REPORT

KENYA STAKEHOLDER CONSULTATION ON MALE CIRCUMCISION IN THE CONTEXT OF HIV PREVENTION

September 2006

1. Background

Two decades of observational studies suggest that male circumcision, the oldest known surgical procedure, can partially protect men from acquiring HIV. Results from the Orange Farm Intervention Trial, South Africa (showing at least a 60% reduction in HIV acquisition among circumcised men aged 18 to 24 years) prompted the Joint United Nations Programme on HIV/AIDS (UNAIDS) to issue a position statement and develop a United Nations Work Plan on Male Circumcision and HIV.

The UN agencies believe that the results of the South Africa trial are promising, but that there is a need to wait for the results of the remaining two trials (one in Kisumu, one in Rakai District, Uganda) which are expected during 2007, before recommending to Governments that male circumcision should be promoted as one method of preventing HIV infection. However, in anticipation that the remaining two trials will confirm that male circumcision is indeed strongly preventive, the UN agencies recommend that Governments start to prepare now for the possible roll out of large scale programmes to provide male circumcision as part of HIV prevention some time in 2007.

The UN Work Plan focuses on supporting countries to prepare to scale up provision of male circumcision, and on increasing the safety of male circumcision that is already being provided, pending results of the two remaining ongoing trials, and on laying the policy and programming framework for future decision making at country level.

In 2005, UNAIDS stated that, although it was premature to recommend male circumcision services as part of comprehensive HIV prevention, governments should take steps to ensure current male circumcision is conducted by trained practitioners in safe, well-equipped settings to reduce post-operative complication rates. 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, UNAIDS developed a Work Plan focused on improving the safety of current practices, synthesizing male circumcision knowledge, and developing tools for countries to collect relevant policy and programming information. These include:

- Rapid assessment tools to determine male circumcision prevalence, complication rates by provider, acceptability and service availability mapping
- A Manual for Male Circumcision under Local Anaesthesia that provides detailed guidance on different surgical techniques and emphasises male circumcision as an entry point for male sexual and reproductive health
- Guidance on training, regulatory and licensing issues
- Operations research tools and resource needs assessments
- Modelling the potential impact of male circumcision on HIV epidemics and its cost-effectiveness
- Human rights, ethical and legal considerations, particularly for adolescent consent for surgical procedures.

Working with countries to determine the potential role of male circumcision within their comprehensive HIV prevention programmes is essential. The first countries moving forward with support from the UN Work Plan on Male Circumcision to gather data necessary for informed decision-making include: Lesotho, Zambia, Tanzania, Swaziland and Kenya.

2. The Kenya consultation process

As part of the initial country consultation a preparatory meeting with key informants and stakeholders was carried out on 31 August. During this meeting the rationale and generic objectives for the country consultations were shared and discussed. The meeting resulted in:

1) Consensus on the National AIDS Control Council (NACC) taking the leadership for the consultation process
2) Agreement on priority constituencies to be represented in the consultation - government, research community, civil society, select development and UN partners, traditional male circumcision practitioners, leadership of major non-circumcising population group (the Luos).
3) Drafting of a preliminary invitation list for the two-day Kenya stakeholder consultation
4) Establishment of a small technical group to revise the generic objectives and agenda to better reflect the Kenya situation

The Kenya Stakeholder Consultation on Male Circumcision in the Context of HIV Prevention was held on the 7th – 8th September 2006 at the Mayfair Holiday Inn, Nairobi. Invited were several participants representing researchers, government officials, health service providers in both modern and traditional sectors, programme implementers, religious leaders and community leaders. A comprehensive list of participants is provided in the annex.

The meeting was hosted by the NACC with funding through the UN Work Plan on Male Circumcision and HIV and was technically supported by the UN Regional Working Group on Male Circumcision (MC).

