insertion tool but can be inserted using inner ring
- Dumbbell shaped body with inner ring
- Under WHO review

INNOVA PANTY CONDOM
- Made by Acme Condom Company, Columbia
- Made of polyethylene
- Re-usable thong panty with replaceable FCs – this means it has no outer ring as panty holds condom in place.

Silk Parasol panty condom (Janesway)
- Made by the Silk Parasol Corporation
- Panty type condom with reusable panty and refill condoms
Belgium Female condom
- MEDITEAM, Belgium
- Made of natural latex with external flange
- Prototypes fabricated and these have been evaluated in a student population

Origami Female Condom
- STRATA various product design have been developing a new FC in the US- The ORIGAMI FC. A phase 1 feasibility and acceptability trial funded by NIH was awarded last year.
- Made of biocompatible non-allergenic silicone

Hindustani Latex Female Condom
- HLL who have experience in FC1 & Reddy manufacture have designed a latex FC that looks very similar to FC2.
- The cost of this condom will be much lower than existing prices.

Making new FC designs available: The regulatory process, why is it so complex?

Female Condom technology
- To be effective female condoms need to:
  - Completely line the vaginal canal
  - Free from holes/defects
  - Not break, slip or leak during use
  - Correctly packaged for storage & correctly labeled
  - Not contain (or release) toxic, sensitizing or irritating substances
  - As a relatively new class of devices, new designs vary and human and laboratory studies are needed to provide evidence of safety and efficacy.

How do FCs get approved?
- The international standard for FCs has recently been finalised
- There is no generic specification
- There is no prequalification scheme
- Different products are in different stages of development
- Different products have been licensed by different regulatory authorities by individual countries.
- CE mark-has required variable evidence
- Therefore the effectiveness and safety of each female condom design has to evaluated by experts on an individual basis.
A “Standard” specifies the minimal requirements for key properties that ensure safety and effectiveness of a product. A “Specification” is a statement of the buyer requirements and covers all attributes (safety, efficacy, performance, design, packaging, labelling) of a product that may not be fully specified in a standard. A specification must be a detailed, unambiguous statement of a buyer’s requirements and describe the means by which they will be verified.

UNFPA requested WHO (RHR) to convene a review to provide guidance on what FCs could be included in the UNFPA public-sector procurement programme. In addition, WHO/RHR in collaboration with UNFPA offered to evaluate Dossiers provided by other manufacturers of both latex and synthetic female condoms that had or were due to come onto the market in 2006. Review of Product Dossiers included (manufacturing process, quality assurance processes/procedures, clinical trials & technical specifications).

The Female Condom Technical Review Committee was established to undertake a review of dossiers in 2006 and 2011. Prepare recommendations and submit individual confidential reports to each manufacturer requiring clarifications, or additional information for completion of the review. Standardized the definition of failure modes (2006). The review continues beyond the meeting to collect all required information. Independent factory assessments are undertaken.

The FC2 was approved by the review committee for bulk procurement, following the 2006 meeting. Other female condoms are still under review. More manufacturers are requesting a review process. It is anticipated that some products may be approved in the first half of next year.
UNFPA Global FC initiative – successes in programming

Bidia Deperthes, UNFPA

Key statistics

- 34 million people were HIV positive in 2010
  - 80% HIV transmission is due to unprotected sex = sex without a condom
  - Globally every day, 7000 people become newly infected with HIV

Women and AIDS

- Half the sky - globally women make up half the people living with HIV.
- Risks are especially pronounced for young women and girls.

Female Condom

There is hope! There is FC!
- A powerful tool for women and girls to reduce HIV risk
  - Available now!

Principle number 1:
No commodity, no programme!
DONOR SUPPORT IN 2009

37.8 million female condoms

Other: includes IPPF, MSI, Japan, Netherlands and others.

Increases beyond expectations

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Quantities of female condoms (in millions)

2010 data

| Female Condoms distribution by donors in 2010 |
|---|---|---|
| Donors | Quantity | Value (in US$) |
| DFID | 5,000 | 3,300 |
| IPPF | 39,000 | 26,286 |
| PSI | 2,898,315 | 1,941,166 |
| UNFPA | 9,852,149 | 5,813,821 |
| USAID | 5,611,000 | 3,560,009 |
| Total | 18,405,464 | 11,344,582 |

UAFC: 2.8 million in Cameroon and Nigeria

Principle number 2:
No programming, low utilization!

