

31 August 2005

## United Nations Work Plan on Male Circumcision and HIV

### Background

The association between male circumcision and HIV risk has been noted for nearly 20 years. There is a strong geographical correlation between male circumcision practices and lower HIV prevalence, and numerous observational studies have 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, 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. Follow-up in the Orange Farm Study in South Africa, which was 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 male circumcision intervention offered to the control group. Trial data were analysed and results demonstrating a 65 % protective effect (95% CI 40-80%) for adult male circumcision were presented at the International AIDS Society conference in Rio de Janeiro, Brazil July 26; 2005. The DSMB for the other two trials, which are funded by the National Institutes of Health of the United States, met June 29, 2005 and recommended that the studies continue as planned.

If male circumcision is confirmed in the remaining trials to provide significant protection against the acquisition of HIV, as suggested in the observational studies conducted to date, opportunities will arise to strengthen male sexual and reproductive health services for improved prevention of HIV and other sexually transmitted infections (STI), particularly in high prevalence countries where the demand for male circumcision may increase. Many questions are likely to be raised, however, about strategic approaches to service delivery (e.g., timing of circumcision, prioritization and quality of services, partnerships between the public sector and private and traditional sectors). Safety remains a concern, with particular attention needed to the prevention and management of clinical complications as well as to the supervision and monitoring of safety standards for male circumcision performed by health workers, lay, religious and traditional circumcisers. Effective ways to promote safer sex and guard against behavioural disinhibition post male circumcision remain to be determined and evaluated. This issue is particularly important for young women who would potentially be at increased risk of HIV acquisition if circumcised men were less likely to use condoms.

There is now some urgency to plan for increased support to countries wishing to consider the implications of the Orange Farm Study results for their national HIV policies and programmes. The two other randomized controlled trials currently recruiting and following

men in Kenya and Uganda will likely not present interim analyses until June 2006; however, both trials are conducting sensitivity analyses to determine when they will have power to report results.

Regardless of the trial results, it is recognized that action is required now in many areas to improve current circumcision practices and to provide up-to-date information on male circumcision and HIV acquisition risk to health providers and the public. Even in the absence of confirmatory evidence from randomized controlled trials, the Orange Farm results may lead to increased demand for circumcision services, heightening the importance of urgently addressing safety issues. Policy discussion in high HIV incidence countries on the role of male circumcision within the context of HIV risk reduction strategies is likely to follow over the coming year.

The proposed activities focus on improving the safety of current practices while laying the scientific, technical and ethical framework for policy discussions that will become more intense in 2006, if and when scientific corroboration is forthcoming. The activities do not focus on policy development at global or regional level as this is considered premature given available knowledge and likely future developments. However, the products of this work undertaken by UNAIDS, WHO, UNICEF, UNFPA and their partners will support in-country discussions and on the ground action to improve the safety of male circumcision in places where it is currently being practised.

This work plan was developed collaboratively by the UN partners involved. The time frame for the activities detailed in the plan is from September 2005 to July 2006. Each concept note is free standing; however, each is critical to accomplishing the overall goals of enhancing safety and laying the policy and programming framework for the provision of guidance and operational tools in the event that scientific findings set the stage for the promotion of male circumcision within HIV prevention strategies, particularly in high HIV incidence countries.

This work plan and resource needs proposal does not contain proprietary or confidential information. The proposed projects will involve the creation of intellectual property but will not involve collaboration with for-profit companies. The proposed project involves research using human subjects but does not involve clinical trials. The projects do not involve research using vertebrate animals, recombinant DNA, pathogens or toxins identified as "select agents" by U.S. law, or biohazards or genetically modified organisms or plants.

**Summary of proposed activities September 2005 to July 2006**

	<b>Item</b>	<b>Time frame</b>	<b>Responsible [supported by]</b>	<b>Resources (US\$)</b>
1	Assemble briefing packs for use with policy-makers, programme managers and partners, including key publications, fact sheets, maps, Q&A, reference lists and slides	Sept 05 to Dec 05	WHO [UNAIDS]	75,000
2	Develop technical guidance on clinical and programmatic approaches to male circumcision, in an appropriate human rights framework. Pending the results of the ongoing trials, priority will be placed on preparation of guidelines on pre-circumcision assessment, including the role of HIV testing and counselling, and on clinical procedures to ensure safety and minimize and manage complications.	Sep 05 to Aug 06	WHO [other technical partners]	260,000
3	Bring together key regional partners and stakeholders on male circumcision and HIV to review emerging information, document experiences, and provide programming and technical support to countries in South and East Africa wanting to increase the supervision and safety of current circumcision practices through training, regulatory and licensing improvements.	Sep 05 to Jun 06	UNAIDS [UNAIDS RST, WHO/AFRO, UNFPA, UNICEF and other partners]	205,000 plus UNAIDS and WHO internal funds
4	Develop an operations research plan, research agenda and tools. Pilot in two settings and revise before promoting their use in current programming.	Sep 05 to Jun 06	WHO, (UNAIDS, UNICEF, UNFPA and technical partners)	180,000

