

STRATEGIES AND APPROACHES FOR MALE CIRCUMCISION PROGRAMMING

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**World Health
Organization**



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1. EXECUTIVE SUMMARY

A strong geographical correlation exists between male circumcision practices and lower HIV prevalence, and numerous observational studies have also identified lack of circumcision in men as a risk factor for acquisition of HIV, particularly among men at higher risk of acquiring HIV. Randomized controlled trials were therefore initiated to assess the safety and efficacy of male circumcision in reducing female to male HIV transmission in Kenya, Uganda and South Africa.

The Orange Farm Study in South Africa showed at least a 61% protective effect for male circumcision performed by adequately trained medical practitioners. At the time of this meeting, results from the Kenya and Uganda trials were not available, although subsequently the findings were published revealing at least 53% and 51% reductions in risk, respectively.

The UN activities on male circumcision to date have focused on two main objectives: improving the safety of male circumcision services and providing coordinated, consistent, and up-to-date guidance and support to governments and other development partners in preparation for eventual decision making on the role of male circumcision in comprehensive HIV prevention programming. The purpose of this consultation was to review current models and practices for male circumcision service delivery to identify core elements of good practice, and to propose innovative models and approaches for the provision of comprehensive male circumcision services that promote male sexual and reproductive health as an integral component of HIV prevention strategies. The specific objectives of the consultation were:

1. To review and discuss current models, approaches and practices for safe male circumcision service delivery.
2. To explore alternative strategies for service provision based on a public health approach within a human rights and ethical framework.
3. To explore the opportunities for strengthening male sexual and reproductive health service delivery and determine ways of ensuring that male circumcision services are situated within the broader context of male sexual and reproductive health service delivery as services are scaled up.
4. To consider the role of different service providers including public, private, traditional, and mid level providers for male circumcision service delivery.

Approximately 50 participants attended the meeting including temporary advisers' from Africa, Europe, Israel, Republic of Korea and United States of America; as well as headquarters and/or regional representatives from WHO, UNAIDS, UNICEF, and UNFPA.

A number of issues were discussed from which key recommendations were made. In relation to HIV testing and counselling it was agreed that HIV positive status should not be a discriminating factor for the provision of male circumcision services. Participants agreed that past experiences from the introduction of contraceptives and other reproductive health technologies provide a source of lessons applicable to the introduction of male circumcision for HIV prevention. Country presentations highlighted the diversity and heterogeneity of male circumcision practice and experience among countries, particularly in Africa.

On the question of how to roll out male circumcision services, the following recommendations were made:

Who should be prioritized for roll out?

- **Geographically**
 - Countries/regions/districts with low male circumcision, high HIV prevalence
 - Consider low prevalence, and high incidence areas

- **Population /Age specific**

Reactive

- Those who are already demanding services

Proactive

- Adolescents (15 -18 years). Need to consider local epidemiology, age of sexual debut, age of traditional circumcision
- High risk groups e.g. Truck drivers, uniformed services, STI patients, miners, sero discordant couples.
- In the long term consider neonates through Maternal and Child Health or other services

The minimum package for male circumcision services

- Offer of HIV testing and counselling
- Active exclusion of symptomatic STIs and syndromic treatment where required
- Provision and promotion of correct and consistent use of male and female condoms
- Counselling on risk reduction and safer sex
- Male Circumcision as described in the WHO/UNAIDS/JPIEGO Technical Manual for Male Circumcision under Local Anaesthesia

Roll out strategies

- Centres of excellence
- A campaign approach
- Integration into existing services
- Special events
- Responding to demand for services

In order to meet the anticipated demand for services after the announcement of the results of the male circumcision clinical trials, the group recommended that non-physician (mid-level) providers be trained in surgical techniques for male circumcision under local anaesthesia. It was felt that this was the only way to make services available and accessible to men. There was a lengthy discussion regarding traditional providers performing circumcision. Even though the group recognized the importance of using skilled providers, there was a general sentiment that traditional circumcisers could not be ignored. It was also suggested that little is known about traditional circumcisers and the procedures used. For this reason, traditional circumcisers need to be studied further and recommendations made about how to involve them. In addition, the issue of the acceptability of female providers needs to be carefully considered and investigated because most (non-physician) mid-level providers are female; however, numerous examples exist of women either providing male circumcision or assisting in operations in culturally-acceptable ways and there was support for women playing these roles.

It was acknowledged that the scale up of services will cost money and therefore donors will need to support scale up. However, sustainability needs to be considered from the start. Studies have consistently found that cost of male circumcision to potential patients is a significant determinant of acceptability of male circumcision. For this and equity reasons, generally services should be inexpensive and free wherever possible, depending on the country context.

Strategies need to be worked out at the country level, consulting with people who can bring the necessary tools, understanding and experience to determine the best approach for each country.

2. BACKGROUND

A strong geographical correlation exists between male circumcision practices and lower HIV prevalence, and numerous observational studies have also identified lack of circumcision in men as a risk factor for acquisition of HIV, particularly among men at higher risk of acquiring HIV. It has been difficult, however, to unravel to what degree the apparent protective effect of male circumcision is due to confounding variables, as many factors such as religion and ethnicity are associated with male circumcision and also have a major influence on risk behaviours. Randomized controlled trials were therefore initiated to assess the safety and efficacy of male circumcision in reducing female to male HIV transmission in Kenya, Uganda and South Africa.

The Orange Farm Study in South Africa confirmed the association between male circumcision and reduced HIV risk that has been reported from observational and epidemiological studies over the past decade. The study which was funded by the Agence nationale de recherches sur le Sida (ANRS) was stopped in mid-April 2005 on the recommendation of the study's Data Safety Monitoring Board (DSMB) and the male circumcision intervention was then offered to the control group. Trial data were analysed and results demonstrated in an intention-to-treat analysis an unadjusted 60% protective effect (95% CI 40-80%) for adult male circumcision (61% adjusted, and 76% protective effect in a per protocol analysis). The DSMB for the other two trials, in Kisumu, Kenya and Rakai District, Uganda, funded by the National Institutes of Health of the United States, met in June 2006 and recommended that the studies continue as planned with another interim review anticipated for mid-December 2006.

The participants of this meeting were working under the premise that if male circumcision was confirmed in the remaining trials to provide significant protection against the acquisition of HIV, as suggested by the Orange Farm trial, it would undoubtedly be necessary to scale up the provision of male circumcision services and to strengthen male sexual and reproductive health services for improved prevention of HIV, particularly in high HIV prevalence countries where the demand for male circumcision might increase. It was anticipated that many questions were likely to be raised about strategic approaches to service delivery including: what would be possible approaches to prioritizing populations and ages, what would be the costs involved and who would deliver the services?

In line with the call for universal access to prevention, care and treatment, if the level of effectiveness of male circumcision demonstrated by the South African trial was confirmed, then it would be necessary to include the practice of male circumcision as an integral part of prevention measures and techniques for HIV prevention. Indeed, based on currently available information, in some countries there is already an increasing unmet demand for male circumcision. Given this fact and the possibility that the two remaining trials could possibly confirm the previous results, it was clear that there was a need to start to prepare for improving service delivery while awaiting the remaining trial results. As a result, if male circumcision was proven to be effective, planning for increasing the provision of safe circumcision services would already be underway.

Regardless of the trial results, due to the increased demand already observed in some countries, action is required now in many areas to improve the safety of current male circumcision practices and to provide up-to-date information on male circumcision and HIV acquisition risk to health providers and the public.

Subsequent to the meeting, the NIH made an announcement on December 13 2006, that the Kisumu and Rakai trials were being immediately stopped because the interim analysis showed significant reductions in HIV incidence; a 53% reduction in HIV infection in circumcised men in Kisumu and a 51% reduction in Rakai.

3. PURPOSE OF THE CONSULTATION

The purpose of the consultation was to review current models and practices for male circumcision service delivery to identify core elements of good practice, and to propose innovative models and approaches for the provision of comprehensive male circumcision services that promote male sexual and reproductive health as an integral component of HIV prevention strategies. The specific objectives of the consultation were:

1. To review and discuss current models, approaches and practices for safe male circumcision service delivery.
2. To explore alternative strategies for service provision based on a public health approach within a human rights and ethical framework. Strategies explored will consider:
 - Alternative models of service delivery e.g. vertical versus integrated
 - Different packages of interventions that could be implemented with the male circumcision procedure, including during preparation and follow-up
 - Initial age groups to be prioritised to make the biggest impact and the numbers of men to be reached
 - The costs for implementing services and the cost effectiveness of different strategies
3. To explore the opportunities for strengthening male sexual and reproductive health service delivery and determine ways of ensuring that male circumcision services are situated within the broader context of male sexual and reproductive health service delivery as services are scaled up.
4. To consider the role of different service providers including public, private, traditional, and mid level providers for male circumcision service delivery.

Approximately 50 participants attended the meeting from Africa, Europe, Israel, Republic of Korea and the USA with expertise in planning and providing clinical services in developing countries. Participants also included headquarters and/or regional representatives of WHO, UNAIDS, UNFPA and UNICEF.

Background documents available at the meeting included: a WHO/UNAIDS background paper on *Male circumcision: global determinants of prevalence, safety and acceptability*; a UNAIDS document on *Safe male circumcision and comprehensive HIV prevention programming: Guidance for decision makers on human rights, ethical and legal considerations*; a draft report from EngenderHealth *Implementing facility-based family planning & other reproductive health services: lessons applicable to introduction of male circumcision for HIV prevention* and a UNAIDS Best Practice publication on *Collaborating with Traditional Healers for HIV Prevention and Care in sub-Saharan Africa: suggestions for Programme Managers and Field Workers*

At the meeting's opening, the situation was described as a good example of marshalling evidence and establishing causality and, in the case where the decision is made to move forward, determining how to do so practically. For other health issues, decisions have been made to move forward on the basis of considerably less evidence, or had not been made despite greater evidence. This meeting was held in an anticipatory phase awaiting confirmation from the two ongoing trials. The role of the UN, with WHO in the lead, is to set an international agenda and provide definitive advice to the world regarding male circumcision (MC) services. Recommendations made at the meeting are to be used to determine how to move forward, balancing MC with other areas of prevention and looking at various factors such as resource needs, costs, financing, recruitment and training.

4. UN MALE CIRCUMCISION AND HIV WORK PLAN

Since 2005, the Inter-Agency Task Team (IATT) on Male Circumcision and HIV Prevention, spearheaded by UNAIDS and composed of headquarters and regional representatives of WHO, UNAIDS, UNICEF, UNFPA and the World Bank has been implementing the first UN Work Plan on Male Circumcision and HIV. This work has been supported financially by The Bill and Melinda Gates Foundation, UNAIDS, the US National Institutes of Health (NIH), and the French Agence nationale de recherches sur le SIDA et les hépatites virales (ANRS). The first Work Plan had two main objectives: improving the safety of male circumcision services and providing coordinated, consistent, and up-to-date guidance and support to governments and other development partners in preparation for eventual decision making on the role of male circumcision in comprehensive HIV prevention programming.

Activities of the work plan include:

- A technical reference manual, *Male Circumcision under Local Anaesthesia*, has been developed with inputs from surgeons and general practitioners in developed and developing countries, using the experience of the surgical teams in the three randomized controlled trials in Kenya, South Africa and Uganda. This document is due to be published by WHO/UNAIDS/JPIEGO in the first quarter of 2007.
- Five country stakeholder meetings have been held in Swaziland, Lesotho, Kenya, Zambia and United Republic of Tanzania. The meetings brought together key stakeholders within the countries to begin discussing male circumcision and define the knowledge gaps to be filled for decision making on promoting male circumcision within comprehensive HIV prevention programmes. The country meetings were followed by a regional meeting in Nairobi that was attended by stakeholders from the five countries and four other countries from the region to review the results of country meetings, share experiences, follow up on progress, identify technical support needs within countries and, where appropriate, define preparatory action plans.
- Development of an Information Package for policy makers and programme managers, which is near completion.
- Development of a Situation Analysis Tool Kit for rapid assessments of the knowledge about MC in a country, determinants for it, and capacity of the health care system to increase MC services at country or district level.
- Work has begun to model the impact of male circumcision at population level under different post-circumcision sexual risk and behavioural scenarios.
- Work has begun to estimate the resources needed for male circumcision services in various scenarios and to assess cost effectiveness.

A second UN Work Plan on Male Circumcision and HIV is under development, with WHO in the lead. The activities will provide the framework and guidance for countries to improve the availability and accessibility of safe male circumcision services. Low male circumcision, high HIV prevalence countries will be prioritized for roll out. The activities will not be implemented as stand-alone; support will be given to countries to integrate male circumcision into their HIV prevention strategies and strengthen male sexual and reproductive health service provision and surgical facilities.

The key objectives of the work plan are to:

1. Set global norms and standards and provide policy and programme guidance for the provision of safe male circumcision services,
2. Provide technical support for accelerated action to roll out safe male circumcision services in selected countries,
3. Develop guidance for the implementation of effective, culturally sensitive male circumcision communication strategies for regions and countries,
4. Coordinate the setting of global research priorities, commission research and develop systems for monitoring and evaluating male circumcision services

5. HUMAN RIGHTS, LEGAL AND ETHICAL ISSUES

An overview of the UNAIDS guidance document for decision-makers which is currently at the late draft stage was presented.

Male circumcision raises human rights issues, as is generally the case with medical and health procedures. If countries decide to scale up, male circumcision should be promoted and conducted with full adherence to medical ethics and individual human rights. Taking a human rights-based approach to the initiation or expansion of male circumcision services requires measures that ensure that the procedure can be carried out safely, under conditions of informed consent, without coercion and without discrimination.

Health-care workers have both an ethical and legal responsibility to offer services to people without discrimination. It is a violation of international human rights standards to deny male circumcision on non-medical grounds, including grounds of race, religion, ethnic origin, or sexual orientation, or for members of key populations such as prisoners, men who have sex with men or male sex workers.