Building service providers

Training of service providers was essential
- Build knowledge
- Combat wrong attitude
  - Stigma
  - Discrimination
  - Judgment
  - Misconception
  - Myths
  - fears
Session 1:
FC technology and programme update

Reaching out effectively to users!
Creative marketing strategies.

Global awareness campaigns

Condomize! Don’t compromise!
- Condom-month(s)- Swaziland, Ethiopia, Rwanda
- Carnivals-T&T, Brazil
- Music festivals
- The Conferences- World YWCA
- World Cup 2010- SA
- Vienna AIDS 2010
- ICASA 2011

Negotiate safer sex
-especially in marriage

-“Married women are encouraged to present the FC as a FP method... to avoid accusing her husband of having other partners or being a risk to his wife”

Appealing to both partners

“If both partners are motivated to use the female condom, there is a far greater likelihood that it will be use”

Convincing men of the benefits of the female condom

Young people

Don’t ask what they need.... Ask what they want!
Challenges

- One manufacturer
- Price
- 2010 WHO EML-condom
- Donor support commodity
- Low availability
- Little funding for programming
- Limited countries with budget line and integration in national condom strategy
- Research gap

Opportunities

condoms are more prominent than ever

Way forward

- **Intensify** this beautiful – challenging – work we started
  - Equip women & girls with tool for their protection
  - Skill them to negotiate safer sex
  - Motivate men and boys to embrace responsible sexual behavior
  - Engage governments and donors – do not give up on female condom...it is a life saving tool for many women and girls ... and their partners

- Merci
- Danke
- Gracia
- Gracias
- Dank je wel
**Session 2:**
Experiences and plans for dual FC programming

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**ACMS social marketing in Cameroon—preparing for FC2 & Reddy**

*Lilly Claire Ekobika, ACMS*

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**Variety in Female Condom Programming:**

**Case study: Cameroon**

Lilly Claire EKOBIAK

**UAF Project Manager**

Cameroon overview

- **Population:** 28 million inhabitants
- **HIV prevalence rate**
  - HIV prevalence: 5.1%
  - Women aged 15-49 most infected (6.8%) than men (4.1%)
    - 25-29: women (8.3%), men (5.1%)
    - 30-34: women (8.4%), men (8.3%)
  - Girls aged 15-24 three times more infected than boys of the same age group.

- **Contraceptive prevalence rate**
  - 44% of contraceptive needs unmet
  - Contraceptive prevalence: 15%
    - 9.6% of women aged 25-29 reported having used FC as contraceptive method
    - 1.6% of women aged 30-34 reported having used FC as contraceptive method

**Decisions making in the couple**
- Only 18% of women take decisions concerning health issues in their couple (even when it concerns their health).

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**Key facts**

- Women are more vulnerable to HIV than men
- Unmet needs in family planning with regards to child spacing
- Very low condom use as contraceptive method (namely FC)
- Women low capacity in decision making and safer sex negotiation

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**Cameroon Background in FC Programming**

- **FC distribution 2002-2009**
  - Low scale marketing of FC
  - Distribution network limited to few women community based associations and pharmacies

- **FC distribution 2009 till date**
  - UAF funding to enable FC programming scale up
  - Strengthening distribution network (e.g. CBs, introduction in hairdressing salons)
  - Innovative strategies to enable better product uptake: advocacy, mass media campaigns with artists, distribution through women friendly sales points etc.