5	A. Model impact of male circumcision at population level under different post-circumcision sexual risk and behavioural scenarios. B. Estimate the resources needed for male circumcision services in various scenarios	Sep 05 to Nov 05	UNAIDS	25,000 35,000 plus UNAIDS internal
6	Convene a scientific meeting in Africa to examine available data from studies and the results of impact modelling (cf. item 5A), and implications for policy and programming.	July 06	UNAIDS [WHO]	120,000
7	Develop and field test a rapid assessment tool for use at country level to document male circumcision practices, identify key providers, and assess social-cultural determinants of circumcision	Sep 05 to Mar 06	WHO [UNAIDS]	50,000
8	Develop simple programmatic tools for circumcision interventions in countries where uptake of services is increasing – to include supervision, standard setting, certification, accreditation, and monitoring and evaluation	Jan 06 to Mar 06	WHO [UNAIDS, technical partners]	90,000
	TOTAL EXTERNAL REQUEST			1,040,000

## **Major Activity 1: preparing briefing packs for policy makers, programme managers, etc.**

### **Background and Rationale**

Male circumcision is a seemingly simple surgical procedure practiced in many areas of the world. In some areas, it is practiced in infancy, primarily either for health reasons (it is generally thought to improve hygiene and reduce infections) or for traditional reasons of group membership and identity. In other areas, it is performed later, as one of the rites of passage for young boys when they approach or reach puberty. In many other areas of the world, it is not practiced at all and this avoidance is often linked to group identity as well. When performed primarily for health reasons, male circumcision is more often performed by health professionals; when performed for issues of group identity, it is more often performed by persons with specific traditional roles but no medical or health training.

This variety of ways in which male circumcision is used, how it is performed and how it or its avoidance is linked to group identity forms the context against which results from a recent trial of male circumcision for HIV prevention must be seen. For years, observational studies have found an association between male circumcision and reduced HIV prevalence. The role of culture and differences in sexual behaviour between groups that have circumcised and those that have not has made the interpretation of these observational studies difficult. Now a randomized controlled trial in South Africa has demonstrated a strong reduction in HIV incidence among adult males seeking male circumcision. In parts of the world where HIV continues to spread rapidly, this will likely be greeted as unequivocally good news. Strong feelings about male circumcision, both for and against, and the difficulty in moving from this one trial to an actual intervention to promote the practice make the response more complicated. Policy makers, programme planners, and implementers need background information and materials to help them decide whether and how to act on this recent information.

### **Goal and objective**

The goal of this element of work is to provide policy makers and programme planners and implementers with the most up-to-date and objective information on male circumcision and HIV to enable them to decide if and how they should respond to the developing science on the topic.

### **Project design and implementation plan**

Briefing packs on male circumcision and HIV will be assembled. Although new materials may be developed, no new research will be conducted.. Rather, existing information which has long been discussed and debated in research circles will be compiled. These materials include:

- general background information on male circumcision: where it is traditionally practiced, where it is promoted for health reasons, at what age it is conducted, where it is avoided;

- maps showing where male circumcision is practiced;
- description of various ways in which male circumcision is practiced, with observed complication rates in various settings;
- a summary of the research on the acceptability of male circumcision in various settings;
- a summary of the observational studies which have shown a correlation between male circumcision and HIV prevalence, including a Cochrane review of the topic;
- the presentation of the results of the recent South African study (and the paper being published on the study when available);
- description of two additional studies being conducted now in Kenya and Uganda;
- the press statement issued by UNAIDS, WHO, UNFPA and UNICEF following the release of the South African study results; and
- an objective presentation of the benefits and the risks of taking action now on the basis of the South African research results;
- selected background papers from the scientific literature and existing policy briefs.

These materials will be packaged in folders for easy distribution and will be widely distributed through the usual channels used by WHO and UNAIDS. Translation into languages other than English is not planned at this time. The composition of each folder will be tailored to the audience in question.

### **Monitoring and evaluation**

Outcomes and indicators: distribution of UN briefing packs by audience, number of countries using them to inform their course of action on male circumcision.

