Regional Consultation on Safe Male Circumcision and HIV Prevention

Nairobi, Kenya

20-21 November, 2006

Meeting Report

UN Regional Working Group on Male Circumcision

1. Background

Evidence from two decades of observational studies confirmed by one randomised controlled trial suggests that male circumcision can partially protect men from acquiring HIV. Results from the Orange Farm Intervention Trial, South Africa showed at least 60 per cent reduction in HIV acquisition among circumcised men aged 18 to 24 years. In the light of this evidence UNAIDS coordinated the development of the first United Nations Work Plan on Male Circumcision and HIV was developed in collaboration with the US National Institutes of Health, France's Agence nationale de recherches sur le sida and the Bill and Melinda Gates Foundation (April 2005-September 2006). Key UN partners from headquarters and regional levels are the UNAIDS Secretariat, WHO, UNICEF, UNFPA and the World Bank. The UN Work Plan focuses on improving the safety of male circumcision pending results of other randomized controlled trials in Kenya and Uganda, and on assisting countries in laying the policy and programming framework for future decision making on male circumcision.

As part of the UNAIDS Work Plan, consultation meetings were in held between July and September in five countries (Lesotho, Kenya, Swaziland, Tanzania and Zambia), chosen because of their stated interest in learning more about male circumcision and HIV. The country consultations provided a platform for stakeholders drawn from government, private, traditional, donor, NGO (Non-Governmental Organisation) sectors and UN to become more familiar with the evidence on the HIV protective effect of male circumcision and to discuss its implications for the development of HIV prevention programmes and male sexual and reproductive health services. These consultations proved valuable in sensitizing various partners to this knowledge and to gaining the perspectives of a broad range of stakeholders on the potential action implications of this knowledge. The regional consultation meeting in Nairobi brought together these five countries along with a number of other diverse participants, to broadly discuss the issue of male circumcision and HIV in sub Saharan Africa.

2. Purpose

The purpose of the regional consultation meeting was to:

1. examine and update the knowledge and epidemiological evidence on the linkages between safe male circumcision and HIV;
2. review the experience, issues raised and conclusions of the five country consultations on safe male circumcision and HIV prevention; and
3. identify support needed by countries to develop policies and programmes on safe male circumcision should the remaining randomised controlled trials reconfirm the protective effect of male circumcision.

3. Participants

The meeting was attended by about 50 participants (see list of participants) drawn from: the five countries which held stakeholder consultations and four others which had expressed interest in learning of this experience (Malawi, Mozambique, South Africa, Zimbabwe); representatives from the UN (WHO, UNICEF, UNFPA, UNAIDS); NGOs (Family Health International, JHPIEGO- Johns Hopkins International Program on Obstetrics and Gynaecology, Sonke Gender Justice); and research and academic institutions (Centers for Disease Control/Kenya Medical Research Institute, Universities of Illinois and Harvard); and donor agencies and foundations (US Agency for International Development and Bill and Melinda Gates Foundation).

4. Summary of meeting agenda

The programme for the two-day meeting was structured into plenary sessions and opened with presentations around each of the principal objectives of the meeting. The sessions were as follows:

- An expert presentation on epidemiological evidence in support of a partially protective effect of male circumcision on HIV acquisition started off the programme.
- Country presentations outlining progress within their countries following their consultations and situation assessments.
- Small group discussions, grouping countries of estimated similar epidemiological situations, were held. The purpose was for countries to determine concrete action steps that would need to be taken immediately in order to respond to potential media requests for the country's perspective if the Data Safety Monitoring Board of the two NIH funded trials in Kenya and Uganda were to recommend that these trials be unblinded (stopped) on 13 December, 2006. They decided on steps to take to safely meet any increased demand for male circumcision services. They initiated discussions to assess what would be required in terms of technical support if a decision were taken to provide safe male circumcision services as part of a comprehensive male sexual and reproductive health/ HIV prevention programme.
- A donor and technical partner panel discussion was also held to discuss their planned and potential support to assessing the need for male circumcision and means of enhancing services.
- During the wrap-up session, clear building blocks were identified to help countries and international partners advance from stakeholder consultations to action-oriented, necessary political decisions and service provision steps if the remaining male circumcision randomised controlled trials show effectiveness.