- **Targeting women and or couples with appropriate positioning statement:**
  - For women who care about their health
  - For men who care about the health of their partners and want the best for them
  - The only female initiated method that protects both against unwanted pregnancy and STIs including HIV
  - Make women feel in control while accompanying pleasure

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**Summary**

- Cameroon Overview
- Key facts
- Cameroon background in FC programming
- Evidence based approach for variety in FC
- Research findings
- Variety in FC programming: added value
- Challenges

---

**Cameroon Background in FC Programming**

*female condoms sales (2002–2011)*
Session 2:
Experiences and plans for dual FC programming

Evidence based approach in FC variety
- Qualitative research: FGD (June 2009)
- 17 FGD in 7 cities in the Project areas
- 164 participants
- Selected criteria
  - Marital status: married and single
  - Socio-economic level
  - Level of exposure to risky behaviors
  - Sexually active

Research Findings on FC2
- Breaks stigma associated to male condom purchase: 4%
- Protects against sexual violence: 32%
- Suitable for men who don’t like MC: 41%
- Expensive: 0,6%
- Fear that it may remain in the vagina: 10%
- Only 0,6% find it suitable for young girls
  - 64% expressed a need for product variety and improvement

Variety in FC distribution: Added value
- Wider coverage of the target
  - Alternative to unfaithful prospects and/or those disappointed by existing one
  - Opportunity to reach greater target
  - Opportunity to avoid market dominance
  - Opportunity for price reduction
- Increasing overall demand:
  - Addresses reluctance to one product dependency
  - Positions FC as MC in a wider variety (size, design, color etc.)
  - Gives room to choice between FC so as to encourage product use
  - Possible choice for people allergic to latex or to polyurethane

Challenges
- WHO approval for condom
- Local testing of condom to be introduce (need for adequate equipments)
- Government authorization for new FC easy introduction in market
- Need for specific marketing mix strategies (Product, price, place, promotion) for smooth cohabitation of both products
- Stock availability
- Availability of pelvic models for new FC

Need for choice for Universal Access to female condom

THANK YOU
FC programme in South Africa
Eva Marumo, National DoH, SA

Session 2: Experiences and plans for dual FC programming

OUTLINE
- Background
  - SA NDOH Public sector FC programme
  - FC procurement figures
  - Good practices
  - Female condom programme component
  - Plans for the next 5 years
  - Research
  - Key issues
  - Conclusion

BACKGROUND
- SA has one of the largest and well established national level public sector condom procurements program
- Male and female condoms are available in the country
- Male condoms are widely available as compared to female condoms
- Current FY male and female condom procurement ratio is 1 billion vs 11 million (budgeted)

BACKGROUND
- One of NSP primary aim is to reduce the number of new HIV infection by 50% with more focus to young people
- Prevention of the sexual transmission of HIV requires a complex of strategies including the distribution of male and female condoms

BACKGROUND
- Male and female condoms are predominantly promoted and distributed for the dual protection, STI/HIV prevention and unwanted pregnancy
- The protective effect of MC and FC in prevention of HIV incidence have major impacts
- MC and FC are important components in risk reduction strategies

SA NDOH PUBLIC SECTOR FC PROGRAMME
- The introduction of the female condom project was initiated in response to a need to increase options available to South Africans women to protect themselves against STI including HIV infection and unwanted pregnancies.
- The programme has been implemented as national level female condom procurement and distribution programme with emphasis on dual protection
- The introductory phase in 1998 has expanded from 19 DOH, 12 NGO, 2 CSW sites and Social Marketing programme
The programme has since expanded to at least more than one distribution site per sub district which includes a range of clinics and non clinical sites in rural and urban sites, HTA’s and HE institutions.

Further expansion is planned to distribute at all PHC facilities and NGO’s as FC item will be on the minimum data set for monitoring.

The programme has been devolved to provinces who plays a greater role in procuring from allocated conditional grant funding and distributing through variety of sites.

Two year open contract administered by National Treasury Contract Management.

Multiple award considered: currently 7 male condom suppliers and one female condom supplier.

Commodity specification is the responsibility of NDoH.

NDoH procures only from the contracted suppliers.

All batched to undergo testing according to NDOH/WHO specifications.

Condoms are distributed through a national system of primary and secondary distribution points.

Condom procurement has been centralised for past years and funds transferred as from the current FY.

The distribution is based on population percentage per male 15yrs and above (16 million).

LMIS is then used for tracing and monitoring of condoms. (still central).