In line with internationally accepted ethical and human rights principles, no surgical intervention should be performed on anyone if it results in adverse outcomes in terms of health or the integrity of the body, and where there is no expectation of health benefit. Nor should any surgical intervention be performed on anyone without informed consent, or the consent of the parents or guardians when a child is not capable of providing consent.

For male circumcision among younger age groups, medical ethics and national laws and regulations should be applied and adhered to, with, as far as possible, respect for the assent of minors and minors' involvement in consent. The starting point of children's rights is that decisions that affect children must be in the best interests of the child. In determining the best interests of the child, children who are capable of doing so have the right to be involved and have a say in decisions that affect them. Article 12 of the Convention on the Rights of the Child provides that: "States Parties shall assure to the child who is capable of forming his or her own views has the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child."

It is recommended that, in those countries considering the initiation or expansion of male circumcision services in the context of HIV prevention, law, regulation and policy be developed to ensure that male circumcision services are accessible, provided safely and without discrimination.

A question was raised on the role of the community in making decisions about circumcision as opposed to an individual rights based approach. What if the community collectively decides on circumcision, how can an individual boy opt out without coercion? It was emphasized that clear guidance needs to be developed for providers. It was also discussed that depending on the society men who are not circumcised, or those who are circumcised could be stigmatized and this needs to be considered in programme efforts to scale up.

While the current draft of a human rights guidance document is targeted towards decision-makers, the challenge is to simplify things when providing materials for service providers, who will need very clear guidance. The suggestion was made to look at the experience of countries with regard to HIV testing without parental consent.

In this ethical context, it was also brought up that HIV positive status should not be a discriminating factor for the provision of male circumcision services. This was an issue addressed a few times during the meeting, including in the discussions on prioritizing strategies. The issue is largely about targeting sero negatives for prevention efficacy while ensuring that positive men are not denied services. Programmes would have to be very careful in their targeting strategies as it could lead to further stigmatization and discrimination if positive men are denied services. Findings are expected in 2008 from a randomized controlled trial in Rakai District, Uganda assessing whether HIV-positive men who become circumcised are less likely to transmit HIV to women than HIV-positive men who are not circumcised. Depending on the results, consideration may be given to revising the recommendations with respect to serostatus and male circumcision further. Male circumcision should not be perceived as a proxy for HIV negative status, in the sense that a circumcised man is assumed to be seronegative. The UNAIDS guidance stipulates "non-discrimination in access to male circumcision services" and that "HIV status should not negatively influence access to male circumcision".

6. LESSONS FROM REPRODUCTIVE HEALTH TECHNOLOGIES SCALE UP

Past experiences from the introduction of contraceptives and other reproductive health technologies provide a source of lessons applicable to the introduction of male circumcision for HIV prevention. The presentation and background paper (see appendix III for full paper) highlighted some of the lessons learned and issues that need to be considered as male circumcision scale up is planned.

A key message is that – it is more than a question of just introducing a method and building capacities – a system is needed, along with a well-defined strategy. Introduction must be considered within the broad context of the health system overall. From past experience critical issues that need to be considered for scale up were identified (see box 1); there is a need to plan for scale-up and sustainability from the start, however, a one-size-fits-all strategy will not apply in all settings. Developing local ownership and political support that includes the relevant stakeholders and leadership by committed individuals and groups also is imperative.

Box 1. Critical issues to consider for new technology introduction

1. Begin with a well defined strategy that plans for scale-up and sustainability from the start
2. Develop local ownership of programmes and strong political support
3. Focus on the fundamentals of care* for facility-based service delivery
4. Understand the limits of training
5. Link training to supervision
6. Increase access through non-physician providers
7. Explore alternative models for service delivery
8. Design holistic programmes that address supply and demand
9. Capitalize on opportunities to work with men
10. Adequately address the many issues needed for going to scale

*Informed and voluntary decision making, assuring medical safety for clinical procedures, and quality assurance

Case study examples were given including; the improvement of post-abortion care (PAC) in Colombia: initially, aspects of PAC other than the innovative use of manual vacuum aspiration (MVA) received less attention, resulting in increased use of MVA to treat abortion complications but no increase in family planning use among PAC clients. When the programme was then reoriented to focus initially on the broader concept of PAC, with counseling & family planning training provided before MVA training, better results were obtained. A second example was the well-planned implementation of vasectomy in Mexico. **The phased introduction strategy involved a comprehensive approach for training, and assisting facilities in the introduction, organization, and management of services including supervision and promotion of vasectomy.**

Lessons to be drawn for male circumcision from past family planning/ reproductive health implementation are:

- **Careful introduction of male circumcision for HIV prevention** will avoid many of the pitfalls experienced over the past several decades by family planning (FP) and other reproductive health (RH) service programmes as they introduced new technologies. Lessons have been learned about how effectively to introduce new technologies in settings with limited resources and there is no need to repeat the mistakes or learn the lessons again with the introduction of MC for HIV prevention.
- **Working with the public sector is critical.** The public sector provides most clinic-based services in resource poor settings; in general, this sector is most accessible to the largest number of people. Unfortunately, the public sector is often the hardest to work with (relative to the private and not-for-profit sectors) and the most difficult in which to effect change. Nevertheless, given the important role that the public sector plays in provision of health services, and most likely will play in male circumcision services, it is critical that we invest in public sector programmes and find effective ways to work with and not around the public sector.

- **Sustained, long-term efforts are critical to success.** Clinic-based services require sustained resources and long-term efforts. There is a need for real continuity in terms of funding and in terms of approach if significant impact is to be made. It is critical to look beyond a short-term focus or approach and to come to grips with the need for a more long-term commitment if new technologies are to be provided safely and effectively, if the services are to be accessible to the greatest number of people, and if the innovation is to be sustainable in the long run.

7. CURRENT MODELS, APPROACHES AND PRACTICES FOR SAFE MALE CIRCUMCISION SERVICE DELIVERY: REVIEW OF COUNTRY EXPERIENCES

The diversity and heterogeneity of male circumcision practice and experience among countries, particularly in Africa, was made evident through the various country presentations. The presentations outlined the country rates of male circumcision, the reasons for circumcision, where it is provided, the main providers, the costs and the complication rates. A summary of some of the issues presented is provided below. Providing safe male circumcision is one of the key objectives of the scale-up strategy, and complication rates in different countries and by different practitioners were discussed throughout the meeting. It was noted that major differences between complication rates can also be due to differences in surveillance and reporting that need to be kept in mind. Erectile dysfunction (ED) was not noted as a complication of circumcision in any of the presentations; however it was noted as a not uncommon reason for male circumcision requests.

Zambia

In Zambia the rates of male circumcision are low at about 17%. Male circumcision services are mostly hospital based; 85% in the University Teaching Hospital (UTH) and Livingston Hospital; 5% by the private sector and 2 - 5% by traditional providers. An overall increase in demand for hospital based services has been seen over the past 3 years. Ninety one percent of male circumcision is performed for the purpose of prevention, 63% on individuals aged 14-35, with the overwhelming majority of those requesting being Christians. The complication rate is about 3%. A study done prior to the setting up of services in UTH in 2004 indicated a high acceptability of male circumcision. The main barriers to services are cost (USD \$3), fear of complications, fear of sexual impotence, and social/cultural reasons.

South Africa

Male circumcision is probably the oldest and most commonly performed operation in South Africa, performed mainly during the cold season. It is commonly performed in four provinces, and is on the increase in a fifth. The main reasons for male circumcision differ between provinces: in some it is performed for cultural reasons and in others, for medical reasons. Social and sexual factors also play a role. The age of circumcision varies from one culture to another but it is mainly performed in adolescence. A law has been passed making the minimum legal age 18 years. The cost is highly variable; costs range from R100 (USD 14) in public hospitals to R500 (USD 68) by private, practitioners, to between R3000 to R5000 (USD400 - 600) by traditional practitioners. The main barriers are: cultural - in particular, a man may not be considered circumcised unless it is done by a traditional provider - financial, pain and safety, human resources, and public hospital overload. Aspects of the Orange Farm trial were described in the presentation, and the advantages of the forceps guided method listed. In the Orange Farm study 3.8% adverse events were recorded. In contrast, traditional male circumcision showed a much higher adverse event rate, including 20 deaths among 5833 circumcisions in one report.

United Republic of Tanzania

About 70% of adult males are circumcised, mostly in the "circumcising belt". In the "non-circumcising belt" more than 90% are not circumcised. Country mapping shows an inverse correlation between male circumcision rates and HIV prevalence. Most circumcisions are done in a traditional setting by traditional practitioners, although not necessarily accompanied by traditional ceremonies. Male circumcision is also done in the public health system, mainly by junior health workers, who do not have formal or standard guidelines. Although adverse events occur, particularly in the traditional circumcisions, the prevalence is not known, nor are they well-documented in the public health system. Challenges identified included scaling up and delivering the service to the remaining 30% of males who are mainly from the non-circumcising belt; formalizing male circumcision in the public health delivery system; and safety of current male circumcision services, given that it is mainly delivered through traditional systems. The opportunities identified for institutionalization include: wide cultural and religious acceptance for male circumcision, increasing acceptance among non-circumcising communities and the wide availability in health centres.

Kenya

Approximately 80% of Kenyan men are circumcised; only 3 out of 43 ethnic communities in Kenya do not traditionally circumcise males. Male circumcision is practiced mainly for two reasons: cultural (as a rite of passage into adulthood and a mark of ethnic identity) and religious (Muslims and Nomiya Church). Other reasons include medical/therapeutic, hygienic, aesthetic, and peer pressure. Most male circumcision is carried out traditionally, but increasingly, parents and young men are seeking male circumcision services in health facilities for reasons of "modernization," urbanization, cost, time away from school and safety. The typical age for circumcision is between 8-16 years. The cost varies with the health facility and provider: USD 3-15 in public facilities and USD10-95 in private, with higher costs for services provided by medical officers than other cadres of staff. One study among the Bukusu found complication rates of 17% for untrained medical providers and 35% for traditional providers. A complication rate of 1.7% has been found in the Kisumu site where the randomized controlled trial is taking place. The main barriers for male circumcision uptake included the lack of history of male circumcision; cost and time away from work; availability of trained health staff; concerns over safety and pain; and lack of resources (instruments and supplies).

Ghana

Nationally the prevalence rate is about 96% although specific institutional statistics are not available, as the majority of male circumcision is carried out by unlicensed practitioners. Male circumcision is generally considered a way of cleansing the male after birth, a practice with roots in traditional religious beliefs and customs, and is taken for granted due to societal expectations, especially in southern Ghana. In most of Ghana's ethnic groups the uncircumcised male is considered to be unclean and suffers from social rejection by peers and females. Male circumcision is performed in early childhood, generally during the neonatal period, but also during adult life. It is performed by different practitioners with varying backgrounds and training. 70-80% are performed by traditional surgeons (Wanzams), who are found in almost all rural and urban communities and are recognized as spiritual leaders, and with whom the cost is relatively cheap. Other factors are the lack of knowledge of modern practice by the citizenry and less commitment and interest in male circumcision by trained health professionals, as well as a weak medical-legal system. Wanzams perform circumcisions generally without anaesthesia, using sharp knives designed and produced locally (sometimes "sterilized" through boiling). The remaining circumcisions are performed by experienced theatre nurses, experienced nurse anaesthetists, medical assistants and medical practitioners, who all use basic instruments in the hospital theatre. Two centres use a modern instrument called the Gomco Clamp.

Israel

HIV incidence in Israel is 0.2% per year. 99.9% of male infants are circumcised, the majority (Jews) on the 8th day after birth. Muslims circumcise at birth or up to a few months later. Christians follow the social/cultural influences of their neighbors. Religious reasons and societal norms are the main factors making Israel a country with close to universal male circumcision. Israeli experience with MC is twofold: 1) neonatal circumcision is performed overwhelmingly by traditional circumcisers (Mohalim) among Jews and by male nurses among Muslims and Christians. Traditional circumcisers are registered, well trained and supervised by a joint committee of medical experts and spiritual leaders, They participate in continuing education programmes and are all men. Approximately 52,000 male neonates are circumcised in Israel every year around birth. Locations vary by religion; most often at the home of the parents. 2) Adult MC – Israel has unique experience for over 15 years in the management of massive adult male circumcision in medical settings. Over 50,000 male circumcision surgeries were performed under local (85%) and general anaesthesia in Israel in the last 15 years, covering a range of ages: from six month-old babies (which medically and legally in MC are defined as adults) to 90 year old men, all representing Jews or converts. The majority of these circumcisions were performed on adults who migrated to Israel from Eastern Europe and Ethiopia, where they could not have had this operation for various reasons. Adults receive male circumcision free of charge from doctors only and in a pre-approved medical setting. Complications (0.12%) are under-reported, with studies suggesting documented rates of 0.36% or 1.75% in samples of the total MC population. Renewed legislation (2005) requires all male circumcision-related complications treated in emergency rooms to be reported

to the Ministry of Health. There is no cost for circumcision when performed traditionally, although a gift of USD 100-200 is given voluntarily. MDs can charge up to USD 500. A major challenge is addressing possible complacency of circumcised males with regard to HIV prevention, through communication and advocacy campaigns. A national and International group – The Jerusalem AIDS Project is already developing a communication strategy around this issue based on cartoons.

A national review process and workshop with Jewish and Muslim surgeons, practitioners and several traditional circumcisers in Jerusalem provided input into the WHO/UNAIDS/JPIEGO manual as well as on the training, supervision and techniques of traditional and medical circumcisers which could be adapted for Africa.

Republic of Korea

Male circumcision statistics in 2000 indicated a circumcision rate of less than 10% for infants, over 90% for males 18 years, and less than 10% for those over 70 years. Male circumcision rates have climbed steadily since 1945, with mass circumcision, mainly at birth, beginning in the 1960s and the sharpest increase between 1980 and 1995. Male circumcision is performed mainly between the ages of 10 to 12 years, followed by neonatal circumcisions. The roots lie clearly with American involvement in the Republic of Korea. Rates vary somewhat though not dramatically between regions. Main reasons invoked are hygiene and social conformity, doctor's recommendation, with substantial peer pressure. Urologists are 95% in favour of male circumcision, other doctors less so (71%). Aside from neonates, 10-12-year-olds are the other group typically circumcised. No sexual and reproductive health counselling is provided.