5. Session 1: Update on the knowledge and evidence

Professor Robert Bailey of University of Illinois made a key presentation covering: evidence of a partially protective effect of male circumcision on sexually transmitted infections and HIV from observational studies and the Orange Farm Intervention Trial in South Africa; results of modelling the impact of male circumcision on HIV infections and the cost-effectiveness of male circumcision for HIV prevention; safety of male circumcision; potential risk compensation (increases in risky behaviour sparked by decreases in perceived risk); acceptability of male circumcision; and preliminary results of needs assessment studies of health care facilities in one district in Kenya.

Highlights of the evidence:

- There is compelling observational, biological and clinical trial evidence of a partially protective effect of male circumcision on sexually transmitted infections and HIV.
- Dynamical simulation models on the impact of MC on HIV prevention indicate that male circumcision could avert millions of new HIV infections in east and southern Africa and can be a highly cost-effective intervention by saving costs for treatment of AIDS in the future.
- Studies in sub-Saharan Africa show that acceptability and demand for male circumcision in areas that do not traditionally practice circumcision are high and growing.

- Although it may be viewed as another male controlled HIV prevention method, male circumcision confers other sexual and reproductive health benefits to men and women. One trial in Rakai, Uganda is specifically studying the potential protective effect of male circumcision for females among discordant couples, where the male is HIV-positive and the woman HIV-negative.

Concerns and outstanding issues:
In the light of this evidence, participants discussed concerns and programmatic challenges to providing safe male circumcision services:

- Who should conduct safe male circumcisions? Should it be doctors only, other lower level clinical staff such as nurses and clinical officers, or could traditional health practitioners and traditional circumcisers also provide safe circumcision services?
- Whether certification would be required for practitioners, and, if so, how could it be ensured for providers in non-clinical settings?
- Risk compensation must always be a concern of programming for safe male circumcision and HIV prevention. Although preliminary results from a randomised controlled trial, where intense behavioural counselling was provided, show no evidence of risk compensation among recently circumcised men, the situation in real life, particularly when men would know that male circumcision was partially protective against HIV, may be different.
- Payment for services was identified as a significant impediment for those seeking male circumcision services. Whether services should be free or at what price they should be offered remains an outstanding issue that needs to be considered at country level.
- The limited data on the safety of male circumcision in the region is alarming; male circumcision is provided under sub-optimal conditions in both traditional and medical settings. There was no agreement of how to work with traditional circumcision providers to enhance safety. However, with mobilization of resources, increased safety within the formal health care system is achievable.
- There was agreement that prioritization for male circumcision services should go to high HIV prevalence/low male circumcision areas, where the impact of male circumcision programmes could be highest. There was also recognition, however, that to enhance safety, areas of high male circumcision prevalence (where unsafe circumcision is practiced) would also need to be prioritized.
- Needs for training and resources (equipment and consumables) are widespread.

Implications for policy and programming:
Participants agreed that the evidence for the partially protective effect of male circumcision against HIV is strong and acknowledged that already the demand for safe male circumcision is increasing. The following next steps were agreed upon:

- Regional and country task forces on male circumcision and HIV prevention should be established, or where already established the membership should be enlarged to ensure inclusivity, to coordinate and direct efforts around male circumcision as a potential HIV prevention tool. Women should be included in this process.
- Rapid needs assessments need to be carried out to determine countries' need and readiness for rapid expansion of services, both in terms of human and physical resources, as well as how to deal with political, policy and cultural realities.

- Comprehensive strategies need to be developed and decisive actions taken to respond to present demand and future potential increases in demand. The priority was to meet existing demand before attempting to generate new demand for male circumcision services.
- Pilot or demonstration (how to) projects, monitoring and evaluation systems, training, and supply mechanisms, all need to be considered with the likelihood of having to start NOW!