The successful implementation of the program requires:

- a strong network of partnership between govt., NGO’s, partners, civil society and the private sector
- Well co-ordinated, structured introduction strategy
- Even distribution across SA acc to target population (all provinces expected to maintain and expand sites)
GOOD PRACTICES

The successful implementation of the program requires:

- Clients able to access FCs from clinic and non clinic sites using referral mechanisms
- Inclusion of PDoH, SANDF, DCS procuring from the national tender at tender price
- Social marketing strategy (though not active due to low stock)
- PPP, private companies encouraged to purchase FCs for employees and mostly following the tender specifications

DEVELOPMENTS

- Development and approval of standard operation procedures (SOP) and job aids for National and Provincial level
- Development of national condom policy and management guideline
- Printing and dissemination meetings before end FY
- Dedicated budget line item for female condoms at provinces
- Female condom forecast and quantification conducted in 2010
- 100% increase female condom quantities (6m-11m)

FEMALE CONDOM PROGRAMME COMPONENTS

- Training of providers on female condoms promotion, demonstration and provision
- Providers recording condom distributed including basic information to clients.
- Quality assurance of the commodity
- General site supervisory/support visits
- Analysis of commodity distribution records
- IEC leaflets made available to all sites for marketing the commodity
- Pelvic models for demonstration of female condoms

PLANS FOR THE NEXT 5 YEARS

- The female condom programme has been devolved to provinces that must procure and play a greater role in expanding distribution sites
- Funding made available at provinces for the next funding circle
- Female condoms procurement figures increased from 11m in the current year to 13m in the next FY
- Technical assistance from partners for condom programming to be strengthened

PLANS FOR THE NEXT 5 YEARS

- Ongoing training of health providers at PHC sites on FC promotion, demonstration and provision planned
- Further expansion planned for 2011/2012 and beyond (100% PHC)
- Provinces are to expand distribution through NGO’s, CBO, private sectors

PLANS FOR THE NEXT 5 YEARS

- Female condom recording and reporting through DHIS to be strengthened
- Female condom information and distribution sites to be strengthened in the govt. helpline
- Availability FC at the MMC sites
RESEARCH ON FEMALE CONDOM

More studies on performance and acceptability of female condom to be conducted in SA.
- More studies on female condom use and clientele to be commissioned.
- Ongoing update on review process by female condom technical review committee of WHO/RHR on female condom developments are needed.

CHALLENGES

- Monitoring of and reporting of FC less stringent than MC
- Capacity building
- Tender and procurement processes
- Demand creation

PROPOSED SOLUTIONS

- Strengthening of FC recording plan
- SDO scheduled training on supply chain management, LMIS and SOP’s
- Overlap between contracts
- Plan buffer stock of about 3 months
- Training on FC
- Provider initiated promotion, demonstration and provision

CONCLUSIONS

- Demand is apparently growing
- Need for structured training of all health care providers on FC promoting, demonstration and provision
- Need to strengthen recording and reporting of the commodity
- Need for more studies on FC usage and clientele
- More manufacturers for approved product needed

Thank you
Social Marketing perspectives of dual FC social marketing in Mozambique: preparing for Cupid

Raquiana Mafuca, PSI Mozambique

Background

- Population: 21397,000 (census 2007)
- 11 provinces
- Official language: Portuguese
  - Many divergent local languages, including Changane, Macua, Sena, Ndau etc.

MCH in Mozambique

- Use of modern contraceptive methods is very low: 14.2% (DHS 2003)
- Intention to use a contraceptive method: 40.4% (ibid.)
- Severe problems with the supply chain management of contraceptives in the public system (while 69% of women use the public sector to gain access to contraceptives) (ibid.)

Why the focus on MCH and family planning? (1/2)

- Up till Dec 2010, PSI/Mozambique had a large family planning programme, with three socially marketed products under the family planning brand Confiança:
  - The oral contraceptive Microlette Confiança
  - The male condom Preservativo masculino Confiança
  - Cycle beads Missangas do Ciclo Confiança

Why the focus on MCH and family planning? (2/2)

- PSI/M integrated the female condom promotion activities into the already existent family planning promotion activities (and other PSI programs such as MARPs) from Jan 2010 onwards.
- Underlying idea: promotion of the female condom as a family planning method will minimize the risk of the female condom being solely linked to HIV prevention, as is the case (and problem) with the male condom in Mozambique.

The FC Consortium

The female condom program (Building a Market for the Female Condom in Mozambique) is being implemented by a consortium of Fórum Mulher, Pathfinder International and PSI/Mozambique since the beginning of 2011.