Senegal

The presentation focused very much on the social context of male circumcision in West Africa, where it is performed almost universally. The roots lie in African religious traditions and culture that pre-date Islam and Christianity. Some changes are being observed in the patterns of male circumcision: younger age, performed in a different season, different location (nurse vs traditional provider), different significance. The family and community play an essential role in the socially constructed system, with male circumcision linked to initiation rites. Male circumcision is associated with control over sexuality, with abstinence practiced afterwards. Social follow-up is conducted for several years. Male circumcision is usually performed by the 'blacksmith' or 'shoemaker'. Traditional circumcision has no payment associated with it, whereas the cost at health centres can range from USD 10 to USD 100.

The key messages were the need for a community-based approach and for regarding male circumcision in this context beyond the western biomedical paradigm, taking into account methodological and political implications and integrating the cultural aspects.

Swaziland

Prevalence of male circumcision is estimated at <10%, with no variations between regions. Circumcision is performed by medical doctors in hospitals and private clinics for medical reasons, at an age that is medically indicated. The complication rate is 3%. The fee range is USD 2-100. Very few other services are provided along with the surgical procedure. The main barriers cited are doctors' inexperience and patients' pain and fear of impotence. A male circumcision task force was established to standardize male circumcision country-wide, recruit personnel to perform the procedure, integrate HIV testing and circumcision, and establish the initial population target group. It is proposed to train as many local doctors as possible, to import foreign doctors to perform male circumcisions only, and to train nurses and technicians. A national circumcision centre is planned.

Experience of the Faith Based Organisations' (FBO) / Presbyterian Church of East Africa (PCEA) hospitals in Central Kenya

A separate presentation was made on the experience of FBO/PCEA Hospitals in Central Kenya of performing group circumcisions and education of adolescent boys. The goals of the programme are:

- Reduce the risk of transmission of HIV
- Improve sexual and reproductive health
- Increase the ability to make positive life choices
- Achieve more gender-equitable norms

Boys aged 13-17 are targeted, but girls of the same age may participate in educational sessions. Initially the programme was reaching boys of all socio-economic backgrounds. Challenges included; clashes of cultures, problems with change and innovation, lack of leadership, lack of trained personnel (male-only activity), poor organizational structure at hospitals to respond to this massive surgical intervention and cost recovery intervention limiting access (USD 70), posing the question of sustainability and having a donor funded activity.

Stakeholders and their roles were described, as were the mechanics of the programme: counselling, family involvement, worship, lectures on life skills and sexuality, and pledges on graduation day. The pledges are considered important for both boys and girls to become responsible, and family involvement is an important factor. Lessons learned from the programme were listed, including the acceptability of the approach, the need for careful and intensive planning, and the feasibility of adapting traditional male circumcision teachings to modern circumstances. Cost recovery is a barrier for financially disadvantaged families. The key message is that group hospital-based male circumcision appears to be an acceptable and effective means of influencing risk-taking behaviour.

One participant said that one month is not sufficient for carrying out follow-up. Another participant noted the irony of families having to pay USD70 for the Kenya FBO/PCEA programme, whereas people with AIDS receive free antiretroviral therapy (ART).

8. STRATEGIES FOR MALE CIRCUMCISION ROLL OUT

8.1 Who should be prioritized for roll out?

The presentation on prioritization outlined several factors to consider including age, serostatus, country HIV prevalence, male circumcision rates and cost effectiveness. Much of the discussion centred on the issue of age and serostatus.

Age

In the absence of incidence data, the surrogates that could be considered include prevalence; age (young people in general); average age of sexual experience (young people before sexual debut); certain high prevalence areas, groups, settings; and possibly targeting certain clinical settings, ethnic groups, and regions.

It was underlined that the main objective in targeting male circumcision services is to circumcise men before they become infected. Male circumcision will therefore be most effective if it targets those who are not yet sexually active. The most accurate figure to use for targeting is incidence of HIV infection; age-specific prevalence data is more attainable but less useful. The challenge is that targeting "too late" may decrease impact by inadvertently including more of the "prevalent" population, while targeting "too early" delays the time before prevention impact is felt. A balance between the two may be needed, allocating resources to achieve the right mix. Targeting choices can be affected by the type of epidemic in a country, but not all high prevalence countries are high incidence as well, and conversely, not all high incidence countries are (yet) high prevalence.

We would need to reach boys before median age of sexual debut (typically 15, 16, 17 years) and should also consider boys who are still 'easy to reach', e.g. last year of primary school (12 and 13 years). It was mentioned that there is a need for rapid country-specific methodology to determine the age of sexual debut.

It was noted that adolescents and 25-year-olds are very different in how they make decisions regarding health. Even 12- to 14-year-olds are very different than 16-year-olds. Psychosocial function is less developed in younger people. This fact suggests the need for specific strategies, and not just a global approach of central and satellite facilities. The practical issue of performing circumcision in 10-12-year-olds under local anaesthesia also was pointed out, as it is important to prepare the boys adequately to ensure their cooperation with surgery under local anaesthesia. General anaesthesia for male circumcision would add an additional burden on programmes and, may result in anaesthesia complications and perhaps even deaths; and thus there was a general feeling that the use of general anaesthesia should be discouraged.

One view expressed was the importance of promoting neonatal circumcisions, but only in certain settings with good delivery services and low neonatal mortality. It could also be necessary to consider those communities which carry out neonatal circumcisions and where, once a dynamic is created, there could be increased demand for newborn circumcision. It was noted that in countries with a low circumcision rates, such as Lesotho, targeting neonatal circumcision may be difficult and have low acceptability. It was also mentioned that, although neonates have lower complication rates, when complications occur they tend to be more serious.

One of the key factors is the ease of male circumcision, which varies with age:

- Neonatal (first 28 days of life)/baby (<1 year of age)
Characteristics: Simple, quick; clamps typically used; local anaesthesia; healing time 5-7 days; adverse events <1%; lower cost
- Child (1 year to ~9 years)
Characteristics: Simplicity/speed "worse" than baby but "better" than adult; surgical procedure; but need to use general anaesthesia; healing time not long
- Adolescent/adult
Characteristics: Most difficult; surgical procedure, 30-60 minute operation; local anaesthesia; healing time (until "gentle sexual intercourse": 4 weeks; complete: 2-3 months); adverse events ~3% when performed by adequately trained providers in the right facilities; greater cost; greater potential for perception of immunity from HIV infection and subsequent higher sexual risk taking.

In considering the optimal age to perform male circumcision, there is a trade-off between, on the one hand, the ease and low cost associated with lower age and, on the other hand, the reduced time before the impact of the circumcision programme on the HIV epidemic is noted, associated with higher age.

Serostatus

Serostatus is another important factor. Targeting seronegative men is preferred, as male circumcision is already known to carry the benefit of reducing the risk of infection in this group. As serostatus is often unknown, all men should be offered HIV testing, consistent with the UNAIDS/WHO HIV Testing Policy Statement of June 2004 which describes the conditions for provider-initiated testing. If men test positive, there may be limited benefit in circumcising them - although there may be benefits from the testing and counselling. This may change if observational data on reduced rate of male to female transmission is confirmed in the ongoing trial in Rakai District, Uganda. The ethical issues of targeting seronegative men were discussed and are mentioned in the section on Human Rights, Legal and Ethical issues above.

Other possible factors to consider for prioritization include:

- What are the highest prevalence populations (geographically, urban vs. rural, tribally, risk group, e.g., STI clinic attendees, military, prison/jail)?
- In which areas are health care facilities best able to scale up?
- Which places are easy to reach and of high benefit (e.g. schools)?
- The ethics of economics: society benefits most when resources are used most efficiently
- Cost effectiveness: should one prioritize where the cost effectiveness ratio is likely best, i.e. where the cost is lowest per case of HIV prevented?
- Cost utility: should one prioritize where the cost utility ratio is likely the highest?
- Affordability: if there is only a limited amount of money available, how does one determine where to put it?

Box 2. Who should be prioritized for roll out?

- **Geographically**

- Countries/regions/districts with low male circumcision, high HIV prevalence
- Consider low prevalence, and high incidence areas

- **Population /Age specific**

Reactive

- Those who are already demanding services

Proactive

- Adolescents (15 -18 years). Need to consider local epidemiology, age of sexual debut, development age, age of traditional circumcision
- High risk groups e.g. truck drivers, uniformed services, STI patients, miners, serodiscordant couples.
- Long-term. Consider neonates through maternal and child health services

It was pointed out that, if only high burden countries with low rates of male circumcision are targeted, this will only address a limited number of countries and miss many people who could benefit from male circumcision. In Kenya, for example, although the male circumcision rate is high, there are regions in the country where many men are not circumcised.

8.2 What should be rolled out? The package of interventions

The meeting concluded that there was a minimum, basic package to be provided in all cases, and an extended package where circumstances permit.

Box 3. The minimum package for male circumcision services

- Offer of HIV testing and counselling
- Active exclusion of symptomatic STIs and syndromic treatment where required
- Provision and promotion of male and female condoms
- Counselling on risk reduction and safer sex
- Male circumcision surgical procedures as described in the WHO/UNAIDS/JPIEGO Technical Manual for Male Circumcision under Local Anaesthesia

The positive protective effect of male circumcision on HIV transmission needs to be considered against the risks of complications from the procedure and of increased risky sexual behaviour among circumcised males. Safety and counselling were therefore two of the most important issues addressed. The limited available data on safety of circumcisions performed in traditional settings is alarming, and while providing safe male circumcisions is feasible, it will require resources.

Counselling

Counselling as a minimal requirement to accompany male circumcision achieved a clear consensus, linked intricately to the need to minimize the potential for subsequent higher sexual risk taking. Until now, men have been told that it was unclear whether male circumcision protects against acquiring HIV. However, if we are rolling out services the message would be different and therefore it would be important to have good counselling on safer sex messages to minimize risk compensation. In this context, the issue of risk compensation was among the main issues discussed in determining the minimum package to be offered. In the Orange Farm trials, while the mean number of sexual acts was higher in circumcised men, behavioural factors had no influence on the effect of male circumcision. A separate study in Kenya also found no difference in sexual risk behaviours of men who became circumcised compared to controls. Despite these limited encouraging data, the issue of risk compensation remains critical and requires great attention.

Condoms

The significance of the condom gap was also stressed. Currently averages of only about 5-10 condoms are used per man per year. A male circumcision roll-out strategy will need to be accompanied by a sustainable condom supply, as declining condom use would be disastrous. Country condom supply programmes therefore need to be involved.

Other Reproductive Health Services

A more general issue discussed was whether and to what extent the provision of male circumcision should be accompanied by other, additional services connected with reproductive health. Many participants felt that there is an opportunity to reach a group that is otherwise difficult to reach, and that male circumcision roll out could be used to provide a platform for more comprehensive male sexual and reproductive health services, as men tend not to come to formal health services for preventive care. A narrower view expressed was that the goal is to reduce HIV incidence by increasing the male circumcision rate, and if we try to use it to solve all problems that have not been solved in the past, we may run into major difficulties. Therefore it is important to limit the number of services included in the package.

The discussions concluded that male circumcision service delivery is not just the 'removal of foreskin' approach. The meeting recommended a minimum package of services/interventions that all male circumcision services should provide, as well as an expanded package of components which could be provided at certain delivery points. The minimum package included: safer sex and risk reduction counselling, exclusion of symptomatic STIs and syndromic treatment where required, condom provision and HIV testing and counselling.

The expanded package will depend on the age group to be given priority for service and will need to include community and social aspects. The package could include: counselling on life skills (e.g. negotiation, communication and decision-making), gender-based violence, parenting, substance abuse, health education and use of health services, family planning, information and skills, and vaccinations for children/IMCI.

HIV counselling and testing was discussed throughout the meeting. Although it was agreed that acceptance of HIV testing and counseling should not bar any man from receiving male circumcision services, in line with the move towards provider-initiated testing and counseling (PITC), it was important to ensure that the offer of HIV testing was available in all male circumcision services as part of the minimum package. It would be necessary to establish whether PITC had any impact on the acceptability and uptake of MC services.

It was also mentioned separately that various treatment/testing programmes are ongoing in Kenya. While not directly part of a roll-out package, these avenues can be used to talk about male circumcision with individuals who come for counselling, and to link it to other issues.

8.3 How can services be rolled out? Roll out strategies

In a presentation on how to roll out services, it was pointed out that there are many associated issues, set against the context of prevention failure in southern Africa, with the number of new infections constant or rising 25 years into the epidemic, and a feeling of inevitability and fatalism.

It was acknowledged that no one knows the right way to scale up; it is likely that different approaches will be appropriate in different situations – vertical, integrated, public or private. Sustainability and cultural acceptability are critical factors to consider in scaling up services. A balance must be struck between the need for an effective intervention with the need to meet demand and operate in a culturally appropriate manner. The need to engage local stakeholders was repeatedly mentioned, with dialogue necessary for developing support. Kenya was given as an example where the elders came round in favour of male circumcision after listening to the evidence.

Box 4. Roll out strategies

- Centres of excellence
- A campaign approach
- Integration into existing services
- Special events
- Responding to the demand for services

Centres of excellence

Centres of excellence with satellite clinics was one approach discussed. This approach helped to ensure that there was a centre that could provide supervision and support and practice for updating skills. This approach had been initiated in Zambia with The University Teaching Hospital (UTH) serving as the centre of excellence.

Several participants said that regional centres of excellence should take priority over national centres of excellence. Even though it can be useful to look at individual countries, there is a need to take a participatory approach and share regional experiences among countries. It will be difficult in areas where male circumcision is relatively unknown (e.g. Malawi, Zimbabwe and some South African provinces), while in Kenya it will not be difficult.