The Kenya-specific consultation objectives were:

1. Share and review latest evidence on male circumcision and HIV prevention
2. Discuss the practice and implications of male circumcision in the Kenya context
3. Mobilise and build ownership among various stakeholder groups regarding male circumcision and HIV prevention as an intervention area
4. Identify some possible goals and targets, which the GOK might adopt, once a decision to start implementation is taken
5. Start to identify programme strategies through which the goals and targets might be met
6. Agree on follow-up strategies and modalities

The following items represent description of the central topics deliberated and recommendations reached by consensus during the Kenya consultation:

a) Sharing and Review of Evidence on MC and HIV Prevention

Several studies were shared and discussed in plenary. They included an observational study in Kericho and the Orange Farm Trial the only one of the three randomized trials in the region with available final results. An update of the ongoing trial in Kisumu was also provided.

The Kericho observational study was conducted on a tea plantation and followed up a male cohort of 1378 over a 24 month period. The study concluded:

- That circumcision offered a degree of protection from HIV infection
- Additional studies are required to validate this finding
- Careful attention needed for risk-benefit profile of circumcision

The Orange Farm Trial in South Africa was the first Randomized Controlled Trial in the world on this issue. A cohort of men was followed over an average period of 18 months in a blinded study. Approximately half of the study participants were circumcised and followed up on at designated follow up sessions where a variety of tests were administered and health education and counselling offered to the participants. The other group of uncircumcised men was also followed up at designated times with similar tests being administered.

The study did not go to completion due to the compelling evidence that emerged of significant (60%) protective value of MC against HIV infection to the participants. The study was therefore stopped on the recommendation by the Data and Safety Monitoring Board (DSMB) and all participants were offered MC free of charge.

Further circumstantial evidence came from a brief presentation of data from the Kenya Demographic and Health Survey 2003 which showed support of the protective element of MC against HIV.

In the light of all the existing and emerging data, a question was raised on the rationale to wait for further evidence. However, a consensus was reached that this was good practice and that nothing was lost as preparation has already been initiated by this consultation process to begin policy discussions and decision-making processes in order to respond to the likely increase in service demand following the release of the results from the two on-going studies, as well as to address existing complications around provision of MC services. Additionally, the two on-going trials will provide information on further aspects of the practice of MC, such as protective element for women.

Some participants questioned why MC was being discussed and apparently promoted, whilst they felt that what was really needed was a vaccine or access to an effective female controlled method such as a microbicide. The facilitators clarified the

situation by saying that MC might be shown to be effective, and a possible part of an HIV prevention strategy next year. Whilst it was very important to continue investing in microbicide and vaccine research, neither was likely to be available before 2010 at the earliest.

While MC does not offer total protection from HIV infection, it significantly decreases the risk factor. A metaphor of using a seatbelt while driving was offered as an example of an intervention which does not necessarily prevent death or injury in an event of a car crash, but significantly reduces the risk. At the same time, wearing a seatbelt should not result in increased recklessness when driving and neither should undergoing MC result in behavioural disinhibition/risk compensation. The fact that MC is considered as only one component of a comprehensive accelerated HIV prevention package cannot be stressed enough.

In addition to the scientific studies, two programme experiences were shared from Samburu District and the Kikuyu Mission Hospital. In the Samburu experience the NGO Samburu Aid in Africa (SAIDIA) presented on its experience in raising awareness and sensitisation of traditional providers of circumcision and community on the dangers of mass MC utilizing a single rudimentary and unhygienic tool. MC occurs once every 10 – 15 years in the Samburu community and initiates range in age from about 15 – 25 years of age. SAIDIA focussed specifically at the practice of mass MC and advocated for “one knife, one boy” a deviation from the tradition and sensitisation and awareness on STI and HIV prevention and VCT. This was particularly important given that after healing tradition calls for the young initiates to explore their sexuality.

The experience from Kikuyu focused on provision of life skills, education and counselling, combined with medicalization of the MC practice, for the young initiates. Several subjects are discussed including good and responsible citizenship, STI and HIV prevention and career development. A camp is held annually in December for boys just completing their primary education. A cohort of boys is brought together for training and ultimately MC in a hospital setting. Like times of old, the cohort is given an age set name in addition to the information provided in the camp. This programme is based on the Kikuyu rite of passage for men.

b) Practice and Implications of MC in the context of Kenya

Current statistics describe 84% of Kenyan male population as circumcised. A significant number of the circumcised males, about 85 %, had the operation done by a traditional service provider. From the discussion it emerged that in the Kenyan context MC is carried out mainly for one of the following reasons:

- a rite of passage into adulthood
- a religious obligation
- way of identification with/belonging to a community

Several issues arose in discussion of the practice as it exists in Kenya today. The first was the dominance of culturally obligations in driving MC in Kenya. As a social and community responsibility young boys are subjected to MC performed mainly by traditional providers in rural non-clinical settings.