Conclusion:
The meeting concluded that the concerns and outstanding issues discussed need to be considered at country level as safe male circumcision services are being incorporated into national plans of action for HIV prevention.

6. Session 2: Country stakeholder consultation feedback
Each of the five countries (Kenya, Lesotho, Swaziland, Tanzania and Zambia) where consultations have been conducted gave short presentations on the status of male circumcision in their respective countries and on the follow-up activities to the country consultations. The other four countries who had not had consultations (Malawi, Mozambique, South Africa and Zimbabwe) also gave a brief summary on the status of male circumcision activities in their countries.

- Participants agreed that country consultations have been very useful in convening key stakeholders to get familiar with the evidence, and discuss its implications in their own context.
- The consultations were viewed as the start of a process, resulting in agreements to move from learning of the evidence to active planning to meet increasing demand for safe male circumcision services.
- Countries which have not had consultations expressed interest in doing so, to develop national consensus through evidence-informed discussions among key stakeholders so that they might rapidly move into action should it be needed.
- Discussions highlighted a number of principles to guide development of policies and action plans. These discussions were held assuming the likelihood that male circumcision would be recommended as an HIV prevention tool:
    - Country responsibility to act on the compelling evidence of the protective effect of male circumcision on HIV infection – inaction is unethical for a number of reasons ranging from safety concerns to depriving young men of prevention services in high incidence settings, and is therefore not an option.
    - Integration of male circumcision within broader male sexual and reproductive health and HIV prevention strategies that promote male sexual and reproductive health, including responsible sexual behaviour.
    - Engagement/participation of all stakeholders in the design of strategies and action plans – including faith leaders and traditional practitioners, health service providers, youth, men and women, media and people living with HIV.
    - Development of informative and accurate messages that that position male circumcision as part of a comprehensive HIV prevention package. This was considered particularly crucial to counteract some of the inaccurate messages already available in the public domain and help minimise risk compensation. Members of the media should be included as key partners in the development of these strategies.
    - Development of country and contextually driven approaches by countries for sustainability of programmes– manage balance of bottom-up and top-down

approaches. This will also ensure a sense of community ownership and responsibility.

7. Session 3: Agency support for meeting increasing demand for male circumcision

One of the key objectives of the regional meeting was to provide a forum for technical and donor agencies, and countries, to identify support needs of countries in male circumcision programming. A panel discussion of agencies was held to meet this objective.

It was noted that the first UN Work Plan on Male Circumcision (November 05-April 07) has been largely implemented. A follow-up work plan is being prepared and will assist countries to develop evidence-informed policies and programmes to improve access to safe male circumcision services, including; i) norms and standards for the procedure itself and allied counselling, ii) technical support for accelerated roll-out, iii) guidance for communication strategies; and, iv) coordination and commissioning of operational research, monitoring and evaluation of potential male circumcision roll-out. The second work plan will guide technical and donor agencies to determine how best to allocate resources to improving and expanding male circumcision services. This would also help form effective partnerships and avoid possible duplication and competition amongst agencies.

Partner-specific highlights from the panel discussion of technical and donor agencies:

- ***Bill and Melinda Gates Foundation***–usually supports starters of innovations; Gates supported the first UN Male Circumcision Work Plan; they are currently sponsoring the Rakai Randomised Controlled Trial that is examining male to female transmission. They expressed interest in supporting roll-out through continued support for the joint UN work plan and operations research.
- ***Family Health International*** – provides technical support to governments for developing models of service delivery. They will broadly follow the WHO lead in scaling-up services but work at country level to establish and evaluate model scale-up services.
- ***Sonke Gender Justice (Futures/USAID)*** – A South Africa-based NGO interested in engaging issues related to culture, tradition and gender. They are currently conducting needs assessment on scale-up, including human resources and costing, in Zambia, Lesotho and Swaziland. In Lesotho, the definition of male circumcision is being evaluated because of the inconsistent evidence on the relationship between male circumcision and HIV in the country. Circumcision in Lesotho appears to be incomplete to varying degrees when done in the traditional sector.
- ***USG/USAID*** – are keen to offer support for anticipatory work, but are following WHO/UNAIDS lead in determining whether to accept male circumcision as an HIV prevention tool and, thus, are not funding actual scale-up work. Eight focus countries have submitted proposals for male circumcision support in 2007 – each up to $300,000. These are currently under review.
- ***CDC/KEMRI*** – offer research and technical assistance, including needs assessment and support for operational planning and action. They conduct public health evaluation and are involved in the dissemination of male circumcision research results. They are running a men's clinic in Kenya.