A campaign approach

The role of mass mobilization and the advantages of a campaign approach were discussed. This approach has rarely been used for HIV beyond providing information, but it has been successful in disease control, e.g. immunizations against polio and measles. Child Health Weeks and Months are proving sustainable and valuable in several countries in East and Southern Africa. Such programmes could potentially be extended to adolescents, and are likely to receive strong community support. An analogy was made with measles immunization, where the focus was on 9-month-olds. Within 3 years, all children up to age 4 were immunized.

Setting a starting point, for example with a campaign approach targeted at 14-year-olds, could make the task more manageable. For maximum impact, one would want to have 95-100% of men circumcised. However, it is impossible to achieve this in a short period of time. A multi-year plan is needed, and governments need to decide whom they want to prioritize.

Integration into existing services

The question emerged again as to whether male circumcision should be integrated into existing services considering that the existing system is already seriously challenged. The point was made that male circumcision remains an elective procedure, and that it is important not to undermine existing health services by a rapid scale up that takes health providers away from other critical interventions. However, it was widely acknowledged that for sustainability there needed to be some level of integration with existing services.

Special events

Organizing special events on certain days or during, traditional circumcision seasons was another approach. An example was given in Swaziland where a series of 'Circumcision Saturdays' are planned (and three have been held). On that day several doctors provide circumcisions over the whole day in clinical facilities. It was also suggested that circumcision services could also be organized during certain traditional seasons such as in South Africa where circumcision is traditionally carried out in the cold season.

Mobile teams could be set up to provide outreach circumcision services; these could be linked to PMTCT sites, STI services, or youth friendly health services.

Rapid response teams could be set up, where a team of health workers are flown in from different countries to provide services at certain periods of times as was done with 'Operation Smile' (for cleft palate operations) or cataract operations,.

Responding to the demand for services

A critical issue discussed was about demand and demand creation. It was stressed that one must not create demand for something one cannot provide. Targeting through the promotion of services could lead to capacity problems due to heavy pent-up demand. On the other hand, if only demand management is done, it might for example make male circumcision safer, but it would not change the overall circumcision prevalence over many years, and therefore would not affect HIV incidence. The conclusion was that demand creates action, and both a reactive and a pro-active approach are needed.

It was also suggested that, while there is a need to move quickly, demand is unlikely to be overwhelming, and it would be wrong to dismantle the existing services for male circumcision, and that, if not properly implemented, people could die from poor surgical procedures. Unless there is a huge wave of demand, in which case the WHO could organize a team of doctors to go to Africa, it should be possible to gradually scale-up services. On the other hand, it was also noted that if there was a large demand that could not be met by clinical services, it would be filled by the traditional sector where complication rates were likely to be high. Therefore individual country assessments needed to be done and measures taken to respond.

It was also suggested that there may be an overestimation of male circumcision demand in the same way that condom demand was overestimated in the past. News of the Orange Farm trial results was well publicized in South Africa, but without an increase in demand. On the other hand, there has been an increase in demand in Swaziland due to public discussions and engagement. It was agreed that it is difficult to estimate the current demand levels and therefore national and regional consultations are needed to investigate them. It was concluded that in the absence of real action, the increase in male circumcision demand would probably be modest. It was emphasized that advocacy is needed to have services made available. ART would never have been rolled out without advocacy. In response to the evocation of improved treatment access the WHO/UNAIDS "3 by 5" Initiative was set up and aimed to support countries in putting three million HIV positive people on ART by the end of 2005.

Other service roll out issues

The meeting outlined various other activities that needed to be conducted when considering service scale up:

- Perform a needs assessment

Aside from the obvious differences in HIV prevalence and incidence and male circumcision coverage, countries are not all at the same level with respect to needs assessment and preparedness for scale-up. For example, in Botswana, few needs assessments have been carried out, whereas in Swaziland and Zambia this process has already started. In Kenya, an existing research site could be converted to a centre of excellence. More information is needed on facility preparedness, as well as more country data. WHO reported that a situation analysis tool kit is being developed that will enable countries to assess the current practices, services and acceptability of male circumcision nationally.

- Establish standards for procedures within an appropriate regulatory and policy environment
- Develop a cadre of manpower
 - Involve more nurses, clinical officers, medical students, lay counsellors
- Conduct comprehensive training
 - Establish training centres (in collaboration with existing centres); for example: Male Circumcision Centre of Excellence, with satellite centres (clinics, armed forces, schools, etc.), providing training, monitoring and support/supervision (24h services)
 - Spread out from central to provincial satellites (specific guidelines to specific groups)
 - Conduct on-site and whole site training
 - Incorporate into pre-service training
- Community and public information, media promotion, fund raising
- Work with:
 - The government
 - The community, NGOs and civil society
 - Develop Public Private Partnerships (PPPs) to meet the demand
- Follow-up services, with solid monitoring and evaluation

9. THE ROLE OF DIFFERENT SERVICE PROVIDERS

9.1 Non-physician providers

The group was in agreement that there is a lack of new people to train, and that it will be necessary to see who is already available and look at task-shifting. The use of non-physician providers can be very successful in increasing access in many settings. Experience from family planning and reproductive health indicates that, with sufficient training, non-physicians can be as good or even better than physicians in carrying out some procedures, as they may have more time available and can be trained on other aspects as well. The example was given of a policy change that allowed nurses to provide Norplant in Ghana; the use of nurses for service provision needs to be explored for male circumcision. Other examples were provided in the background paper presentation. It was agreed that the relative role of physicians and non-physicians may depend on the country context.

Other experiences have shown that it is no problem to obtain health personnel, provided they are properly paid, and/or provided with an incentive. In this case, it could be possible to train people quickly. The issue comes down to financial need: with extra money, existing staff could do it. An option is to look at evening and weekend surgery as part of a creative approach to using existing personnel. As nurses are 90% female, they are not necessarily the ideal solution, given possible issues associated with using female practitioners for male circumcision. They are also as overburdened as doctors.

One opinion was expressed that non-medical personnel could also be trained to adequately perform male circumcision surgery. However, the general feeling was that we need to concentrate on training existing non-physician medical personnel first. It would be difficult enough to obtain the necessary permission to train already existing cadres of health personnel.

The general recommendation of the meeting was that non-physician (mid-level) providers should be trained in male circumcision surgical techniques. This was the only way to make services available and accessible to men.

Other issues that were discussed on this topic included:

- Start with an assessment of available capacity and how to use it (clinic-based, mobile outreach)
- Assure competency of providers (public, private and traditional) – standard performance is essential
- Governments need to create unified standards and guidelines for all providers
- Different cadres of medically-prepared/trained persons to provide male circumcision, including physical exams and surgery (physicians, nurses, clinical officers, etc.)
- Non-physician providers such as military paramedics could play a key role
- Auxiliary staff could provide the rest of the package, e.g. prevention/counselling.

9.2 Traditional providers

The role of traditional providers was a major, difficult issue discussed. The potential of traditional providers to supply needed capacity, as well as the established social context in which they operate, was set against the need to ensure that male circumcision is conducted safely. Traditional providers were considered by some as being difficult to incorporate into the health-care system, and their potential role remained somewhat unclear. Licensing, monitoring and supervision could be problems. A separate comment referred to the legal issues of using traditional circumcisers; this is an aspect that countries will need to consider. A question was also raised about the need to clarify WHO's position regarding the use of traditional circumcisers.

Nonetheless, the general sentiment was that collaboration with traditional providers is important. It was also suggested that little was known about traditional circumcisers and about the procedures used. For this reason, traditional circumcisers need to be better studied and recommendations made about how to involve them.

9.3 Female providers

The acceptability of female providers was discussed during the meeting with the concern expressed that there could be cultural resistance to having female practitioners. The experience in Lesotho bears this concern out, where female and even non-circumcised males are not supposed to be involved in male circumcision discussions. A female surgeon who initially worked with the traditional circumcisers to provide safe medical circumcisions was later barred from the circumcision camps. It was mentioned that concessions do, however, tend to be given over time. In Nairobi, for example, women can attend to men in an emergency. In Lesotho even though most men would prefer male doctors to perform male circumcision, there are more female surgeons than male and therefore men accept to surgery performed by females in hospitals. The practical problems associated with a man having an erection on the operating table which could lead to complications such as bleeding and excessive skin removed were mentioned. The issue of the acceptability of female providers needs to be carefully considered and investigated because most (non-physician) mid-level providers are female.

9.4 Certification

A presentation on certification established that the first priority was to ensure safety. The various competencies needed for each element of male circumcision services were described, including, pre-surgical assessment, pre-surgical counselling, circumcision, post-surgical care and referral. Aspects to consider in determining who should provide the service include; knowledge required, task complexity, risk of harm and current evidence. A certification system with published standards can provide direction for the programme and a means of measuring its success. Other aspects to consider include the details of the certifying infrastructure and authority, programme sustainability, management of field operations, a framework for certification decision-making, a certification database, and the various available methods to collect data, which depend on the resources available and measurement goals.

Key actions needed for certification include:

- Identify certifying body at country level (official and traditional)
- Set standards and competencies (using community involvement)
- Prepare and train, using competency-based training sites
- Monitor, supervise, maintain quality control
- Educate the public to seek provider/services that are certified (branded)
- Use a log book system as a personal audit of cases done
- Certification of services, including counselling
- Both facility and individual certification.

10. DETERMINING RESOURCE NEEDS

It was acknowledged that the scale up of services will cost money and therefore donors will need to support it. However, sustainability needs to be considered from the start. Generally services should be free or as nearly free as possible depending on the country context. Modelling can be used to guide the estimations of resource requirements.

In resource needs considerations the following were identified as important:

- Equipment (kits), commodities and expendables, including condoms
- Trained human resources
- Infrastructure
- Information, Education and Communication materials
- Funding for operations research and monitoring
- Health Management Information Systems
- Affordable versus free services
- Use of the military, etc. to provide services
- Advocacy, community literacy campaigns

10.1 Modelling patient flow

A presentation was made showing how the use of 'operations research' (using the term as used in engineering) could help with the planning and logistics problems of male circumcision scale-up. The different aspects of the methodology were described, including forecasting, computer simulation, and optimization, as were the hierarchical steps needed to build such a model for male circumcision.

A surgeon's own experience suggested that the rate-limiting step is getting people on the operating table. It was also noted that the forecasting exercise will be different depending on whether male circumcision is being provided or along with counselling. The number of personnel and the rate at which they can be trained can be viewed as a constraint/cost and would need to be taken into account. While the use of modelling can lead to increased efficiency and not simply higher costs, hiring too many staff can be very costly.

A concern was expressed that the model looks more objective than it really is, as the parameters entered are subjectively assessed. Scaling up clinic data to a larger scale could be dangerous, as it magnifies errors. One participant said he has been using models for 20-30 years for family planning, but that he had experienced major failures. Another disputed this conclusion, arguing that there have been major successes. It was agreed that we need to look to modelling to guide the estimations of resource requirements.

10.2 Cost and cost-effectiveness

Cost is a major determinant in scaling up male circumcision services, and where the cost is low and safe circumcision is available, demand increases in the public/private sector, though less so in traditional settings.

An ongoing project was presented to estimate the cost and model the potential impact of male circumcision in Lesotho, Swaziland and Zambia, and identify the component pieces of a comprehensive male circumcision intervention. The main outputs of the project expected are:

- Cost per person circumcised
- Under various coverage scenarios:
 - Financial resource requirements
 - Number of infections averted
 - Cost per infection averted
- Report on the completeness of male circumcision in Lesotho

Capacity issues in the costing study include bureaucracy, protocol and human resources, all of which are slowing the project implementation down.

The kinds of costs involved depend on the issue and the context. Economies of scale can be relevant. For example the price of antiretroviral drugs fell dramatically due to volume as well as activism. It was noted separately that the potential costs involved can be much more than the strict financial expenditure for the surgical procedure and must be seen in the broader context. These can include public perceptions if a “calamity” happens and political costs of ill-chosen strategies.

For male circumcision provision, significant human capacity constraints are a limiting factor, and the involvement and training of nurses, clinical officers, paramedics, etc. are a critical consideration. Whether and how to involve traditional circumcisers in the delivery of safe circumcision was an unresolved issue.

11. OPERATIONS RESEARCH

Operational research is clearly needed to better understand the various logistical, technical, financial, regulatory, social and resource-related issues, which can have an impact on the effectiveness of MC scale-up. Issues identified for further operations research include:

1. Implementation of a minimum package of services versus an expanded package and post circumcision clubs
2. Risk compensation/messages effectiveness and sexual activity after male circumcision
3. Stigma and discrimination
4. Acceptability
5. Satisfaction
6. Quality assurance issues
7. Data monitoring
8. Adverse events
9. Different providers/techniques
10. New techniques and devices

12. RECOMMENDATIONS AND NEXT STEPS

The key recommendations that arose from the meeting are summarized in the Executive Summary.

The challenge now is to strike the right balance between maximizing impact from a public health perspective, and addressing the human rights angle from an advocacy perspective. Practically, the goal is to maximize the impact on HIV infections while making male circumcision safer. Strategies need to be worked out at the country level, consulting with people who can bring the necessary tools, understanding and experience to determine the best approach for each country.