- Fórum Mulher: Advocacy
- Pathfinder International: Health provider training & consistent user groups
- PSI/Mozambique: Social marketing, community mobilization

Session 2:
Experiences and plans for dual FC programming

If my girlfriend tells me she wants to keep using a condom after a couple of months, she must be telling me this because she’s cheating on me and/or is sick.
FC1 and FC2 in Mozambique (1/)

TIMELINE
• 1999: The FC1 was introduced in Mozambique, and was distributed for free through the national health system as a response to the high HIV infection rate.
• 2006: PSI/M develops a training manual for activists for the FC1
• 2007: PSI/M and Pathfinder do study on the barriers to use of the FC1 among sex workers, market women, women with multiple partners, and HIV+ women (in Portuguese).

FC1 and FC2 in Mozambique (2/)

TIMELINE
• 2007: PSI/M also started to make the FC1 available through pharmacies, barracas and hairdresses, distributing around 100,000 FC1 (sales and free distribution).
• PSI/M then stopped selling the FC pressures of the MoH that the package was the same as the one distributed for free through the public sector.
• 2008: The National AIDS Council starts working with the FC. Currently they have 2 trainers per province, and promoters in each district (with limited capacity and support).

Jeitosa: a new era for female condoms in Mozambique

• See social marketing presentation

The UAFC joint programme, together with the Finnish government, are purchasing 500,000 Cupid Female Condoms for the Mozambique program. i+ Solutions is doing the procurement.

They will be packed in 2-packs (250,000), and will all be pink and vanilla-scented.

The launch is expected in the first quarter of 2012.

Considerations (1/):

Public vs. private sector: a clear distinction
The FC2 as the generic female condom, and Jeitosa as the first FC on the market in Mozambique.

This has repercussions for the distribution system:
FC2: procured by UNFPA, distributed and managed by CMAM and the National AIDS council. The FC Consortium receives FC2 through the NAC, and distributes them for free during promotional & educational activities.

Jeitosa: distributed and managed by PSI/Mozambique and partners.
**Session 2:**
Experiences and plans for dual FC programming

### Distribution system for **Jeitosa**:
- Through PSI/M’s supply chain management system.
  - PSI/M works with sales representatives in all provinces of Mozambique. Possibility of working through Facebook to create a direct and live link between sales representatives and sales outlets.
  - In a few districts, such as Inhambane, PSI works with local CBOs that sell PSI products on credit.
- Jeitosa will be sold primarily in the three program provinces: Nampula, Maputo city and province, and marketing efforts will be focused there. Scaling up to other provinces will be considered at a later stage.

*Hey, I’m in Xipumane market! Want to buy Jeitosa? Get in touch with me and use code-word “blue” to get a 5% discount for purchases above 20 units!*

### Considerations (2/2):

- **The target groups**
  - **FC2**: women and men of reproductive age
    - Subgroups: MARPs (sex workers, wives of miners etc.), youth, PLWHA.
  - **Jeitosa**: women between 18-25 years old, living in urban and peri-urban areas, has a secondary school degree, with some form of own income, and power of negotiation regarding her sexual health.
  - Sheila is 25 years old so that she appeals to the younger group, but older women can also still identify with her.

  *Think of Sheila, the aspirational archetype.*

### Considerations (3/6):

- **Training needs**
  - **FC2**: training is being done through the generic FP promotion activities, and through CBOs that are trained and focus on FC promotion. Promotion of Jeitosa will be integrated into these activities, as well as the consortium members’ activities.
  - **Jeitosa**: marketing strategy is still being developed, but it’s expected to work with:
    - brand promoters, a Sheila on television & radio shows, social media (primarily Facebook, but also Twitter), through female oriented sales outlets, and female brands (fashion, cosmetics etc.).
    - Insertion is basically the same as the FC2: efforts will focus on communicating the function and benefits of the sponge.

### Considerations (4/6):

- **Logistics**
  - Ample storage facilities
    - Cupid FC: Latex
    - Cupid FC: 3 years
  - Sufficient storage space:
    - Cupid FCs are bulkier than FC2s.