While the current practices concerning age at circumcision vary greatly between population groups, most of the practicing communities perform MC as a rite of passage targeting pre-adolescent and adolescent boys, and lowering the age would present its challenges. However, among the traditionally non-circumcising communities the preference seemed to be childhood circumcision.

If MC intervention would be designed for HIV prevention purposes, the procedure should be carried out before sexual debut; whether ideal age would be during infancy or adolescence is a further issue to be deliberated during policy development (linked to informed consent when minors in question). For non-practicing communities, the issue of informed consent was raised as a vital component of the intervention. The consensus reached was that under no circumstances should any individual be compelled to have the procedure done without their full knowledge and understanding of the process and consent.

An assessment carried out in Bungoma district witnessed unacceptably high level of post-MC complications. Of primary concern was the safety and standardisation of the procedure of the boys under going the practice given that a significant proportion of males had the operation done by traditional providers. The presentation on the assessment findings specifically raised the following three problems:

- severe adverse outcomes as a result of seemingly poor hygiene standards and/or poorly performed procedure
- variation in style and extent of circumcision performed, resulting in a wide range of results, which would affect the protective factor against HIV
- presence of 'part-time' untrained MC practitioners taking advantage of the seasonal demand

In the event that the Kisumu trials should produce compelling evidence for the procedure, the meeting reached consensus on the following suggestions regarding safety, costing and accessibility of MC provision:

1) MC should be offered to all males, on voluntary basis, combined with sufficient and adequate counselling explaining the procedure, its effects, and taking into account the right of the individual to make an informed choice.
2) Service to be availed nationally, free-of-charge (questions: who covers cost? Role of private sectors in off-setting some of the workload?).
3) Closer collaboration between the medical fraternity and the traditional circumcisers – perhaps working together within a clinical setting.
4) Registration and licensing mechanism for MC providers. This can be linked to training needs assessment, provision of relevant training and follow-up monitoring of outcomes.
5) Male circumcision should at all times be considered as a component of a comprehensive HIV prevention package.
6) Status as either circumcised or non-circumcised should never result in any kind of discrimination or stereotyping of individuals.

During the discussion on circumcision vs. non-circumcision, an official statement by the traditional leaders of the main non-circumcising community, the Luos, was presented. In essence they concluded that male circumcision is not a cultural practice among the Luos and they do not endorse it (currently approximately 10 % of the Luo men are circumcised). However, they would be willing to spearhead efforts to

take the evidence and debate to their communities for the Luos to decide for themselves. Further, they would not prohibit the practice as long as it was offered on voluntary basis. (Statement attached)

c) Goals and Targets

The Ministry of Health endorsed the meeting and the need for urgent action to start intervening in this area, both in MC as it is practiced today and in relation to HIV prevention in the event of compelling evidence from the Kisumu trail. Of interest to them, from the public health point of view in particular is the issue of safety of the procedure. If the practice cannot be offered under proper circumstances by trained practitioners employing universal precautions, it would be very difficult to promote the practice as part of national HIV prevention agenda.

Given the popularity of the traditional providers, the consensus reached by plenary was that a mechanism of working with them and developing guidelines and protocols for the operation and creation of necessary referral links was urgent.

While the purpose of this stakeholder consultation was not to recommend any quantifiable goals or targets (as this falls within the function of the relevant government institutions), the meeting discussed the following possible result areas:

a) Policy and tools development
b) Capacity of the required set of human resources
c) Continuous evaluation and monitoring of the programme
d) Further research/accumulation of evidence base and periodic revisiting of intervention design

In terms of tools and support from the international community, the World Health Organization (WHO) presented on assessment tools and clinical guidelines that are available. Further, a guideline on MC and human rights has been developed by UNAIDS in support of country-level policy development. Countries are urged to identify and communicate their support needs, so tailored responses can be developed.

d) Way Forward

A multi pronged approach with several processes, to begin immediately and simultaneously, was recommended for the way forward in intervention.