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APPENDIX I: MEETING AGENDA

Strategies and Approaches for Male Circumcision Programming

5 – 6 December 2006

Hotel Manotel, Rue de Lausanne Geneva, SWITZERLAND

Day 1: 5 December	Morning	Chair: D. Serwadda
0830-0900	Registration	
0900-0930	Welcome and Introductions Introductory Remarks	K. De Cock (WHO)
0930-0940	Objectives, desired outcomes of the meeting, review of agenda	J. Perriens (WHO)
0940-0950	The UN Work plan on safe male circumcision	K. Dickson (WHO)
	Overview of the Evidence for HIV Prevention and Lessons from Reproductive Health Technologies Implementation	
0950-1010	Overview of the current evidence on male circumcision and HIV prevention	C. Hankins (UNAIDS)
1010-1015	Discussion	
1015-1035	Implementing facility-based family planning and other reproductive health services: Lessons applicable to introduction of male circumcision for HIV prevention	M. Barone (Engenderhealth)
1035-1045	Discussion	
1045-1110	Tea Break	
1110-1125	Public health, human rights, legal and ethical issues Discussion	Mark Heywood (AIDS Law Project)
	Current Practices and Service Delivery Models	
1125-1220	Current practices and service delivery models: Country experiences from Zambia, South Africa and Kenya	K. Bowa (Zambia) G. Shilaluke (South Africa) S. Koshuma (United Republic of Tanzania) K. Agot (Kenya) S. de la Torre (Kenya, Presbyterian Church of East Africa Experience)
1220 -1235	Discussion	
1235-1315	Current practices and service delivery models: Country experiences from Ghana, Israel, Republic of Korea and Senegal	O. Owusu-Danso (Ghana) I.Schenker (Israel) I.R Cho (Republic of Korea) C. Niang (Senegal)
1315 -1330	Discussion	
1330-1430	Lunch	

Day 1: 5 December	Afternoon	Chair: D. Serwadda
	Strategies for Service Delivery	
1430-1600	K. Dickson Whom do we prioritize for roll out? Discussion How do we roll out services (package of interventions, types of services)? Discussion Role of different service providers (public, private, traditional) /Certification Discussion Introduction to Group Work	G. Schmid/K. O'Reilly (WHO) D. Alnwick (UNICEF) J. Ashton (Consultant)
1600-1630	Tea Break	
1630-1800	Group work to outline possible strategies for service delivery and make recommendations	
1800	Close	
1800-1900	Reception	
Day 2: 6 December		Chair: C. Ryan
0830-0930 0930-1030	Feedback from groups Discussion	Rapporteurs
1000-1030	Tea Break	
	Determining Resource Needs	
1030-1045	Three country study on the cost and impact of male circumcision in Lesotho, Swaziland and Zambia	D. Peacock (Constella Futures)
1045-1100	A preliminary resource requirements model for wide-scale adult male circumcision	E. Hollingsworth
1100-1200	Group work to discuss certification issues, resource needs and make recommendations	
1200-1300	Group work continues to outline operations research issues and review all recommendations	
1300-1400	Lunch	
1400-1530	Feedback from groups Discussion	Rapporteurs
1530-1600	Tea Break	
1600-1630	Review of recommendations Next steps	K. Dickson
1630-1700	Close of the meeting	I. de Zoysa

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Introduction

Male circumcision (MC) has been practiced for centuries. In resource-poor settings, most circumcisions are still done outside the formal health sector as a rite of passage into adulthood or as a religious observance. For over twenty years many ecological studies have shown that there is a strong geographical correlation between MC practices and lower HIV prevalence, and numerous observational studies have also identified lack of circumcision in men as a risk factor for acquisition of HIV, particularly among men at higher risk of acquiring HIV. It has been difficult, however, to unravel to what degree the apparent protective effect of MC is due to confounding, as many factors such as religion and ethnicity are associated with MC and also have a major influence on risk behaviours. Randomized controlled trials were therefore initiated to assess the safety and efficacy of MC in reducing female to male HIV transmission in Kenya, Uganda and South Africa.

The Orange Farm Study in South Africa was the first to confirm the association between MC and reduced HIV risk that had been reported from observational and epidemiological studies over the past decade. The study, funded by the Agence Nationale de Recherches sur le Sida (ANRS), was stopped prematurely in mid-April 2005 on the recommendation of the study's Data Safety Monitoring Board (DSMB) and the MC intervention offered to the control group. Trial data were analysed and results demonstrated a 60% protective effect (95% CI 32-76%) for adult MC (Auvert et al, 2005).

The remaining two randomised controlled trials, funded by the US National Institutes of Health, were carried out in Kisumu, Kenya, among men aged 18-24 years and in Rakai, Uganda, among men aged 15-49 years. The trials, which completed enrolment of patients in 2005, were stopped by the DSMB in December 2006 based on the results of the interim data analysis. The interim results revealed a 53% reduction in HIV incidence in circumcised men in the Kenya trial and a 48% reduction in HIV incidence in circumcised men in the Uganda trial.¹

Now that MC has been confirmed in three randomized trials to provide significant protection against the acquisition of HIV it is undoubtedly necessary to explore ways to quickly scale up the provision of male circumcision services. Particular attention will need to be paid to the high HIV prevalence countries of sub-Saharan Africa where circumcision is not widely practiced. Already, in some settings, demand for MC has risen and MC is being provided in some public and private sites. This opportunity must be used to strengthen male sexual and reproductive health services and the provision of other HIV prevention strategies.

Many questions are likely to be raised, however, about strategic approaches to service delivery including: what are the ranges of possible approaches, which populations and ages should be prioritized, what are the costs involved, and who will deliver the services? Experience from the introduction and scale up of reproductive technologies can provide some useful lessons for MC service delivery scale up.

¹ NIH News Release. *December 13, 2006. Adult Male Circumcision Significantly Reduces Risk of Acquiring HIV. Trials in Kenya and Uganda Stopped Early.* Available at <http://www.nih.gov/news/pr/dec2006/niaid-13.htm>

Lessons learned from introduction and scale-up of reproductive health technologies

Over the past several decades a number of new clinical contraceptives or other reproductive health (RH) technologies – including new methods and novel techniques/equipment for existing methods or procedures – have been introduced on a wide scale in the developing world including, for example, female sterilization using minilaparotomy under local anesthesia, no-scalpel vasectomy, Norplant®, and manual vacuum aspiration for treatment of abortion complications. This paper reviews lessons learned from FP/RH programmes, along with country examples of these experiences – both positive and negative – that highlight these lessons. Adapting and applying these lessons is likely to help smooth MC introduction, ensure that services are safe and good quality, reduce the likelihood of increased risky behaviors in newly circumcised men, and facilitate scale-up and sustainability of MC services.

The many lessons that have been learnt while introducing new FP/RH technologies have direct application to the introduction of MC for HIV prevention. Inadequate attention to introduction may lead to a host of problems, including:

- poor quality services resulting in post-procedure infections or other negative sequelae (due to either a poorly managed introduction or, conversely, if there really is no formal introduction and demand leads to a proliferation of inadequately trained people offering MC services);
- inadequate counseling resulting in uninformed decision making (coercion in the worst case scenario)
- poor communication strategies and inadequate counseling leading to confusion and misunderstandings about the degree of protection conferred by MC, and risk compensation among newly circumcised men;
- low use due to poor reputation of the services or inadequate availability or access;
- cultural- or religious-based opposition from, for example, the community, political or religious leaders, and service providers; and
- services that are not sustainable in terms of coverage and/or quality.

Critical issues to consider for new technology introduction

Listed below are some of the critical issues that need to be addressed as part of the introduction of any new technology, based on lessons learned from introduction of FP and RH technologies over the years. Each is addressed in more detail in the remainder of this paper.

1. Begin with a well defined strategy that plans for scale-up and sustainability from the start
2. Develop local ownership of programmes and strong political support
3. Focus on the fundamentals of care* for facility-based service delivery
4. Understand the limits of training
5. Link training to supervision
6. Increase access through non-physician providers
7. Explore alternative models for service delivery
8. Design holistic programmes that address supply and demand
9. Capitalize on opportunities to work with men
10. Adequately address the many issues needed for going to scale

*Informed and voluntary decision making, assuring medical safety for clinical procedures, and quality assurance

1. It is more than just the method

Figure 1. Issues to address for introduction of a new clinical service



Perhaps the most critical lesson we have learnt about introduction of a new clinical procedure, method or technology, is that it is more than just the innovation itself. Other health systems issues need to be considered and addressed. Fig 1 provides some examples of other issues that need to be addressed during the introduction process. Thinking needs to be in terms of the 'system' into which the new technology will be introduced; the innovation itself is just one piece of the puzzle and focusing primarily on the innovation is unlikely to lead to quality services that address people's health needs (see Box #1). Changes needed as part of the introduction must be incorporated into all ongoing aspects of the system – for example, scope of routine services, protocols and guidelines, training programmes, budgets, new staff orientations, and performance expectations – for them to be sustained after external support ends and internal staff change. It is not enough to transfer new capacities to individuals; innovations must be introduced into the different parts of the system.

Box 1. More than just the innovation

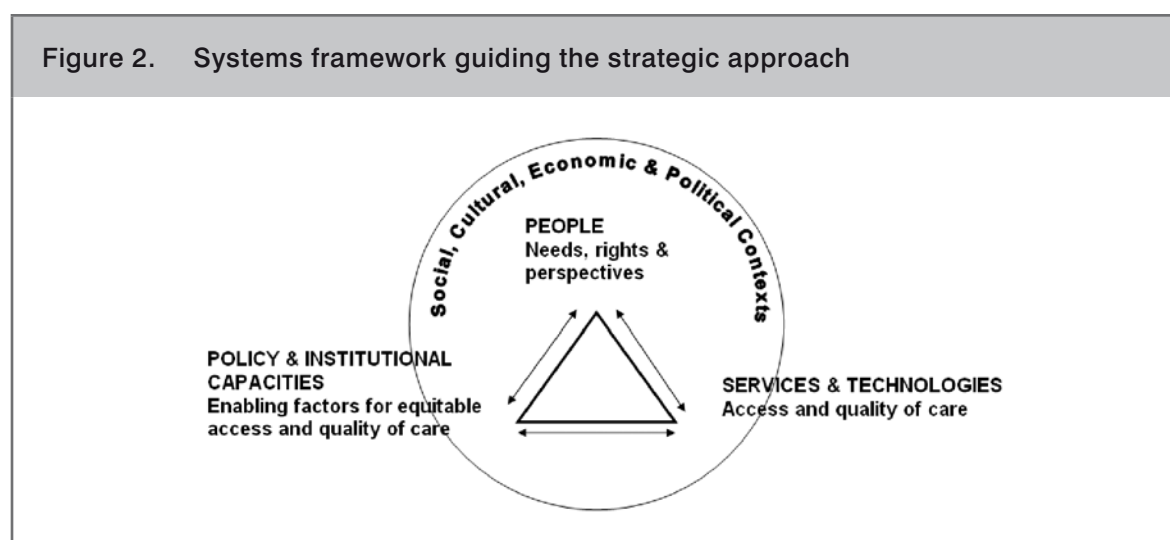
Postabortion care (PAC) includes three elements: treatment of abortion complications, postabortion family planning and linkages to broader RH services. In Colombia, providers were attracted to MVA technology for treatment of abortion complications because it saves resources and is safer for women being treated. Initial introduction activities focused primarily on MVA and other aspects of PAC services such as counseling and family planning (FP) provision, received less attention because they were not new issues and because staff had some experience with FP. While there was good uptake and use of MVA there was not an increase in use of FP among postabortion clients. To promote better integrated and more client oriented PAC, EngenderHealth shifted focus, beginning with what makes up the package of PAC, for example carrying out training in PAC counseling (including family planning) first, before providers were trained to do MVA.

Source: Escandon, et al. 1999.

2. Begin with a well defined strategy that plans for scale-up and sustainability from the start

Given the myriad of issues that need to be addressed in order to successfully introduce a new technology, it is critical to have a well thought-out strategy from the start. This strategy should address all of the various pieces of the puzzle (see Fig 1). Issues related to scale-up and sustainability should be given serious consideration right from the start. As part of the strategy development process, it is important to agree on a goal for the programme. With MC, for example, is the goal to introduce MC as an HIV prevention approach and get as many men who are interested circumcised? Is it to provide safe circumcision services? Is it to use MC as an entrée to working with young men – a population who do not often access health services? Is it to introduce MC within the context of a broader prevention programme? Or, is the goal a combination of these objectives?

The World Health Organization's Strategic Approach to Strengthening Reproductive Health Policies and Programmes has been used in 25 countries to introduce or strengthen a wide variety of reproductive and other health concerns (e.g. comprehensive RH, FP, abortion care, adolescent health, and HIV services). Figure 2 shows the systems framework that guides the Strategic Approach.



The Strategic Approach is a participatory process that promotes in-country ownership and recognizes that decisions related to introduction of new health services require an understanding of the relationships between the three points of the triangle in the systems framework:

1. people, the potential users of the innovation being introduced (What are their needs and perspectives on the innovation? How do we safeguard their rights?, etc.);
2. the policies and institutional capabilities of the service delivery system into which the innovation will be introduced (What is the capacity of the system to absorb the new technology? What changes in policy are needed?, etc.); and
3. the innovation itself, along with the mix of related services and technologies that already exist within the system (How accessible are current services/technologies? What is involved in providing them and the innovation? What is involved in using them?, etc).

The Strategic Approach also takes into account how these interactions are influenced by the broader sociocultural, economic and political context. It is a valuable process that can lead to the development of a realistic introduction strategy and can smooth the introduction of any health care technology or innovation.² Box #2 highlights an example of the successful use of the Strategic Approach in Brazil.

Box 2. Implementing the strategic approach to improve quality of reproductive health services in Brazil

Brazil is the first country where the use of the Strategic Approach has progressed through all three stages of the process. The Stage I strategic assessment, placed priority on improving the provision of currently approved contraceptives before adding new ones. Out of this grew a Stage II demonstration project, conducted from 1995–1997 in São Paulo State. This participatory action-research project designed and tested interventions to enhance the capacity of a resource-poor, decentralized health service system to offer good-quality reproductive health services. Municipal authorities and community women's organizations worked together to plan and manage a variety of activities to expand the range of contraceptive options and introduce services and programmes for men and youth. Considerable improvements in service availability, RH orientation and quality of care were made. The project also demonstrated that expansion of reproductive choice could occur at the municipal level within existing resource constraints.