- ***JHPIEGO*** – offers international public health intervention work and is conducting a pilot male circumcision intervention in Zambia. It has developed an international training package, patient education materials and tools for the training and conduct of male circumcision. It has undertaken assessment work in Mozambique (USAID), Botswana (CDC) and Zambia, in addition to operational research on different service provision models (with Population Services International).

- ***Conclusions***:
  - The UN joint work plan has provided an important coordination and support platform for countries and partners. There is need to keep and use this platform to coordinate and manage support in the next phase. Partner agencies recognize and expect leadership from WHO and its UN partners in defining, strengthening and managing support to countries.
  - Working groups at global and regional levels should be strengthened by being open to other key partners.
  - There is need to build on agency initiatives such as CDC, Futures, EngenderHealth, JHPIEGO Sonke Gender Justice in order to expand and strengthen their support to operationalise male circumcision.

8. Session 4: Country-level action steps: group work discussions

Participants were split into three discussion groups to agree on concrete action steps to be taken to move forward with male circumcision. The three groups were asked to identify specific *strategies* for responding to increased demand for male circumcisions, determine the *actions* necessary to implement these strategies and finally determine *support needs* for implementation of male circumcision within countries during the next six months.

Strategies

Participants agreed that the two priority areas must be to i) respond to increasing male circumcision demand, while ensuring safety; and ii) focus on high HIV prevalence/low male circumcision countries or sub-national units.

- Three core strategies were proposed:
  i. Build clear, consistent and accurate messages for community awareness, understanding and demand for safe male circumcision within the context of broader approaches promoting male sexual and reproductive health and responsible sexual behaviour;
  ii. Strengthen and support capacity building to provide safe male circumcision services – focus on capacity of public, private, traditional and religious male circumcision service providers; and
  iii. Mobilise financial resources and identify key stakeholders for the provision of safe male circumcision service delivery.

Actions

Participants identified immediate actions that countries should consider in evaluating male circumcision evidence and in translating this into policy and programmes, should the remaining randomised controlled trials affirm the partially protective effect seen in the Orange Farm Intervention Trial.

- Some of the immediate actions are:

i. Form male circumcision technical working groups to coordinate and manage stakeholder contributions to the development and implementation of a comprehensive male circumcision and HIV prevention strategy.
ii. Secure national leadership (government, faith, traditional, political) commitment to male circumcision. Issue a country position statement on male circumcision and HIV prevention.
iii. Brief/engage leaders, key stakeholders and opinion leaders (media, traditional, faith, youth, and women) on male circumcision evidence, and agree on a national approach.
iv. Conduct situation and capacity assessment - assess demand for and acceptability of male circumcision; costs of male circumcision services; capacity needs to respond to male circumcision demand; and identify facilitating and constraining factors.
v. Develop a national strategy and action plan – define targets, actions, costs, monitoring and evaluation - gain national and stakeholder endorsement. Develop a short term action plan, of six months, to catalyse action.
vi. Governments and agencies to mobilise resources to support implementation of the male circumcision action plan – these should be additional resources rather than the diversion of resources from other health interventions. The private sector should also be involved in the development of the action plan. Convene and brief donors and other partners on male circumcision. Involve them in the planning and consultative processes.
vii. Review or develop national policy, legislation and regulatory environment – male circumcision for who, by whom, where and how, and what legislation or regulations will need to be addressed to scale-up safe services, e.g., to allow training and deployment of nursing staff to perform male circumcision surgery.
viii. Mount a public information campaign on male circumcision addressing benefits and concerns, but ensure that if male circumcision is to be promoted that services are ready to meet potential resulting demand.
ix. Develop in-country operational experience and support capacity (operational research, demonstration or pilot projects) – gain experience, establish reference points and capacity to provide training, technical assistance and method development.
x. Monitor, document and review implementation experience within countries and be able to share these experiences at regional level.