### **Organizational capacity**

This element is primarily the responsibility of WHO (both HQ and the Regional Office in Africa), with input from UNAIDS, UNICEF and UNFPA. Both WHO and UNAIDS have established networks for the dissemination of materials such as these. Other partners will also use similar mechanisms for dissemination of these materials. For the immediate needs of the August 2005 Ministerial Meeting in Maputo, Mozambique the UNAIDS Regional Support Team will assemble the briefing packs in consultation with WHO-AFRO and UNAIDS Geneva.

### **Major budget lines:**

Staff time 100% FTE for 4 months: US\$ 40,000

Printing of folders and other materials: US\$ 35,000

**Total component:** US\$ 75,000

## **Major Activity 2: Development and dissemination of technical guidance on clinical and programmatic approaches to male circumcision:**

### **Background and Rationale**

Male circumcision is one of the most widely practiced minor surgical procedures in the world with almost 100% coverage in some ethnic and religious groups and none in others. There are many different approaches to the procedure and complications from the surgical procedure do occur. Safety is a paramount concern if countries are to anticipate and prepare for potential increased demand for services in settings where male circumcision is not universally practiced. In addition to the clinical aspects of the procedure, complex social and cultural issues reflecting attitudes to circumcision need to be mapped and understood if circumcision is to be offered with the primary aim of reducing men's risk of acquiring HIV infection. These issues include cultural attitudes to circumcised and uncircumcised men, the impact and acceptability of circumcision at different ages (paediatric, pre-adolescent, adolescent or adult), ensuring protection of and respect for individual human rights, the importance of considering male circumcision within the context of other HIV prevention strategies, the importance of avoiding encouraging higher HIV risk taking by circumcised men in the belief that they are fully protected by the procedure, and the role of pre-circumcision HIV testing and counselling.

While several technical resources on male circumcision are available, particularly from the research into the protective efficacy of the procedure, there is no consolidated guidance for countries on how to respond to an increased demand for services, how to promote safe clinical procedures and minimize the risk of complications, and how to ensure that circumcision is considered within the context of the country's overall HIV prevention strategy.

### **Goal and Objectives**

The goal of this element of the work plan is to develop and disseminate technical guidance on programmatic, social and clinical issues concerning expansion of male circumcision services. These guidelines will assist country programme managers to ensure that male circumcisions are being performed appropriately while minimizing the risk of clinical complications, stigma and discrimination against circumcised and uncircumcised men, and to prevent the undermining of other HIV prevention strategies. The guidelines will be disseminated directly to countries and through multilateral and bilateral technical support mechanisms, and will provide the context for technical support to country programme managers.

### **Project Design and Implementation Plan**

Technical guidance will be developed either as three separate guidance documents or as a single consolidated guideline that covers the following key issues:

- Guidelines on promotion of male circumcision within the community, and traditional and clinical service settings, in the context of local attitudes and circumcision practices and an appropriate human rights framework;
- Guidelines on pre-circumcision assessment (clinical assessment, promotion of condom use and other lower risk sexual behaviours, role of HIV testing and counselling); and
- Guidelines on safe clinical procedures (techniques for paediatric, pre-adolescent, adolescent and young adult circumcision practiced in traditional and clinical settings with strategies to ensure safety and minimize risk of complications) and management of potential complications from the procedure.

The guidelines will be developed by experts from different cultural and clinical backgrounds who have service provision experience in resource limited settings. They will be reviewed through a technical consultation of service providers and policy makers from countries with the greatest interest in expanding and improving male circumcision services. Following a brief field test to ensure acceptability and contextual appropriateness, the guidelines will be disseminated through United Nations agencies and bilateral country technical support to country mechanisms. While the guidelines will be developed and reviewed in English, inputs from experts and programme managers from non-English speaking countries will be actively solicited to ensure wide cultural appropriateness. Once developed, the guidelines will be translated into the major UN languages. Translation into other languages will be the responsibility of individual countries.

### **Monitoring and Evaluation**

Outcomes and indicators: number of countries using guidance documents to design and implement, monitor, improve and sustain the quality of male circumcision services.

### **Organizational Capacity**

WHO has long experience in convening technical advisors to prepare guidance on complex health issues and has established mechanisms for wide consultation, field testing and dissemination of such guidance to developing country governments and programmes. WHO will work with other UN partners, bilateral technical assistance partners, and countries to consult widely in the development of the guidelines.