- **Identification of a lead government agency**

Several institutions and government ministries were put forward, including the Ministry of Health, NACC, Ministry of State for Youth Affairs and the National Coordinating Agency for Population and Development (NCAPD).

Recommended action: Government to convene meeting within one week to select lead agency and chart a way forward for a national response

- **Formation of a Steering Committee and technical groups**

Subsequent to the identification of the lead government agency an overall Steering Committee and possible two technical groups may be formed: 1) a task force overseeing the intervention and policy dialogue on MC and 2) a working group to provide technical expertise and drive implementation on the ground.

The two technical groups are strongly recommended to bring together the highest expertise in the country to be vibrant and responsive to the national needs. Membership to the two groups and Terms of Reference (ToRs) should be determined by the lead government agency/Steering Committee in partnership with selected researchers, policy makers, medical professional and development partners. Validation of the two groups will be made at a wider consultation meeting of all stakeholders.

Recommended action: Lead agency to establish Steering Committee and Technical Groups immediately following the initial meeting (action point 1)

- **Identification of Key Stakeholders**

It was also agreed that a comprehensive list of stakeholders should be developed with a view of inviting them for a wider consultation on this issue. It was suggested that a wide array of stakeholders be considered including other traditional judicial systems such as the Luo Council of Elders and religious groups.

Recommended action: The Steering Committee should consult key constituencies and draft a list of key stakeholders to be briefed on the on-going dialogue and included in a wide consultation and follow-up action plan.

- **Policy Issues**

Two activities were brought forward as important in this area: 1) the development of protocols for safe operations on MC 2) development of a policy guiding provision of MC nationally and 3) identification of centres of excellence.

The scope of the documents to be produced is not to be limited to the guidelines but to reach beyond this and address the issues of providers, their training needs, inclusion of traditional providers, provision of MC kits etc. Drafting of these documents can start immediately taking into account and referring to the expertise and knowledge available at the meeting. It was agreed that traditional providers should be seen as critical and important partners and involved at all stages of development.

Recommended action: After validation by wide stakeholder consultation, the technical groups to be tasked by the Steering Committee to develop time-bound action plans and start work on the key policy and guideline documents.

- **Media partnerships/communication strategy**

Media was identified as an important partner especially in the development of an effective communication strategy for the dissemination of the trial results within the next 12 months. It was agreed that training and sensitisation on the issues surrounding the practice is essential for accurate coverage. The media should specifically be made partners to achieve responsible and accurate reporting on the role of MC as part of HIV prevention agenda specifically to avoid misinformation resulting to:

a) Behavioural disinhibition/risk compensation among circumcised men, b) stigmatisation of non-circumcised men

c) Confusion between policy on male circumcision vs. female genital mutilation/cutting.

Recommended action: Media partners to be identified and co-opted to one of the technical groups to help develop a communication strategy and media training/sensitization plan.

- **Documentation of best practices**

Documentation of present knowledge and good practices for scaling up and replication of interventions was also agreed upon. Experiences such as the Kikuyu mission Hospital and SAIDIA should be documented for follow up and potential development of models for replication.

Recommended action: Technical group working on implementation issues to arrange collection of experiences/good practices and identify further knowledge gaps.

- **Political Will**

Endorsement from the highest political office of the presidency and the cabinet was also recommended as a way forward to accelerate the process of policy development and enactment.

Recommended action: Steering Committee to draft a parliamentary briefing kit as soon as possible.

- **Regional Consultation**

  As a separate way forward item, planned regional consultation was discussed. The consultation is to take place in the next couple of months and it is likely that the progress in Kenya will be looked upon by other countries as an example.

Recommended action: The Steering Committee will make preparations for the Kenya representation in the Regional Consultation and follow up.