### Challenges (1/2):

- Diverging classifications/categories of (female) condoms in different countries (e.g. India and Mozambique).
- Market research must take into consideration that ample time must be spent on getting approval from the bio-ethics board of the MoH in order to do a consumer use study (have the participants try out the Cupid during the research).
- Communication around the use of the sponge.
- Beware of not plotting the two FCs against each other. They should re-enforce each other’s promotion.

### Challenges (2/2):

- Communication surrounding the materials of which the FC2 and Cupid are made of. Anti-allergenic vs. latex.
- If both FCs are being sold in the private sector: think of market segmentation and pricing according to the differing target groups. You need to have a solid marketing strategy!
- Working in provinces with diverse cultures. IPC messages will have to be adjusted according to the region → work with local staff.
FC2 TRAINING IN SOUTH AFRICA. Transition from FC1 to FC2

23 November 2011
Maya Gokul

Transition from FC1 TO FC2
FC2 is the FHC second generation female condom made from synthetic nitrile providing DUAL PROTECTION – equivalent to FC1 in terms of safety, efficacy and performance:
- Same size, shape as FC1
- Same inner ring
- Same oil based lubricant
- Same packaging
- Same method of insertion and use

Material is strong, soft, and transparent.
Conducts heat, so sex feels natural.
FC2 is lubricated with silicone based lubricant.
Can be inserted in advance or a few minutes before sex.
Does not require immediate removal.
Rolled outer ring is soft.
Rings pleasurable for both men and women.
FC2 is non-allergenic.
Great option for men and women allergic to latex.
No Noise

Main Goal
Support to Department of Health, NGOs and Private Sector in their Prevention Strategies and Transition from FC1 to FC2 in South Africa

PRE TRAINING PLAN
- Discussion with Eva Marumo – National DoH
- Introduction of Support to:
  - Provincial DoH
  - Districts and Sub Districts - Coordinators and Trainers
  - NGOs and Private Sector and Tertiary Institutions
**TRAINING OBJECTIVE**

- To contribute to the reduction of STIs/HIV and Unintended pregnancies in SA
- To introduce and promote the use of FC2 in the nine Provinces, Districts and Sub Districts of SA including Private Sector
- To train all categories of Service Providers on FC2

**SA - PRESENT STATUS of FC2**

Past discussion
All Health Facilities in SA must provide FC2, however this is only possible after training of Site staff with consultation with coordinators

Training provided for:
- Professionals – Doctors, Nurses and Social Workers
- Semi Professionals – ENs and ENAs
- Health Promoters, Counsellors, Field Workers
- Data Capturers and Volunteers

**NUMBERS TRAINED**

- June to November 2010 - 573 Participants
- January 2011 to date - 1085 Participants

Promoted and Demonstrated FC2s at:
- SA HIV/AIDS Conferences and training with RHRU/ MatCH
- Outreach Volunteer Project (CHW)
- Dance for Life
- Decision for Life
- Life Line
- Operation Upgrade
- Tertiary Institutions

**SUCESSES**

- Increased number of FC2 sites in SA
- Increased number of health providers trained
- High demand of FC2 by Facilities
- High demand for FC2 Training by Provinces and Districts, Women Groups (Unions) and Tertiary Institutions

**SUCESSES (Cont)**

- SA HIV/AIDS Conference stand promotion and networking
- Lesser concerns, myths and misconceptions regarding FC2
- 360 degree turn around of participants mindsets due to the Values, Beliefs and Attitude discussion
- Increase in male participation due to MMC Programme

**CHALLENGES**

- Demand for FC2 created however supply in some services is insufficient/unavailable
- Condom Procurement System and Logistic management
- Some services are still having FC
Preparing for introduction:
Research and regulatory progress achieved for the Women’s Condom

Kim Whipkey, PATH

Steps toward Woman’s Condom introduction

Woman’s Condom: performance objectives
- Easy to handle and insert
- Easy to use (especially for new users)
- Stable during use
- Comfortable for both partners
- Easy to remove

About PATH
Advancing technologies, strengthening health systems, and encouraging healthy behaviors

Woman’s Condom: product development
- User-driven process
- Iterative and interactive
- Interdisciplinary

- Involve couples as “co-designers.”
- Combine “naïve” and experienced users to balance input.
- Design evolves and is refined over time.
- Different viewpoints challenge the process.