### **Major budget lines:**

- Staff time 50% FTE for 11 months (US\$ 55,000),
- Compilation and review of clinical procedures and development of draft technical guidance [contract] (US\$ 20,000)

- Compilation and review of programmatic approaches and male circumcision situation assessment and development of draft programmatic guidance [contract] (US\$ 20,000)
- International consultation to review draft guidance documents (\$100,000)
- Finalization of guidelines (final technical editing, layout, printing, translation and dissemination (US\$ 65,000)

**Total component: US\$ 260,000**

**Major activity 3: Bring together key regional partners and stakeholders on male circumcision and HIV to review emerging information, document experiences, and provide programming and technical support to countries in Southern and Eastern Africa wanting to increase the supervision and safety of current circumcision practices through training, regulatory and licensing improvements.**

### **Background and rationale**

The association between male circumcision and HIV risk has been noted by many researchers for nearly 20 years. Full results from ongoing trials have not yet been published nor made publicly available, but results from the first randomised controlled trial indicate a strong correlation between male circumcision and a protective effect of risk of HIV acquisition by men. They must be carefully assessed and considered in the context of the cultural acceptability of promoting male circumcision, the risk of complications from the procedure, the additional risk associated with male circumcision performed under unhygienic conditions, and the potential to undermine existing protective behaviours and prevention strategies that reduce the risk of HIV infection. If male circumcision is found to have a protective effect against HIV transmission in the three trials, it will join proven preventive tools such as male and female condoms. The potential for negative or uncertain results in the other two trials cannot be ruled out at this stage. However, as with vaccine and microbicide research, preparation for possible positive findings, even though these may be some years away, can help ensure that a new preventive modality increases the options available for people to choose from, without leading to abandonment of existing effective strategies such as correct and consistent condom use. In anticipation of this potential key milestone in HIV prevention, there is a clear need to adequately prepare policymakers, service providers and others.

### **Goal and objectives:**

To best prepare and equip a country response to male circumcision this proposal outlines an approach in two stages:

The first step is to hold two regional consultative meetings with key regional partners and stakeholders on male circumcision, such as governments, civil society groups, the multilateral and bilateral donor community, etc. Many questions are likely to be raised and need to be addressed at the regional meetings about strategic approaches to service delivery (e.g., timing of

circumcision, prioritization and quality of services, partnerships between the public sector and private and traditional sectors). Safety remains a concern, with particular attention needed to the prevention and management of clinical complications as well as to the supervision and monitoring of safety standards of male circumcision performed by health workers, lay, religious and traditional circumcisers. Effective ways to promote safer sex and guard against behavioural disinhibition post male circumcision remain to be determined and evaluated. This issue is particularly important for young women who would potentially be at increased risk of HIV acquisition if circumcised men were to be less likely to use condoms.

As a second step, the findings from the regional meetings will be used and transformed into a technical framework for policy discussions and serve as a basis for provision of technical and programming support in the country context in 5 selected countries in Eastern and Southern Africa.

The overall goal of the country workshops is to equip policymakers and service delivery functions in the selected 5 countries in Southern and Eastern Africa to be able to respond to the anticipated increased demand for male circumcision services.

Two working group meetings and 5 country workshops shall have been held before June 2006. The workshops will contribute to a higher degree of knowledge on male circumcision which, if the results of the first trial are confirmed by the two other trials, is expected to lower the incidence of HIV.

### **Project design and implementation plan:**

The project is part of a bigger framework that is worked out jointly by UNAIDS, WHO, UNICEF, and UNFPA.

The regional stakeholder meetings will review emerging information, document experiences, and provide programming and technical support to countries in Southern and Eastern Africa. In this way the regional level will collect best practices and evidence from the work on male circumcision and then, as a next phase, use the findings in a country context.

The country workshops will be conducted in 5 selected countries in Southern and Eastern Africa and the countries will be selected after careful review in the two working meetings with expert groups.

Invited participants to the country workshops are key regional partners and stakeholders on male circumcision and HIV interested in increasing the supervision and safety of current circumcision practices through training, regulatory and licensing improvements.

### **Monitoring and Evaluation**

This part of the total project will be evaluated at the end of each meeting and workshop. There will be a follow up on how the findings are used in each country.

### **Organizational capacity**

UNAIDS, WHO, UNICEF, UNFPA and others have strong representation and networks in all countries in Southern and Eastern Africa and are able to gather the key stakeholders and are also well equipped to conduct the workshops and meetings as proposed.

The strong links between Governments, civil society and the multilateral system in the countries will be used and further developed through the project.

### **Major budget lines**

Staff time 65% FTE	US\$ 70,000
Two workshops	US\$ 60,000 (30,000 each)
Technical support to countries	<u>US\$ 75,000 (5x15,000)</u>
<b>Total component</b>	<b>US\$ 205,000</b> (additional to UNAIDS and WHO regional administrative and technical support)

### **Major Activity 4: Develop an operational research plan, research agenda and tools. Pilot in two settings and revise tools before promoting their use in the scale-up of male circumcision.**

### **Background and Rationale**

The association of lowered risk of HIV infection and male circumcision has been noted in many observational studies; systematic reviews of these data have supported this conclusion, as has one randomized controlled trial (RCT). Two additional RCTs are in progress and will have interim analyses, likely in June 2006. There is urgency to acquire by that date information sufficient to provide direction on operational aspects that programme managers and other decision makers will need to monitor at country or district programme level if they wish to implement and continuously improve male circumcision programmes.