The challenge for Stage III was to test whether and how the model could be replicated in other municipalities. The Stage III scaling-up project worked in four additional municipalities from 1997–1998. Baseline diagnostic activities and subsequent interventions revealed that deficiencies in RH care and barriers to improvements were fundamentally similar in all municipalities involved and many of the lessons learned in Stage II were directly applicable. Other Stage III interventions included the development of briefing papers summarizing key findings and lessons from the Stage II project, and a series of policy dialogues and workshops with national-level policy-makers and other stakeholders.

A comprehensive evaluation, conducted from 1999-2000, showed that the project led to sustained improvement in the quality of RH services. Although funding had ceased, many project initiatives and changes in service delivery continued. All municipalities involved saw the "project" as an ongoing activity. Service statistics demonstrated increased utilization and numbers of new users, as well as expanded contraceptive choice.

Source: http://www.who.int/reproductive-health/strategic_approach/brazil.en.html

Although it is important to recognize that a one size strategy will not fit all settings, in general there are three phases the strategy should include: a) introduction, b) expansion and c) institutionalization (see Table 1). These phases may, in some cases, overlap and run concurrently.

² See Fajans P, 2006. Country experiences with the strategic approach can be found at: www.who.int/reproductive-health/strategic_approach/

Table 1. Examples of activities during each phase of introduction of an innovation

Introduction (pilot phase)	Expansion	Institutionalization (“going to scale”)
<ul style="list-style-type: none"> • Engage key stakeholders as partners • Meet with key policy makers to build support & obtain commitment • Conduct needs assessments • Develop national introduction strategy • Train small group of well-qualified clinicians • Identify champions to support and advocate for the new technology • Support & work with a few high quality sites to implement demonstration projects • Develop preliminary training and client education materials • Operations research • Monitoring & evaluation 	<ul style="list-style-type: none"> • Review lessons learned & disseminate results from introduction • Get buy-in and cultivate partnerships with larger number of stakeholders • Develop & disseminate national service delivery guidelines • Develop/adapt training standards & materials (e.g. curriculum, job aids) • Train trainers, supervisors & providers • Engage the community • Develop client information & education materials • Support & work with additional sites • Register unique equipment or supplies • Develop performance monitoring guidelines • Introduce quality improvement approaches • Establish linkage and referral mechanisms • Operations research • Monitoring & evaluation 	<ul style="list-style-type: none"> • Incorporate the new services into the national monitoring, training, supervision and management information systems • Ensure any unique equipment/ supplies needed are included in the nation supply chain, including that they are on the MOH list of basic medical equipment • Integrate training into pre-service system (e.g. medical and nursing schools) • Support expansion throughout the health system • Ensure quality of services is maintained • Monitoring & evaluation

Box #3 presents a country example of how a comprehensive strategy can lead to successful introduction, expansion and sustainability of an innovation.

3. Develop local ownership of programmes and strong political support

Developing local ownership of programmes at the national, regional and district levels, and in the community, is essential for successful introduction and sustained services. Equally as essential is developing strong political support among stakeholders within the health system, as well as outside of it as appropriate for the innovation (for MC, this might include community-based organizations working on HIV prevention, activists, traditional circumcisers, etc). Developing this ownership and support should begin at the start. Ideally the strategic planning process should be lead by the government – either the MOH or some group composed of members from various departments or divisions of the government – working in collaboration with others such as local NGOs and private providers. Guidance provided by international NGOs, UN agencies or donors experienced in introduction of new technologies is invaluable and can help prevent many of the common pitfalls that might otherwise be encountered.

Box 3. Starting with the strategy: a successful national programme for expanding vasectomy services in Mexico

In 1989, Mexico's largest provider of FP services, the Instituto Mexicano del Seguro Social (IMSS), working with EngenderHealth, initiated a long-term strategy for the introduction of no-scalpel vasectomy (NSV) including moving provision of services from hospital to primary care settings. The introduction strategy involved a comprehensive approach for training and assisting facilities in the introduction, organization, and management of services including supervision and promotion of vasectomy. The phased introduction included: 1) training a core group of doctors off-site; 2) establishing four pilot sites to demonstrate effectiveness of NSV and gain practical experience; 3) conducting comprehensive whole-site training to develop integrated vasectomy services at the primary care level, including training providers in NSV on-site, developing skills of all facility staff involved in providing vasectomy and related medical services, building support among administrators, and providing technical assistance to supervisors; and 4) expansion of the number of NSV sites.

Well over a decade after the introduction of NSV services, the demand and acceptance of vasectomy in Mexico has increased steadily and remains strong (from 6,000 per year in the late 1980s to over 21,000 per year in the early 2000s). By the time USAID concluded its support to the Mexican FP programme in 1999, the vasectomy programme was well institutionalized. The day-to-day implementation of the programme continues very much according to its original design. The strength of the programme and the fact that the public sector accounts for the vast majority of all vasectomies performed in Mexico speak to the strong political support that the programme received during its introduction. The programme also benefited from the close coordination that existed between the major government departments and public sector service delivery organizations who worked together in an inter-institutional group.

The fact that NSV is offered by general and family physicians in primary healthcare facilities made the service more accessible and helped to strengthen the concept of integrated care. The vasectomy programme served as a crucial introduction point for male services in Mexico. The vision of men's RH services has gradually shifted across all institutions. Strategies to develop and implement a much broader definition of sexual and reproductive health services for men are now being examined.

Sources: Cisek and Juarez. 2003 & Jezowski, et al. 1995.

For lasting impact, it is crucial to identify and cultivate champions for change, and sustained leadership by a committed individual or group within the system or institution who believe in the value of the innovation being introduced. This can help to smooth introduction, get buy-in, address resistance, and increase the changes of lasting impact. Ideally these individuals will also have the capability to commit resources to the introduction process and help ensure long term commitment. Over the years, experience has shown that programmes are unlikely to be sustainable when payments are made to facilities or institutions for each procedure performed, staff costs are covered, or providers are paid because they have to do more work. Once there is no longer an outside source of money, there is also no more programme

4. Focus on the fundamentals of care for facility-based service delivery

This service delivery model, developed by the ACQUIRE Project,³ is a distillation of EngenderHealth's decades of work in introduction and support of clinic-based FP/RH services. The Fundamentals of Care evolved from the vast and varied experiences of RH programmes and are based on years of listening to what communities and clients said they desired and what managers, supervisors, and providers said they needed to provide high-quality services. The three essential elements of the Fundamentals of Care are:

- informed and voluntary decision making;
- assuring medical safety for clinical techniques and procedures; and
- quality assurance.

In essence these fundamentals underlie the success of past FP and RH activities around the world all are critical for MC services. They are routine and basic, yet their finer points often are not well appreciated or understood, and are considered "old hat" by many programme managers. Without this focus on fundamentals, no amount of innovation, evidence, or best practice can be integrated into programmes and sustained. The Fundamentals of Care are built upon a framework of clients' rights and staff needs.⁴ This model ensures client-centered care on the one hand and an enabling atmosphere for service providers on the other, with the end result being good-quality care.

Informed and voluntary decision making refers to the process by which an individual arrives at a decision about health care, based on up-to-date information, knowledge, and understanding of all available options, including details of procedures and their consequences. It assumes that individuals have both the right and the ability to make their own health care decisions. Through effective client-provider

interaction, appropriate counseling, and safeguarding clients' rights, providers can enable voluntary decisions that help clients achieve good health and practice health behaviors.⁵ Barriers to informed and voluntary decision making persist for many clients around the world as a result of social factors, laws, policies, service delivery practices, resource constraints, and service providers' attitudes (see Box #4).

Medical safety for clinical procedures is a critical issue for both clients and providers, encompassing the procedures themselves and the clinical environment in which they are carried out. Clinical techniques and procedures are considered safe when skilled providers are practicing according to updated, evidence-based standards, guidelines and infection prevention protocols, within a physical structure appropriate for managing clinical services and with access to resources to support safe clinical services. Clearly safety of circumcision is an issue in the minds of men – in a review of studies conducted in areas of nine sub-Saharan countries where circumcision is not widely practiced, willingness to be circumcised was high, although concerns about safety were among the most consistent potential barriers to use of MC.⁶ An example of improving medical safety of clinical FP is described in Box #5.

Quality assurance is a continuous process requiring strong management systems that create a positive enabling environment for service providers to carry out their work. Provider performance is key to quality care, and provider support of new services (as opposed to opposition or bias) can make or break introduction of a new technology at the service level (see Box #6). To improve performance, providers need clear job expectations, feedback on performance, motivation, adequate infrastructure, supplies and equipment, up-to-date knowledge and skills, and simple, practical tools to continuously improve quality (see Box #7). Quality assurance is strongly linked to supervision (discussed below). As any new service is expanded outside demonstration project sites – sites that received significant technical, financial and moral support – it becomes a challenge to maintain the same degree of quality that was seen at those original sites.

3 The ACQUIRE Project (Access, Quality, and Use in Reproductive Health) is a five-year global cooperative agreement funded by the USAID. ACQUIRE is managed by EngenderHealth.

4 For details on client's rights and staff needs see EngenderHealth, 2003a.

5 Client-provider interaction includes all encounters, both verbal and nonverbal, that an individual has with a health care worker. Counseling is a specific form of client provider interaction aimed at helping clients confirm or reach informed and voluntary decisions about their health care and to understand the details of their chosen treatment, procedure or family planning method.

6 Westercamp and Bailey. 2006.

Box 4. Informed choice for female sterilization in Latin America

Between 1998 and 2001, EngenderHealth collaborated with MOHs, other government agencies, and NGOs in the Dominican Republic, Guatemala, and Mexico to determine whether women receive adequate counseling and information for making an informed and voluntary choice to end fertility. While the studies provided strong evidence that most women choose sterilization voluntarily, findings also indicated that many decisions were not fully informed. In two of the three countries, many women reported that they received little or no information about their contraceptive options and that they were not told about the risks of surgery nor what to expect during and after the procedure. The studies indicated that providers tended to tell clients what they felt they needed to know, rather than ask clients about their needs and interests and tailor information to an individual's knowledge gaps and circumstances.

Important exceptions to women making their own autonomous decisions included a few cases in which husbands decided for their wives and others in which doctors decided that sterilization was indicated on medical grounds. Postpartum sterilization clients experienced the least-effective informed choice safeguards. Some clients reported that they were not informed about their contraceptive options during their antenatal visits, and that they felt rushed to make a decision about postpartum sterilization while under the physical and emotional strain of labor and delivery. Of particular concern was the finding that the right and ability of women at high risk of future pregnancy-related complications to make an informed choice was sometimes overridden by the physician on medical grounds.

Source: EngenderHealth. 2003b.

Box 5. Improving medical safety of female and male sterilization procedures in Bangladesh

In the late 1970s, female and male sterilization were the primary family planning methods available in Bangladesh. In 1979 and 1980, there was an apparent increase in the number of deaths related to these procedures. Detailed investigation found that anesthesia overdose and infection (primarily tetanus) were the leading causes of death attributed to tubal ligation. Common practice was to administer intramuscular or intravenous medications (most commonly a combination of Demerol, Phenergan and diazepam) in addition to local anesthesia during female sterilizations. Vasectomies, on the other hand, were for the most part preformed under local anesthesia alone – use of systemic sedatives and analgesics was relatively uncommon. There were no vasectomy-related deaths attributed to anesthesia during this period; all were related to post-procedure scrotal infections. It was common practice at that time for surgeons to do vasectomies without wearing gloves. To improve medical safety of female and male sterilization procedures, EngenderHealth worked with local counterparts to introduce minilaparotomy under local anesthesia to reduce the risk of anesthetic complications during tubal ligation, and to improve infection prevention practices in sites providing both tubal ligation and vasectomy.

Sources: Grimes et al. 1982 & Rosenberg et al. 1982.

Box 6. Importance of provider support

After the Yuzpe method of emergency contraception (EC) was approved by the US FDA in 1998, many providers feared that the use or wide availability of these pills would result in 'irresponsible sex.' Providers felt that this behavior could contradict or counteract existing information messages or prevention methods. Studies showed, however, that women who use EC do not abandon contraception; neither do they use EC as their main means of family planning. Organized efforts by the women's health community in the US operating on many fronts helped to address provider's concerns and shift their opposition and biases to support of EC. In 2000, EC prevented over 50,000 pregnancies in the US and the dramatic increase in use of EC may be responsible for a significant part of the decrease in abortions seen throughout the US between 1994 and 2000.

Sources: Jones et al., 2002; Glasier & Baird, 1998; Graham et al., 2002

Box 7. COPE® for continuous quality improvement

COPE® (Client-Oriented, Provider Efficient Services) is a process and set of tools developed by EngenderHealth to help supervisors and staff continuously improve the quality of the services they provide; to make services more responsive to clients' needs; and to make their work environment more efficient, cost-effective and supportive. COPE® provides staff with practical, easy-to-use tools to identify problems and develop solutions using local resources, and it encourages all levels of staff and supervisors to work together as a team and even to involve clients in assessing services. The process emphasizes staff involvement and ownership of services, self-assessment, and teamwork. It recognizes staff members' understanding of local conditions and resources, and provides a forum for discussion among staff. COPE® has been adapted and used to improve the quality of a variety of health services, including FP and other RH care, prevention of mother-to-child transmission of HIV, antiretroviral therapy, child health, maternal health, and cervical cancer prevention.

Source: EngenderHealth. 2003a.

5. Consider the service site as the organizing point for training

It is crucial to understand the limits of clinical skills and other training in the context of introduction of new technologies. While clinical skills training is essential, it is not sufficient for introduction of a technology and resulting quality services. All of the other pieces of the puzzle (see Fig.1 on page 1) are equally as critical to success of the programme.