Woman’s Condom: ease of use and good sensation
Session 3: Training, education and marketing

Woman’s Condom: acceptability and performance

Three-country design verification study¹
- Majority of users found the device comfortable, easy to insert, and stable during use.

United States Phase 3 comparative performance, failure mode, and safety study²
- Woman’s Condom had fewer failures and less slippage, and it was preferred by men and women when compared with FC1.

South Africa comparative performance and acceptability study³
- Woman’s Condom performed well and was preferred over two other female condom designs.


Steps toward Woman’s Condom introduction

Technology transfer: Shanghai Dahua Medical Apparatus Company

Formative research on Woman’s Condom in China

- Conducted in collaboration with Shanghai Institute of Planned Parenthood Research (SIPPR); Dr. Wu Junqing.
- Focus group discussions with 9 potential user groups (n=18).
  - University students (60m)
  - College-educated professionals (60m)
  - Married couples (60m) residing in urban Shanghai
  - Migrant workers (60m)
  - Women in entertainment industry
- Key findings.
  - Notable interest in using Woman’s Condom for STI prevention, pregnancy prevention, and dual protection.
  - 50% of participants said Woman’s Condom would make “some” different or a “great difference” in their lives.

Steps toward Woman’s Condom introduction

China performance and failure mode study of Woman’s Condom

- Partners: SIPPR (Dr. Wu Junqing) and Fudan University Obstetrics and Gynecology Hospital (Dr. Huang Zirong).
- 59 couples used 234 condoms in total.
- Nonclinical breakage (2); Clinical breakage (0).
- Total failure rate = 4.3%
  - This rate is comparable to total failure rates of other approved female condom products.
  - Misdirection occurred in 5 uses (2.1%), slippage in 3 uses (1.3%) and invagination in 2 uses (<1%).
Session 3: Training, education and marketing

**Additional clinical studies underway**

- **In the United States**
  - CONRAD: Performance and failure mode study with prostate-specific antigen (PSA) as biomarker of semen exposure (2010-2011).
  - National Institute of Health: Contraceptive effectiveness study (2010-2012).
    - Data to be submitted to USFDA as a premarket approval (PMA) application for a Class III Medical Device.

- **In South Africa and China**
    - Compares four female condoms: Woman’s Condom, FC2, Cupid Condom, and Reddy 6.
    - Funded by UAFC.

**Woman’s Condom: regulatory strategy**

- **Complete**
  - CE technical dossier on production and OIVDC
  - Submitted by Dahua
  - CE Mark (2010)

- **In process**
  - Shanghai FDA application
  - Submitted by Dahua
  - Chinese regulatory approval (2011)
  - WHO Female Condom Technical Review Committee or WHO UNFPA pre-qualification
  - Clearance for public-sector procurement (2012)

- **In future**
  - PMA application and Dahua factory audit
  - USFDA PMA application (2013-2014)

**Steps toward Woman’s Condom introduction**

- **Women’s Condom design**
- **Manufacturing**
- **Regulatory approval**
- **Market introduction**

**Protection Options for Women (POW) Product Development Partnership**

Partnership among PATH, Dahua, CONRAD, and NICHD launched in 2011.

**Goal:** To create sustainable markets for the Woman’s Condom using a total market approach.

- Develop market potential in China
- Develop market potential in sub-Saharan Africa
- Build global market potential
- Build evidence through clinical validation
- Advocate to raise awareness and build demand globally and regionally

**Develop market potential in China**

**Distribution Channels**

- **Private Sector**
  - Online
  - Pharmacy and other retail outlets
  - Hotel chains

- **Public Sector**
  - China family planning system
  - China Center for Disease Control and Prevention
  - Social marketing and local NGOs
Session 3: Training, education and marketing

Africa market introduction strategy

- Select one country for introduction based on health need, country readiness, and willingness to support introduction.
- Assessed 10 countries across multiple criteria as potential market introduction sites.
- Currently exploring potential partners in South Africa.
  - Marketing and distribution partners
  - Market research firms
  - Social marketing groups
  - NGOs
  - Researchers
  - Advocacy groups
- Create partnerships in the private and public sectors to build towards sustainability.

Steps toward introduction

Thank you!

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