Male Circumcision and HIV Prevention Stakeholder Consultative meeting
September 7th and 8th, 2006

Participants

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Kenya stakeholder consultation on male circumcision in the context of HIV prevention

Dates: **7 – 8 September 2006**
Venue: **Mayfair Holiday Inn, Nairobi**

Agenda

Time	Discussion Topic	Presenter
Day 1: Morning		
8:30 – 9:00	Administrative arrangements for participants outside of Nairobi	UNAIDS
Session One: Introduction & Current Situation re. MC & HIV Chair: Director of Medical Services, Ministry of Health (TBC)		
9:00 – 9:10	Opening and welcoming remarks	DMS or NACC Director a.i.
9:10 – 9:20	Statement by UN in the context of the country	Chair, UN Theme Group on HIV/AIDS
9:20 – 9:35	Male circumcision in the context of a comprehensive HIV prevention programme	David Alnwick, UNICEF Regional HIV Adviser/member, Regional MC Working Group
9:35 – 10:35 10 mins. 10 mins. 30 mins. 10 mins.	Evidence on male circumcision and HIV prevention: ▪ Circumstantial data from the KDHS on relationship between male circumcision and HIV risk ▪ Kericho observational study ▪ Findings from Orange Farm randomized control trial ▪ Kisumu randomized control trial	 NACC/NASCOP (TBC) Dirk Taljaard Dr. Kawango Agot, UNIM Project, Kisumu
10:35 – 10:45	Translating Research into Practice (TRIP) - issues that need consideration, and processes leading to evidence based decision making and policy, and areas of decision making in public health	Dr. Kizito Lubano, KEMRI/CDC
10:45 – 11:00	TEA/COFFEE BREAK	
11:00 – 11:30	Plenary Discussion	Chair
Session Two: Country context of male circumcision Chair: Dr. Richard Muga, Director of National Council for Population Development		
11:30 – 11:45	Background on the topic	Chair, Dr. Richard Muga
11:45 – 11:50	Introduction to group work (*go to the end of this agenda to find topics for the group work)	UNAIDS
11:50 – 12:50	Group work	
12:50 – 13:50	LUNCH	

Day 1: Afternoon		
13:50 – 14:50 15 mins. each	Group work report back to plenary (topics at the end of this agenda) ▪ Groups 1 - 4	Rapporteurs from groups 1 –4
14:50 – 15:20	Plenary Discussion	Chair, Dr. Richard Muga
15:20 – 15:50	Recapping issues and potential strategies requiring further attention (consensus building)	Chair, Dr. Richard Muga
15:50 – 16:00	Closing of Day 1	DMS/NACC Director a.i.

Day 2: Morning		
9:00 – 9:15	Recap of Day 1	UNAIDS
Session Three: Strategies for MC programming Chair: Professor Alloys Orago, Director a.i., National AIDS Control Council		
9:15 – 9:30	Introduction to programme possibilities (building on group work from Day 1)	David Alnwick (UNICEF)
9:30 – 10:00	Assessment tools	George Schmid (WHO)
10:00 – 10:30 10 mins. each	Programme and assessment experiences ▪ MC initiatives in Samburu ▪ PCEA initiative ▪ Findings of a health facility capacity assessment in three districts/adverse effect assessment	 Daniel Lekupe, SAIDIA Rev. Wilfred Kogo Dr. Kawango Agot and Dr. John Opeya, UNIM Project, Kisumu
10:30 – 11:00	TEA/COFFEE	
11:00 – 11:40	**Key needs for follow up/next steps** ▪ Technical Working Group ▪ Regional Consultations	Chair
11:40 – 12:00	Concluding Remarks	DMS or designate
12:00 -	LUNCH	

Topics for group work:

Group 1: Cultural issues around circumcision vs. uncircumcision - what would need to be done to increase number of men who are safely circumcised (both in groups which traditionally circumcise, and groups which traditionally do not circumcise)

Group 2: What kind of interaction between the modern medical sector and traditional providers is desirable and possible?

Group 3: How to minimise 'Risk compensation', and what other HIV prevention activities could be linked to provision of MC?

Group 4: Programmatic approaches to increasing proportion of boys/men who are safely circumcised.

All the presentations, group work guidelines, as well as the statement from the Luo Supreme Council of Elders could not be attached as part of the report as they are large files but can be obtained from Charles Mwai email: cmwai@nacc.or.ke or Mira Ihalainen email: mira.ihalainen@undp.org