Positive results of one or both of the on-going studies would likely lead to international consensus that male circumcision is an important HIV prevention tool. Of importance will be not only the technical aspects of the trials, but also the broader public health and cultural issues they raise. These include effects on sexual behaviour, community impact on HIV incidence, male circumcision uptake within the community following the trials, cultural impact of enhanced circumcision rates and others. Two existing large scale male circumcision programmes offered by nongovernmental organisations will provide the

testing ground for the refinement of operational tools which could be used in scaled up male circumcision programmes to enhance quality and safety.

## Goal and Objectives

Goal: To understand the effectiveness of male circumcision as an HIV prevention tool and how to implement it; to pilot operational research tools to monitor programmes and improve their quality and safety.

Objectives:

1. To acquire the information needed to implement male circumcision as an effective HIV prevention tool;
2. Develop, pilot test and refine practical operational research tools.

## Project Design and Implementation Plan

Objective one.

There are undoubtedly differences among the three study designs and in the breadth of information that they collect(ed). To be ready with the information required for programme decisions in one year, and for efficiency, as much information as possible must be acquired from the current studies. It is possible that design issues may make comparison across studies more difficult than desired and that issues of importance to scale-up of male circumcision will not be acquired by the studies or acquired differentially. For example, is there long-term follow-up of the Orange Farm cohort after the study was stopped to observe changes in sexual practice or HIV acquisition in the control group (some of whom will now be circumcised)? What was the community impact of Orange Farm study, i.e., what is happening in the Orange Farm community given the study results? How are changes in sexual practices being measured across studies? What are the dynamics of HIV transmission in each intervention community and how is this being measured? What is the acceptability of male circumcision in each community, and by males and females?

Suggested approach:

A. Convene a meeting of each study team, and expert consultants, to review the study designs, locations, and instruments of each study.

- **Ensure there is as much quality and harmony as possible among the studies and, where possible, implement changes or institute supplemental data collection** (funding may be required);
- **Determine supplemental studies which may be needed to determine the full impact of each of the three studies.** Such studies might include long-term follow-up of study participants for HIV acquisition or sexual behaviour changes, community surveys of attitudes toward male circumcision and reasons for uptake/nonuptake, community impact of HIV or STI incidence.

While funding for such studies is not sought at this time, it is hoped that funding would be readily forthcoming to capture the information, as the window of opportunity is or will be closing;

#### Objective two

The UN family will need to know where and how to place its resources. Certainly, the three studies emphasize Africa where the greatest need or impact of enhanced male circumcision might well occur, but the implications for countries outside of Africa should also be considered. Countries seeking to investigate the role of enhanced male circumcision and ways to implement and assess the need for enhanced male circumcision will value UN guidance.

Suggested approach:

**B. Review rates of male circumcision, by country (and subunit, if possible), with age of circumcision and cultural reasons, in middle- and low-income countries** to assist in prioritizing countries and areas for implementation (commissioned paper, if this is not already being done or in existence);

**C. Determine the best approaches to "rapid, large-scale circumcision."**

Among the questions to be answered are: what is the best health care approach to conduct male circumcision on a large scale, what is the needed training of health care providers, the satisfaction level of patients, what are costs, etc. This activity is probably not reasonable nor ethical by June 2006, due to a lack of evidence to institute a policy to implement male circumcision broadly. It is possible that such a comparison may be possible in South Africa, if male circumcision is advocated for there. In the interim, in partnership with existing male circumcision programmes carried out by nongovernmental organisations, operational research tools to monitor programmes and improve their quality and safety will be piloted and refined.

**D A toolkit to determine individual and community impact of circumcision when carried out on a community level.** What will happen to, and how to measure, HIV rates or STI rates (e.g. reduced cervical dysplasia/cancer due to lessened HPV transmission), in individual males, in couples, in women, at community level, on the long term? How do behaviours, condom use, etc, change?

- A meeting of experts, both content and geographically representative, would be held to determine needed information and to survey available instruments. Where needed, survey instruments would be devised. A field testing of individual elements and, finally, the entire toolkit would be held;

**E. Development of an operational research agenda.** This agenda will outline the current and long term information needs, and means of addressing those needs, if enhanced male circumcision is implemented on a broad scale.

- A meeting of content experts and geographical consultants would be convened to identify research needs and means of addressing those needs. Suggested studies and study designs

with temporal consideration of when studies are needed would be included.