Experience from FP/RH programmes around the world suggests that considering the service site as the organizing point for training – i.e. using a whole-site training approach – is best during introduction of a new technology. Whole-site training (WST) is an approach to training aimed at meeting the learning needs of an entire site by, assessing the site's training needs, tailoring training to different levels of staff, emphasizing teamwork and sustainability, applying a range of training strategies, and linking supervision and training. WST training allows for the entire site to be 'prepared' for the new service, helping to prevent problems that often arise when only one person (or at best a few people) from a service sites goes off for training and upon return tries to introduce a new service. The likelihood of successful introduction of the innovation is increased with WST because it builds support among administration and other pertinent staff, including shifting negative staff attitudes that may exist; addresses counseling and informed choice issues; identifies infrastructure, supply and equipment needs; and ensures appropriate infection prevention practices are in place, to name a few. The country examples in Box #8 highlight the benefits of WST.

Box 8. Advantages of whole-site training

In Mexico, the Instituto de Seguridad y Servicios Sociales para los Trabajadores del Estado (ISSSTE) developed regional training centers for their NSV programme. While this centralized, off-site training was successful in helping physicians develop a solid NSV technique, it did not provide a comprehensive approach for introducing and institutionalizing vasectomy services at the trainee's own facility. Once this became apparent, ISSSTE modified its training approach to conduct whole-site training leading to more successful introduction of NSV.

In the early 1990s EngenderHealth began activities to improve infection prevention in FP programmes in Nepal. District staff traveled to Kathmandu for training. They were to return to their districts, train others, and implement proper practices at their site. This approach met with little or no success—infection prevention was not measurably improved. Key problems included: workshops were highly sought-after and often the most appropriate staff did not attend; the curriculum provided too much information; training was conducted in an upgraded facility, far more modern and well-equipped than those found in the districts; newly trained staff found their colleagues resistant to change; follow-up was inadequate; basic supplies were often not available; and supervisory visits to district facilities were rare. Once it became clear that institutional change would not occur unless a new approach was used, a whole-site training approach, that included establishing supervisory teams, training on-site, and linking training to supervision, was adopted. A broad range of barriers to quality service delivery (over and above inappropriate infection prevention practices) became apparent. Training and supervision teams worked with the sites to address many of these problems and at the same time, began to develop a system that would provide ongoing support for quality of care.

Sources: Cisek and Juarez. 2003. and Stanley, et al. 2001.

A variety of approaches can be used to meet a site's training needs as part of a WST approach, including different types of trainings and training conducted at different locations. For example, types of training could include orientations to new services or concepts for all staff at a site, and knowledge updates and skills training for those who will be directly involved in provision of the innovation. The locations for training can be on-the-job (i.e. training that occurs as staff conduct their daily activities), on-site (i.e. organized training workshops that occur at the service site where the staff will use the new skills), and regional or central trainings (i.e. training that occurs somewhere other than where the services will be provided; often referred to as off-site training).

One training strategy that has been successful is to use off-site training early in the programme – this initial clinical skills training might even occur in another country – with the goal that this first group of select individuals trained become trainers and advocates/champions for the new technology. Then, in the second phase of introduction, these trainers would do the clinical skills training on-site, as well as train additional trainers. The country example in Box #3 included successful use of this two-tiered type training strategy. For sustainability, it is critical to establish local training capacity, eventually integrating training into ongoing pre- and in-service training programmes within the country (see Box #9).

Another important training issue is how much training is needed. Training to competence is the key. Competency-based training is learning by doing; it focuses on the specific knowledge, attitudes and skills needed to carry out the procedure.⁷ Emphasis is on the trainee's actual performance with the new procedure or skill. Competence is based on the trainer's objective assessment and evaluation of overall performance according to established national and/or international standards. A clinical skills checklist (also called competency-based qualification checklists), which includes critical steps the trainee must perform satisfactorily, can be prepared based on the standards, and used to evaluate trainees. Such clinical skills checklists have been developed for a variety of FP and other RH services for example, NSV, IUDs and Norplant implants, as well as other health care services.⁸ As with other clinical and surgical procedures, there will not be a 'magic' number of circumcisions a provider must

7 Sullivan R, et al. 1997.

8 See No-Scalpel Vasectomy Curriculum, 1997 (currently being revised), EngenderHealth; IUD Course Notebook for Trainers, 2006, JHPIEGO; Norplant Implants Course For Nurse-Midwives. Trainers' Notebook, 2000, Uganda Ministry of Health.

perform during training in order to be competent – it will depend on various factors including each individual trainee's previous surgical experience, manual dexterity and capacity to learn. Certification is best left in the hands of an authorized entity in the country such as; the Ministry of Health, a professional body such as the medical or nursing council, or an educational institution (e.g. medical or nursing school).

Box 9. Establishing local training capacity

The five year Safe Reproductive Health (SRH) Programme was designed to introduce and expand hospital-based reproductive health services in major public sector health systems in Egypt. One year following the close-out of the project, an evaluation showed that some improvements were sustained, while others had been discontinued. Turnover of trained staff, especially nurses for counseling and infection prevention, had diminished the capacity developed in the early years of the programme. No system had been set in place to train new staff to ensure ongoing capacity in these areas. In the absence of an externally supported training programme, new training needs had not been met.

EngenderHealth had a different experience in Turkey, where one component of increasing access to quality long-term and permanent FP options was to build strong public sector training capacity. The approach to in-service training focused on capacity building and sustainability. Initially a select group of Turkish doctors were sent outside the country to be trained in female and male sterilization by minilaparotomy and NSV, respectively. The doctors eventually became master trainers and their sites became national training centers. Over the years, Turkey's training programme became institutionalized through the development of a training infrastructure that includes both residency and in-service training programmes – 10 teaching hospitals with minilaparotomy training in their ob/gyn programmes; 15 teaching hospitals with NSV training in their urology residency programmes; 4 national training centers for minilaparotomy; and an additional 4 national training centers for NSV.

Sources: EngenderHealth, 2000. & Searing, et al. 2003.

6. Link training to supervision

To make training as effective as possible and to support quality services, it is important to link training to ongoing supervision. In other words, when the training stops, the supervisory system and the supervisor must take over, providing follow-up, a supportive environment for staff to use the new skills they have learned, and additional on-the-job training as needed (or at least the ability to recognize when additional training is needed). Training providers without institutional support does not produce change that is fully incorporated into the actual delivery of services. Inappropriate training, poor follow-up and weak supervisory systems often result in poor quality of care. Box #10 presents a country example of problems that can arise when training is not linked to supervision. Whole-site training, mentioned above, is one approach to linking the supervisory and training systems. It involves both internal and external supervisors in assessing training needs and in planning, developing and conducting training to meet the identified needs. Supervisors then provide follow-up and support trainees, regardless of where they were trained.

Box 10. When training is not linked to supervision

In Uzbekistan, EngenderHealth conducted contraceptive technology updates as part of a postabortion care programme. Supervisors were not included in the training. Some providers were unable to practice what they had learned because of supervisor resistance to new ways of doing things. This experience highlighted the need to garner supervisor support and keep them involved with the activities of the new PAC programme.

Source: Escandon, et al. 1999.

Facilitative supervision is an approach to supervision that emphasizes mentoring, joint problem solving, and two-way communication between the supervisor and those being supervised – traditional "inspection" is not conducive to helping sites achieve continuous quality improvement. Instead of finding fault and leveling blame at individuals, the emphasis is on determining whether or not existing work processes are planned, designed, and implemented in such a way as to achieve high-quality services that meets clients' needs. The key components of facilitative supervision include: supervisors as a catalyst for quality improvement; joint problem solving, with full staff participation and using simple, practical tools; facilitative styles of communication and support; and supervisors with solid technical knowledge of the services provided at the sites they supervise. Box #11 describes the successful use of facilitative supervision in the Tanzanian FP programme.

Box 11. Facilitative supervisors

In Tanzania, the FP programme expanded rapidly in the early-mid 1990s including an expansion in the number of sites that offered all available modern contraceptive methods. Key to the expansion were six zonal doctor-nurse teams whose role was to facilitate the integration of permanent and long-acting methods into existing FP services. They were trained to assist sites in identifying what they needed to provide quality FP services and in meeting those needs internally or with external assistance. Working with the MOH and service sites, the zonal teams ensured that service quality was strengthened. The zonal teams worked with site staff to try to eliminate problems before they occurred. They facilitated communication between the sites and their zonal or central headquarters and between public sector and private sector service providers. They also improved linkages between the various sites in their area as well as between each site and its respective headquarters.

Source: Ben Salem and Beattie. 1996.

7. Increase access through non-physician providers

The reality is, that doctors are simply not accessible to many people around the world, especially in resource poor settings. Physicians are typically clustered in urban areas and are frequently not located in service sites below the district hospital level, although these are the service sites most accessible to many people. Doctors are often overloaded with curative care and preventive procedures end up getting lower priority.

Increasing access to clinical FP/RH services through non-physician providers has been successful in many settings. Over the years, for example, nurses have become one of the major service providers of IUDs throughout the developing world. Clinical officers safely conduct C-sections, minilaparotomy under local anesthesia for female sterilization, NSV, repair of simple obstetric fistula, and a variety of other surgical procedures. In addition, providers such as nurses, midwives, and nurse practitioners – in addition to clinical officers – safely provide clinical services such as IUD and Norplant® insertion and removal, postabortion care including MVA, and cryotherapy for treatment of cervical precancer. Table 2 provides some representative examples of mid-level provision of clinical FP and other RH services.

Table 2. Some published examples of clinical FP/RH services provided by non-physicians

Clinical procedure	Cadre	Country	Reference
C-sections	Assistant medical officers	Mozambique	Pereira et al., 1996
	Clinical officers	Kenya	Dovlo D 2004
Cryotherapy for treatment of cervical precancer	Nurses	Thailand	Royal Thai College of Obstetricians and Gynaecologists/JHPIEGO Cervical Cancer Prevention Group. 2003.
Emergency obstetric surgery	Assistant medical officers	Tanzania	Dovlo D 2004
IUD insertion and removal	Nurses, midwives, physician's assistants & medical students	Many developed and developing countries	For review see Salem, 2006
Minilaparotomy for female sterilization	Clinical officers	Malawi	Solo, et al. 2005a.
	Nurse-midwives	Thailand	Dusitsin et al., 1980
	Paramedics, nurse midwives, midwives, & nurses	various South East Asian countries	Hue, 1980
MVA abortion	Midwives	South Africa	Warriner IK et al. 2006
	Doctor assistant, midwives	Vietnam	Warriner IK et al. 2006
Norplant insertion and removal	Nurses & midwives	Ghana	Solo, et al. 2005b.
		Indonesia	Affandi et al., 1987
		Kenya	Bradley et al., 2001
	Clinical officers	Malawi	Solo, et al. 2005a.
NSV for male sterilization	Medical assistants, nurses, midwives, & paramedicals	China	Xu, et al., 1993
	Clinical officers	Malawi	Solo et al. 2005a
	General and family physicians*	Mexico	Cisek and Juarez; 2003.
	paramedics	Thailand	Ratana-Olarn, 1991
	Paramedics, nurse midwives, midwives, and nurses	various South East Asian countries	Hue, 1980.
Postabortion care including MVA	Nurse & midwives	Ghana, Kenya, Nigeria & Uganda	EngenderHealth and Ipas. 2001
		Zambia	Mtonga & Ndhovlu. 2001
Wide range of surgical procedures	Clinical officers & medical assistants	Malawi	Adeloye, 1993.

*vasectomy historically largely performed by urologists

Increasing access through non-physician providers has often required working at both the policy and programme levels to: a) effect change in policies that restrict provision of specific clinical services to physicians or even to specialist physicians (e.g. ob/gyns or urologists); b) conduct demonstration projects where non-physicians provide the clinical methods; and c) provide TA to incorporate non-physician provision into services and programmes (see Box #12).

Box 12. Increasing Norplant access in Ghana

The training of more than 600 nurses in Ghana to insert and remove Norplant® has had a significant impact on the acceptor rate, quality of services, and number of sites providing such services. Prevalence increased 10-fold from 0.1% in 1998 to 1% in 2003. When Norplant® was introduced in the mid-1990s, training was restricted to physicians, in part because the existing policy was not explicit about whether nurses could perform insertions and removals. When women initially came for Norplant® services, there was often a long line and no doctor available, and as such the method was there but not really accessible. These difficulties were documented and used to help bring about the necessary policy change. As a result, the 1996 *National Reproductive Health Service Policy and Standards* clearly spelled out that nurses were allowed to provide Norplant®.

Source: Solo, et al. 2005.

8. Explore alternative models for service delivery

The goal of service delivery is to give people maximum access to quality services. Limited access – often a major barrier to use of health services in resource poor settings – may be related to living long distances from facilities, transport costs, costs of services themselves, stigma associated with a particular services, inconvenient hours that conflict with family/home/work/school responsibilities, etc. There are many models for delivering health services and there is no one ideal or preferred approach that works in all settings or for all services, although in general it is desirable to provide services at the lowest level of the health system feasible. The choice of which model(s) to use, and thus where and when to deliver services, should be made primarily with the objective of optimizing access to safe services for clients. Another factor that must be kept in mind is the timing of delivery. In the case of MC, that could be infant, pre-adolescent, young adult and/or adult.

Vertical versus integrated services. Services are vertical if they are delivered by dedicated providers or in facilities dedicated to a specific service. For example, HIV testing provided at a stand alone VCT Center would be considered vertical. On the other hand, when services are provided by a range of staff and available at sites providing a wide variety of services, they are considered integrated. HIV counseling and testing provided by a variety of the staff working in a primary health clinic would be an example of integrated services.

Services tend to be more integrated at lower levels of the health system, such as primary care, and less integrated in secondary and higher level facilities. In general, integrated services are more available to larger numbers of people because they do not require visits to specialized facilities – which may be few and long distances from where many people live – and because they are provided by more staff. Integrating new technologies into existing services usually allows for an innovation to be introduced, and eventually scaled up, more rapidly since this approach builds on health infrastructure already in place. Box #13 presents a country example of successful integration of PMTCT services into existing reproductive and child health services.

All services, however, do not lend themselves to being integrated in the truest sense of the word; for example surgical sterilization or C-section, and it may be that MC will fall into this category as well. Services which by their nature are more vertical, can be more integrated if there are good linkages between services sites and effective referral mechanisms in place.