Support needs

The support needs identified were primarily in reference to technical guidance and assistance from the UN.

i. WHO/UNAIDS joint statement on male circumcision – there is need for clear communication on the next steps from the UN. These should be clear and unambiguous statements and support WHO, UNAIDS, UNFPA, UNICEF principles.
ii. Normative and technical guidance – assessment, planning, surgical procedures, standards, ethical considerations and monitoring and evaluation.

iii. Technical support from WHO/UN partners and others- situation analysis, strategic and action planning, training, communication.
iv. The UN, technical agencies and national governments to mobilise funding to support assessment and service provision.
v. Documentation, knowledge and experience exchange as countries experiment with different models of service provision.
vi. Establish a clearing house of information resources to ensure access to standard evidence-informed knowledge and messages.
vii. Develop information and communication strategies and tools for social change communication that places key audiences at the centre of design, implementation and evaluation of evidence-informed communications programming.
viii. Information, advocacy, partnership development and coordination.

- ***Conclusions***
  - There is no time to spare; the UN, partner agencies and countries need to be prepared with clear points on what to do by 13 December in case an announcement is made to unblind (stop) the two remaining trials.
  - This is necessary preparatory work whether the remaining two trials are unblinded in December or not.
  - Although countries may differ in their responses to the male circumcision and HIV prevention evidence, the key issues are similar.
  - Male circumcision is an opportunity to provide and improve other reproductive health services.

9. Session 5: Immediate next steps

International level

1. UN to prepare and issue joint statement if the two randomised controlled trials are stopped by 13 December which will advise on what the UN position is and what next steps will be taken, including convening of a policy meeting.
   - Finalise information and briefing packages to facilitate communication with policy makers; prepare model PowerPoint presentations.
   - Use modelling data to clearly indicate imperative for action on male circumcision – i.e. numbers of HIV infections and deaths averted by different levels of male circumcision coverage such as 10, 30, 50 or 80 per cent over next 10 years.

2. Issue normative and technical guidance – by March 2007.
   - Global male circumcision meeting (end Jan 2007) to review research results, and arrive at policy and programming recommendations, and issue consensus statement on what needs to be done: will be held if one or more of the ongoing randomised controlled trials are stopped.
   - Framework for improving quality and coverage of existing services- technical manual and training framework developed; accreditation of service providers.

3. Secure funding for i) Second UN Work Plan on Male Circumcision and HIV and ii) NGO-driven operational research projects.

Regional level

4. Establish male circumcision support team of the UN and other partners whose roles would be to provide: i) technical and programming support; ii) information and communication; iii) knowledge hub and clearing house – First quarter 2007.

5. Prepare and facilitate country support work plan for first half 2007 – proposed priority countries: Lesotho, Kenya, Malawi, Swaziland, Tanzania and Zambia. The work plan would:
   - assist with needs assessment;
   - develop models to respond to increases in demand;
   - establish initial training centres/ centres of excellence;
   - improve quality and coverage of existing of male circumcision services;
   - develop local strategies for social change communication; and
   - promote local consultations.

6. Convene expanded regional working group to coordinate 2007 work.

7. Secure Health Ministers and National AIDS Coordinating Authority directors' support for male circumcision. Identify upcoming leadership opportunities such as Southern African Development Community NAC Directors and Africa Union Ministers of Health meeting.

Research

8. Develop a coordinated research agenda among partners- priorities identified, projects developed and funded. Some of the key research areas are:
   - Complete the clinical trials in Kenya and Uganda
   - Undertake/advocate for further research into immunohistochemistry of the foreskin and the keratinisation process
   - Plan and conduct operational research, monitoring and evaluation for ongoing improvement of services
   - Examine suture less techniques for adult circumcision which may be appropriate in resource-limited settings.

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