### **Monitoring and Evaluation**

Very simply, the projects proposed will be conducted. If there are projects that collect data, e.g., addenda to the ongoing two circumcision studies, suitable monitoring and evaluation plans will be developed.

### **Organizational Capacity**

WHO will take the lead, supported by UNAIDS, UNICEF, UNFOA and technical partners to develop the operational research plan. WHO has established mechanisms for field testing and dissemination of guidance on operational research to developing country governments, bilateral technical assistance development and research partners.

### **Major budget lines:**

- Staff time 50% FTE for 11 months (US\$ 50,000)
- Individual projects
  - o Meeting of study teams and international consultants (A) \$25,000--but possible projects not costed
  - o Review of male circumcision patterns (commissioned paper) (B) \$5,000
  - o Development, pilot and field testing of operational research tools in two existing NGO programmes (C) US\$ 50,000
  - o Toolkit to measure impact of community circumcision (D) \$40,000
  - o Development of operational research agenda (\$10,000)

**Total component:** US\$ 180,000

## **Major Activity 5A: Modelling the potential impact of male circumcision on HIV incidence and prevalence**

### **Goal and objectives**

Several observational studies have shown that male circumcision is associated with a significantly reduced risk of HIV infection among men in sub-Saharan Africa.<sup>i</sup> In a meta-analysis of 21 studies, Weiss et al.<sup>ii</sup> found a 50% reduction in risk among circumcised men compared to uncircumcised men (RR 0.52, 95% CI: 0.4-0.68). Results of the first randomised controlled trial conducted in Orange Farm, South Africa, have recently been released and show that male circumcision reduced the transmission of HIV from women to men in this setting by 60-70%.<sup>iii</sup> If these results are confirmed by ongoing randomised controlled trials in Kenya and Uganda, they will have profound implications for the prevention of sexually transmitted HIV. The objectives of the initial modelling exercise will be:

1. To investigate the immediate impact of a reduction in sexual transmission of HIV in sub-Saharan Africa and consider where it might have the greatest impact;
2. To consider the relative effect of male circumcision on men and women (considering that male circumcision reduces transmission from women to men but has not to date been shown to do so from men to women);
3. To investigate the potential impact that male circumcision will have on population level incidence, prevalence and deaths over the next ten to twenty years in sub-Saharan Africa (under different post-circumcision sexual risk and behavioural scenarios).

### **Project design and implementation plan**

A first attempt at modelling the impact of male circumcision at population level in sub-Saharan Africa will be conducted by a small group of scientists based at WHO and UNAIDS (Geneva), University of California at Berkeley, and INSERM (Paris). A simple transmission model, assuming a Weibull survival distribution and allowing the contact rate to decline exponentially with prevalence at a rate determined by the steady state prevalence of infection, will be used to explore the long term impact of male circumcision on incidence, prevalence and deaths. The model will firstly be applied to the South African data assuming varying levels of reduction in transmission (25%, 50% and 75%). Finally, the transmission model will be applied to all countries in sub-Saharan Africa, using the best existing estimates of male circumcision rates, to estimate the reduction in prevalence, the number of cases averted and deaths prevented in the next two decades following 2005. Results will be written up for scientific publication and presented at a larger scientific meeting to be convened by UNAIDS in Africa (possibly at the South African Centre for Epidemiological Modelling and Analysis) to examine all available data from studies and the results of impact modelling, with implications for policy and programming (see Major Activity 6). Further modelling initiatives will be discussed at this meeting. Finally, the methodology and results will be

presented at the annual meeting of the UNAIDS Reference Group on Estimates, Modelling and Projections<sup>iv</sup> for comments and recommendations.

### **Monitoring and Evaluation**

If male circumcision is confirmed to provide significant protection against transmission of HIV, action will be required in many areas to improve current circumcision practices. An increased demand for circumcision services is expected and systems should be put in place to monitor and evaluate levels of male circumcision and the impact on various measures of the HIV epidemic. Better data on male circumcision rates, by ethnic group and age, are required and these can be collected either through dedicated surveys or national population based surveys such as Demographic and Health Surveys. Further studies are also needed to assess change in sexual behaviour as a result of male circumcision, to assess acceptability and safety of male circumcision, and to investigate links with traditional practices.

### **Organizational capacity**

In-house capacity at UNAIDS and WHO exists (through trained epidemiologists, statisticians and mathematical modellers) to analyse the impact of male circumcision on the HIV epidemic. In addition, work by individuals or small groups are vetted and endorsed through the UNAIDS Reference Group on Estimates, Modelling and Projections that was established in 1999 to advise UNAIDS, WHO and other international organizations on HIV epidemiology and methods relevant to understanding the dynamics of the epidemic.