Box 13. Integration of PMTCT into reproductive and child health services in Tanzania

In 2003, EngenderHealth working with the Tanzanian MOH, the Evangelical Lutheran Church, and the Elizabeth Glaser Pediatric AIDS Foundation, established PMTCT services within existing reproductive and child health (RCH) services at hospitals, health centers and dispensaries. Comprehensive PMTCT services are now available in antenatal care clinics, the labor ward and post-delivery at 22 sites in Arusha Region in Northern Tanzania. Introduction activities included: participatory assessments and planning; community sensitization; simple renovations; training on PMTCT, counseling and client provider interaction skills, FP, and stigma reduction; reorganization of client flow as needed; assuring availability of supplies; and supportive supervision. In total, over 6,000 women receive counseling each quarter, with nearly all accepting HIV testing. The percentage of women and their infants receiving Nevirapine has increased over time to approximately 80% and 55%, respectively. In addition, modern contraceptive use following delivery has increased. In 2005, we began introducing VCT into FP and other RCH services (postnatal care and under five clinics), including couples counseling, in 15 of the 22 sites. This has led to increased service quality and client satisfaction, increased numbers of FP clients and use of contraception, strengthened postnatal care, and comprehensive RCH services available under one roof. HIV-negative women receive ongoing counseling to negotiate safer sex. HIV-positive women are referred for care and treatment, and followed up to ensure they are accessing services.

Source: Mphuru, et al. 2006.

Static versus outreach services. Static services are those that are offered regularly at established health facilities. Outreach services – also called mobile services – are provided at a facility that normally does not offer the service, such as a church, school or health clinic (see Box #14). In some cases, mobile services might actually be provided in a vehicle such as a van, camper or bus. With outreach services, the services are taken to where the people are. Strengths and limitations of these two approaches are presented in Table 3 on the next page.

Box 14. Mobile services to increase access

Mobile services, on a seasonal schedule, are used to provide a large percentage of sterilizations services in Nepal. Mobile services are usually offered at rural health clinics. Trained staff visit the clinic for a specified period of time (e.g. 5-10 days) and bring the supplies and equipment they need to provide male and female sterilization services. These mobile services reach a large number of clients, but have the potential to create conditions that can lower quality of care. Historically, poor sanitation, poor infection prevention practices, crowding, lack of privacy, long travel and waiting times, and a stressful working environment were problems encountered at mobile service sites. EngenderHealth and local partners implemented a quality of care programme focusing on mobile services to resolve these issues.

Source: Stanley, et al. 2001.

When outreach service are provided on a regularly scheduled basis (e.g. weekly, monthly), the outreach sites are sometimes referred to as satellite clinics. Outreach services can also be provided through a mass campaign, where services are an occasional event, provided for a designated period of time in a specific location. Campaigns may be designed to systematically cover geographic areas where static services are unavailable/inaccessible, or to reach a specific target group. Campaigns have been used for HIV testing, polio immunization, and cervical cancer screening. Alternatively, campaigns may be organized around visiting surgeons who provide services such as obstetric fistula repair or eye surgery for trachoma complications. A mass campaign-type approach could be appropriate for MC in some circumstances, for example, during school vacations for adolescent boys.

Table 3. Strengths and limitations of static and outreach clinical services

	Static clinical services	Outreach clinical services (mobile)
Strengths	<ul style="list-style-type: none"> • Services are available regularly. • Better availability and storage of equipment and supplies. • Easier continuity of care. 	<ul style="list-style-type: none"> • Greater access to services • More convenient for clients, as less time and money are spent to travel to a distant static site. • Increased community participation.
Limitations	<ul style="list-style-type: none"> • Access to services may be limited if they are not available at widely distributed sites. • On-going efforts required for promotional activities. 	<ul style="list-style-type: none"> • Requires intensive planning, organization, and coordination (supplies, equipment, staff, community linkage for promotion). • Cost and time for “mobile” team, linked with type of transportation, geographic terrain, and quality of roads. • Conditions in the temporary facilities may lead to a lower quality of care. • Limited time for counseling and less privacy may mean client information is compromised. • Follow-up care or treatment of complications may be problematic.

Adapted from Alliance for Cervical Cancer Prevention, 2004.

9. Design holistic programmes that address supply and demand

As noted above, taking a whole-site, whole-system approach results in availability of quality FP/RH services. Clearly, developing capacity to provide quality services is necessary with any innovation, but it is usually not enough. It is also necessary to create demand for new services, although getting men to come to MC services, at least in some settings, may not be a problem given the level of interest and demand for the procedure that has already been seen in some sub-Saharan African countries. Ideally, a coordinated package of integrated interventions creates synergy between supply and demand, ensuring that quality services are in place and that there are people interested in using them. Mutually reinforcing communication strategies that impact on knowledge, attitudes and ultimately behavior yield the best results in terms of stimulating demand. Mass media are effective in creating knowledge, but interpersonal communication has a greater impact on changing attitudes that actually influence behavior. Men have less contact with health workers than do women, and personal contacts – friends, relatives, and co-workers – are key to introducing new ideas and providing support for behavior change. Using satisfied clients to inform other men about vasectomy has been a successful strategy in a variety of settings. Individuals that are exposed to messages from multiple sources are more likely to take action, therefore, multimedia campaigns are most likely to succeed. Box #15 describes the use of a coordinated supply and demand approach to increase men's use of RH services in Guinea.

Box 15. Addressing supply and demand to transform men into clients in Guinea

Guinea's Ministry of Health and EngenderHealth used a "supply-and-demand" framework to increase access to and stimulate public demand for men's RH services. Capacity to deliver men's RH services was built at two public-sector health centers in Conakry. Staff were trained on the introduction of the services; training including dealing with negative attitudes and biases, and understanding the benefits of services for men. Staff consulted with men in the community on how to develop a more supportive environment for men's services. To stimulate demand, local partners engaged in activities such as training of peer educators, developing messages about male involvement, facilitating lectures by imams in mosques, and radio/TV broadcasts. Staff enthusiastically implemented changes to make services more welcoming to men and took part in outreach efforts with men in the community. Men's use of RH services and the local community's approval of and interest in such services rose notably after the intervention. The one-year evaluation found that the number of men visiting a health facility on their own had risen sizably, as had the number who accompanied their wives during FP/RH care visits.

Source: EngenderHealth, 2003d.

10. Capitalize on opportunities to work with men

In many settings, men do not tend to come to formal health services for preventive care. And, although men may be the main decision makers regarding the use of FP in many cultures, they otherwise play a limited role in FP/RH of their partner and usually they themselves take little responsibility for contraception. When men do come to sexual and reproductive health service sites with their partners, service providers – who are used to talking with women – may not feel comfortable working with men. Male-friendly service initiatives have worked to make facilities more welcoming to men and to change staff attitudes and improve their comfort providing services to men. Programmes have used innovative approaches to engage men when they do come to FP and RH service sites with their partners, as well as to draw men in to health services (see Box #16).

Box 16. Involving men in reproductive health decisions

To increase the constructive participation of men in RH decision making, EngenderHealth programmes have taken advantage of occasions when men are already within health facilities to provide targeted information, counseling, and services for men. For example, in Turkey, husbands are often present at the time of their wives' abortion due to a legal spousal consent requirement, thus providing opportunities for educating men about how to more actively support their partner in preventing future unintended pregnancies. Group education sessions for men whose wives were undergoing an abortion proved popular and allowed for discussion of myths and misconceptions about FP methods and on plans for future contraceptive use. "Postabortion vasectomy" services were offered to interested men at some of the health facilities conducting abortions. Another component of the programme targeted men accompanying their wives during prenatal visit and was designed to help couples adopt postpartum practices that promote family health.

A recent study in South Africa on men's low utilization of VCT has led to new strategies to promote this service among men. EngenderHealth's Men as Partners (MAP) programme is using existing community-based educational workshops to promote VCT with men. These interactive educational sessions explore a range of VCT-related issues including men's fears of HIV testing, issues around serodiscordancy, living healthily with HIV, antiretroviral treatment, and PMTCT. The MAP programme is also mobilizing peer educators to play an active role in encouraging men to test for HIV and utilize mobile VCT services offered in their community. Community campaigns have reinforced these efforts with slogans such as "Be courageous, get tested," "My girlfriend's status is not my status, so I get tested," and "Show your strength, know your HIV status."

Sources: Pile, et al. 1999. & Levack, 2004.

MC will provide a platform for more comprehensive male health services. Taking advantage of men's presence at a health facility for MC will allow providers to engage men in discussions about their broader health needs through provision of information and counseling in areas such as HIV risks, safer sex and contraception, including good condom instructions, and to provide other health services (or effective referrals to such services) such as VCT and STI prevention and treatment. Additionally, MC services will provide opportunities to talk with men about playing constructive roles in promoting gender equity, decreasing gender-based violence, and ensuring good health in their families and communities.

11. Going to scale

Going to scale can be defined as making quality services broadly and routinely available in a sustainable manner. Pilot projects in demonstration sites provide insights into how the innovation will work and be accepted, and also provide evidence that the innovation is safe and effective in that country. Pilot projects tend, however, to have a high level of focus on quality and a limited scope. They often take place in sites such as teaching hospitals or model clinics – optimal rather than typical sites. When new services are introduced in more typical sites, challenges not encountered in pilot sites, such as shortages of staff and resources, may arise. Pilot projects also receive funding and resources that simply cannot be replicated in typical service-delivery settings.

Box 17. Registering unique equipment & supplies

NSV requires two specialized instruments – a ringed clamp and dissecting forceps. In Mexico, despite IMSS's well thought-out introduction strategy (see box #3), the process for budgeting and procurement of the surgical instruments was overlooked. They were not registered to be included on the basic medical equipment list, they were not included in the budget, and no local or regional sources of the instruments was identified. For years, most service sites continued to use the original instruments that had been donated as part of EngenderHealth's USAID-supported project. Since the instruments were not included in the normal IMSS supply chain, it became difficult to replace the instruments or purchase them for newly trained sites once USAID support was phased out.

Source: Cisek and Juarez, 2003.

If new practices are to be sustainable, the commodities necessary for expanded services will eventually need to be available easily, locally and through standard channels. Box #17 describes a country example where adequate attention was not paid to this issue. For services to go to scale, training must not rely only on special courses, which can be expensive and hard to maintain. Successfully taking an innovation to scale means that ongoing mechanisms remain in place for improving staff performance, such as preservice training, on-the-job training, and supportive supervision. Staff taking on a new area of work need institutional support. Political support is key, as policies often need to be changed in order for a new service to go to scale. Public awareness is a final challenge in taking pilot projects to scale. Even when a needed service is introduced, people may not use it because, for example, they are unaware that the service is available, they are uninterested because of myth and misconceptions or lack of perceived benefit, they fear they will be treated poorly, or they believe that services are low quality.

Box number 18 below presents an example of successful scale-up of PAC services in Ghana.

Box 18. Expanding PAC nationally through the reproductive health programme in Ghana

Postabortion care (PAC) services were successfully scaled up in Ghana by integrating PAC into the national RH programme. In 1992, PAC was included in preservice training for physicians and was subsequently incorporated into the national RH standards. Then, in 1998, as part of the national safe motherhood and RH programme, PAC was added to training in lifesaving skills, FP, and other RH. National PAC guidelines were developed that included several important strategies: using existing regional teams to provide supportive supervision and monitoring; increasing access through both the public and private sectors; and planning for sustainability of services. In addition, midwives were approved to provide PAC services, greatly expanding access for women in rural areas. Factors contributing to the success of scale up included providing systematic training with good follow-up and supervision, training a wide range of providers, incorporating PAC in RH guidelines and standards, ensuring ongoing and sustainable supplies of MVA equipment, and getting buy-in and participation from important stakeholders, ranging from the MOH to NGOs to grassroots and community groups.

EngenderHealth and Ipas, 2001.

Conclusion

Careful introduction of MC for HIV prevention will avoid many of the pitfalls experienced over the past several decades by FP and other RH service programmes as they have introduced new technologies. Many mistakes were made and likewise many lessons have been learned about how to effectively introduce new technologies in settings with limited resources. There is no need to repeat the mistakes nor to relearn the lessons as MC is introduced.

It will be critical as MC introduction efforts get under way to keep in mind that it is more than just the innovation. Successful introduction will require a systems approach that takes into consideration not only MC itself, but issues related to the potential users, the capacities of the service delivery system, and the other prevention approaches and technologies currently available, all within the context of the broader sociocultural, economic and political context in the setting into which MC is being introduced. One off activities, such as clinical skills training or developing educational materials, will not be enough; such focused approaches have not led to successful introduction of FP/RH technologies, and are not likely to be successful for introduction of MC either. Programmes will need to be designed to introduce MC in a broader prevention context, without losing sight of the importance of other risk reduction options, especially condom promotion and provision. Counseling, for example, will not only need to ensure that decisions are well informed, but will also need to ensure that men understand that MC does not provide complete protection and that other risk reduction approaches continue to be necessary.

The public sector provides most clinic-based services in resource poor settings; in general, this sector is most accessible to the largest number of people. Unfortunately, the public sector is often the hardest to work with (relative to the private and not-for-profit sectors) and the most difficult in which to effect change. Nevertheless, given the important role that the public sector plays in provision of health services in general, and most likely will play in MC services, it is critical that to invest in public sector programmes and find effective ways to work with – and not around – the public sector.

Sustained, long-term efforts will be critical to successful introduction of MC. Clinic-based services such as MC require ongoing resources and long-term efforts. There is a need for real continuity in terms of funding and in terms of approach if significant impact is to be made. It is critical to look beyond a short-term focus and to come to grips with the need for a more long-term commitment if MC is to be provided safely and effectively, if MC services are to be accessible to the greatest number of people, if MC is to be sustainable in the long run and if, in the end, MC is to be an effective HIV prevention approach that contributes on a large scale to stemming the HIV pandemic.

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