### **Major budget lines**

Activity	Resources (US\$)
External support including travel	25,000

<sup>1</sup> Siegfried N, Muller M, Volmink J, et al. Male circumcision for prevention of heterosexual acquisition of HIV in men. The Cochrane Database of Systematic Reviews. Issue 3. Art. No.: CD003362. DOI: 10.1002/14651858.CD003362., 2003.

<sup>1</sup> Weiss HA, Quigley MA, Hayes RJ. Male circumcision and risk of HIV infection in sub-Saharan Africa: a systematic review and meta-analysis. *Aids* 2000;14(15):2361-70.

<sup>1</sup> Auvert B, Puren A, Talaard D, Lagarde E, Sitta R, Tambekou J. Impact of male circumcision on female-to-male transmission of HIV. 3<sup>rd</sup> IAS conference on HIV Pathogenesis and Treatment. Rio de Janeiro, July 2005. (TuOa0402)

<sup>1</sup> The UNAIDS Reference group on Estimates, Modelling and Projections is based on collaboration between individuals from national HIV programmes, academia, the UN system and NGOs, coordinated by a secretariat based at Imperial College, London. The group advises UNAIDS and WHO on HIV epidemiology and demography to ensure that global estimates and projections of HIV prevalence and its impact are based on the best current understanding of the dynamics of HIV transmission.

## **Major Activity 5B: Estimate resources needed for male circumcision services in various scenarios and conduct a comparative economic evaluation**

### **Goal and objectives**

The overall goal is to design and implement effective and feasible programme activities to reduce the worldwide incidence of HIV infection. The primary objective of the proposed work is to estimate the resource needs to implement a programme of male circumcision in countries with high or potentially high incidence of HIV infection and to conduct an economic evaluation comparing the effectiveness of male circumcision and other HIV prevention interventions.

### **Project design and implementation plan**

Cases averted by male circumcision would be expected to be proportional to HIV incidence and to the number of additional males circumcised through the programme. It follows that programmes would focus initially on groups with high incidence or with high risk behaviours. The initial target population might be seen as all uncircumcised males aged 15-24 in high incidence countries (Sub-Saharan Africa, Haiti and Guyana).

Establishing a cost estimate for scaling up of male circumcision services would require the following steps:

Step 1: Determine baseline estimates in the target countries of the proportion of males aged 15-24 who are circumcised.

- Where current data do not exist, this will require surveys in high incidence countries.

Step 2: Estimate the current costs of providing circumcision in the target countries.

- Where current data do not exist, this will require surveys of health facilities and traditional practices in the target countries

Step 3: Estimate the complication rates both inside and outside the formal health system.

- This information should be available from national level health records or other sources

Step 4: Establish a target coverage rate for the percentage of circumcised males.

- The target rate needs to be based upon a scientific assessment of the level of coverage that will be required in order to ensure a significant impact on HIV incidence.

Step 5: Estimate feasible rates at which circumcision services could be scaled up, and the capacity requirements for doing so.

- This will require agreement between stakeholders about the most appropriate delivery models for circumcision services, and the rates at which they could be scaled up from current levels.
- The capacity requirements will include any possible need for additional staff time, for improvements to existing facilities or sanitary conditions in traditional settings, and for additional training.

**Step 6:** Estimate the unit cost of implementation for each delivery model, including the cost of treating possible complications.

- Unit costs for scaling up may differ from the unit costs of the current facilities and practices if there is a significant change in the method of delivery

The estimation of total resource need is then a simple process of multiplying the target population by the estimated coverage rates and the estimated unit costs.

A comparative economic evaluation of male circumcision for HIV prevention will be conducted, based on a review currently underway by S. Forsythe under the direction of the Economic Advisor at UNAIDS and the Secretariat of the UNAIDS Reference Group on Economics. This evaluation will determine the costs of potential programmes for male circumcision and how effectiveness will compare with those of other HIV prevention interventions.

### **Monitoring and evaluation**

The monitoring and evaluation of any planned scale up of male circumcision services will require additional components to current resource tracking and AIDS accounts. These will need to track the costs of provision of circumcision services both inside and outside the formal health system.

### **Major budget lines:**

- Compilation of information from literature surveys and country surveys to determine circumcision rates, unit costs, capacity requirements and delivery models. US\$ 5000
- Comparative cost study: external consultant US\$ 10,000
- Meeting to validate findings US\$ 20,000

**Total component:** US\$ 35,000

**Major Activity 6: Convene a scientific meeting in Africa to examine available data from studies and the results of impact modelling and implications for policy and programming.**

**Background and rationale:**

Preliminary meetings have already been held to discuss the possibility of an update of the Cochrane Review published in March 2005. For this purpose, the ANRS has agreed to the sharing of the research data from the Orange Farm trial with the Cochrane Review Team. To discuss the findings, their interpretation, and to study available data from the two ongoing trials and the results of the modelling (Activity 5A) and their implications for programming and policy recommendations, a scientific meeting of key partners will be convened in Africa, possibly in collaboration with the South African Centre for Epidemiological Modelling and Analysis. It will consider differing conclusions and varying magnitudes of effect. Understanding differences among the trials and acquiring as much information as possible from the on-going trials will be important to understanding their combined results.

**Major budget lines:**

Background papers: US\$ 20,000

Scientific Meeting in Africa: US\$ 100,000

**Total: US\$ 120,000**

**Major Activity 7: Develop and field test a rapid assessment tool for use at country level to document male circumcision practices, identify key providers, and assess social-cultural determinants of circumcision**

**Background and rationale**

There is urgency to acquire information sufficient to provide direction at country or district level to programme managers and to other decision makers wishing to assess the need and acceptability of programmes to enhance rates of male circumcision. These include information on the need for and desirability of male circumcision. Practical tools will be needed at country and district level to acquire such information for programme planning. A two-step process is envisaged.

- **A toolkit for a district or country wishing to determine the need for, and ability to implement, a broad circumcision programme will be developed.** Implicit in the development of such a toolkit will be the need to develop validated survey designs of how to determine male circumcision status/rates, community and individual perceptions on circumcision (male and female), what might change those attitudes, availability of male circumcision resources, where potential clients might go for information, to whom they might go for male circumcision,

attitudes of those who might influence policy, e.g., government, religious.

- A meeting of experts, both content and geographically representative, will be held to determine needed information and to survey available instruments. Where needed, survey instruments would be devised. A field testing of individual elements and, finally, the entire toolkit would be held;

**Major budget lines:**

Staff time: FTE 35% US\$ 30,000

Meeting costs: US\$20,000

**Total component:** US\$ 50,000

**Major Activity 8: Development of programmatic tools for safer male circumcision**

**Background and rationale:**

Regardless of trial results, demand for and uptake of male circumcision services may increase over the coming years, especially in Southern and Eastern African countries severely affected by AIDS. There is a need to improve current male circumcision practices in many areas. It is now increasingly important to ensure that male circumcision is provided in a regulated and controlled manner and made as safe as possible through training, regulation and other necessary support to providers of male circumcision, in all settings. The health sector should be prepared to play an increasing role in ensuring quality systems for the provision of safe male circumcision and post-circumcision care for all those who seek such services, and the management of any complications. Tools will be developed to support the health sector in its stewardship role at country level, with particular attention to working with private and traditional providers of male circumcision services, quality assessment, improvement, certification, accreditation, and monitoring and evaluation of ongoing circumcision activities.

**Goal and objectives:**

To develop tools that can be used to support the health sector in meeting any increased demand for and uptake of male circumcision services, and in monitoring and evaluating ongoing male circumcision activities.

**Project design and implementation plan:**

Three sets of activities will be implemented:

- a) A guidance note will be prepared to present and discuss possible approaches to the setting of clinical standards for male circumcision, and quality assessment and improvement procedures and tools. This document

will be based on the principles and methods laid out in WHO'S document on "Standards for quality HIV care: a tool for quality assessment, improvement, and accreditation" (2005), adapted as useful to the issue of male circumcision. A small working group composed of health systems experts who participated in the preparation of WHO's guidelines and health providers with expertise and experience in the provision of male circumcision services in African settings will be convened to guide the preparation of this guidance note.

b) Following the successful efforts of a number a key partners to develop a common approach to monitoring and evaluation of national AIDS programmes, UNAIDS, WHO and other key partners will work together to propose methods for the monitoring and evaluation of male circumcision activities or programmes. A subgroup of the monitoring and evaluation teams will be convened to gain consensus on a core set of indicators for monitoring and evaluation of male circumcision efforts, and define measurement approaches. Of particular concern will be the monitoring of the quality and safety of male circumcision.

c) Case studies will be commissioned of approaches used in African settings for ensuring safer male circumcision practices. Such approaches include South Africa's programme for the accreditation of traditional male circumcision schools and the strengthening of the associated education about sexual health, and social and sexual responsibility; and programmes for training private medical practitioners in safer male circumcision practices in West Africa. Two such case studies will be commissioned, and published.

**Major budget lines:**

Activity:

a) March-July 2006; US\$ 30,000

b) February - August 2006; US\$ 40,000

c) December 2005 - August 2006; US\$ 10,000 each case study for a total of US\$ 20,000.

**Total component; US\$ 90,000**

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