Male Circumcision
and
HIV Prevention

Country Consultation Meetings

Lesotho Country Consultation Meeting Report

Lesotho Sun Hotel
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List of Abbreviations/Acronyms

ABC	Abstain, Be Faithful and Condom use
ANRS	Agence national de recherche sur le sida;
ART	Antiretroviral therapy
DHS	Demographic and Health Survey
KYS	Know Your Status
LA	Local anaesthetic
MC	Male Circumcision
MoH	Ministry of Health
MoHSW	Ministry of Health and Social Welfare
NIH	US National Institute of Health
PEP	Post-exposure prophylaxis (PEP)
PMTCT	Prevention of Mother-to-Child Transmission
RCT	Randomised controlled trial
SADC	Southern African Development Community
UTI	Urinary tract infection

Summary

The Lesotho Country Consultation Meeting for Male Circumcision and HIV Prevention was the first of five such consultations planned for July-September 2006 in Lesotho, Kenya, Swaziland, Tanzania and Zambia. The meeting was originally planned to be held for two days, but in Lesotho it was decided that it would be a one-day meeting (held on 25 July, 2006) due to competing demands of the key stakeholders. The meeting was opened by Dr T. Moorosi, the Director General of Health Services. Dr Angela Benson, the WHO Representative for Lesotho, made the opening remarks on behalf of the WHO and UN family. The meeting was attended by over 70 participants from MoHSW (Ministry of Health and Social Welfare), local NGOs working on HIV, traditional leaders and health providers, academics, UN and other multilateral and bilateral agencies working in Lesotho.

The objectives of the meeting were as follows:
1- Review and discussion of latest evidence on Male Circumcision (MC) and HIV Prevention at global, Africa and country level;
2- Discuss implications of MC within Lesotho context: acceptability; health service delivery; traditional practices; counseling and consent; ethical and regulatory issues; and
3- Discuss strategies for follow-up for programming.
There were three sessions which mirrored the objectives.

Before the presentations were made Advocate B. Sekonyale, a member of the Senate stated the 'ground rules' for the meeting in order to guide participants on the appropriate language to use due to the sensitivity of male circumcision in Lesotho. This basically meant restricting direct reference to male human anatomy.

In the session presenting the latest evidence on MC and HIV prevention, Dirk Taljaard, an investigator of the Orange Farm study, presented the results of the first randomized controlled trial (RCT) to show the protective effect (60%) of safe male circumcision on female-male transmission of HIV.

David Alnwick, from the UNICEF Regional Office made a presentation on comprehensive HIV prevention programmes and links to MC. He emphasized what the HIV prevention (SADC Expert Think Tank Meeting on HIV Prevention) held in Maseru in May 2006, noted that multiple partnerships and non-circumcision form a lethal cocktail for HIV infection in the SADC sub-region. The meeting called for increased efforts in these areas. However, he stressed that it is important to educate the public that MC is not a 'magic bullet' for HIV prevention and the challenge of trying to link MC to existing HIV prevention efforts.

Dr Gayle Martin of the Futures Group presented a proposal of a study to estimate the cost and model the impact of providing MC for adult males in southern Africa (Lesotho, Swaziland and Zambia). This is in addition to other consultations in the region. An additional component unique to Lesotho is to establish whether men who define themselves as circumcised meet the clinical definition of MC associated with protection against HIV infection. ++discuss this later

During the session on the country context, Advocate Sekonyale and Dr T. Lestie, both western educated and involved in initiation schools, noted that in Sesotho the term for male circumcision and initiation rites, is the same: *lebollo*. They contended that what happens inside the initiation schools is a secret and involves teaching of life skills for the initiates. Dr Palesa Mohaleroe, a practitioner at QEII Hospital presented on surgical services, and ethical and regulatory issues of MC. She gave the clinical definition of MC and remarked that there were challenges to providing safe MC in hospitals in Lesotho such as: shortage of competent health workers resulting in long waiting period, inadequate sterile space for surgery and a general lack of financial resources. She explained the need for health workers to understand informed consent and regulatory issues regarding MC services, especially for adolescents.

The third session involved discussion of strategies for MC and HIV programming. As the UN agencies develop a programmatic framework on MC David shared his views on programming strategies. Some of the strategies for services delivery options include: routine, demand driven or walk-in or appointment-based. He argued for mass campaigns of MC, which have worked in Africa the past in such areas as: polio eradication and measles control. Dr George Schmid of Department of HIV/AIDS, Geneva presented the assessment tools developed by the UN to assist countries prepare for provision of safe MC whilst awaiting results of the trials in Kenya and Uganda. His key message was that the Government of Lesotho should state what they want if they were to scale up MC services and the UN would guide them to reach their goals using the assessment tools. The tools cover four areas: guiding safe circumcision practice; assessing the need for MC and the ability of health services to meet that need; assessing health services and client behaviour once a government decides to scale up MC; and measuring the impact of MC on HIV prevention.

The key follow-up steps of the meeting are as follows:

1. *Collaboration of modern and traditional health practitioners in addressing MC and HIV prevention in Lesotho*. Both sectors agreed that they have a common goal which is to address HIV, and that current prevention strategies are not entirely working. The meeting agreed that there is need for a broader-based consultation meeting; identify ways in which MC can be made effective and safer; and find ways of learning from other settings where safe male circumcision services in a clinical hospital and traditional setting.
2. *Improve health service delivery and provision of safe MC:* address unmet need for MC in hospitals; assess capacity needs; and training of providers of MC.
3. *Conduct further research on the nature of MC in Lesotho*: the latest Lesotho DHS (Demographic and Health Survey) showed that HIV prevalence for circumcised males was higher. This raises questions on the nature of MC in Lesotho, timing of MC, questions asked to collect these data. This results need to be examined further in the context of Lesotho. The Futures Group study would collect data on the completeness of MC to address some of these concerns.

Official Opening Speeches

1. Director General of Health Services, Dr T. Moorosi

His Majesty, King Letsie III, Honourable President of Senate, Members of the Diplomatic Corps and Heads of International Organizations, Senior Government Officials here present, Representatives of various organs of civil society, Resource Persons of this important consultation, Distinguished Ladies and Gentlemen, All Protocol Observed.

It is, indeed, my honor and privilege to officiate at this important Consultation. Let me, at the outset, express my gratitude to all of you distinguished participants for sacrificing your time during such a hectic period of the month for this important meeting. I also wish to take this opportunity to welcome in a special way the team of experts and resource persons that have come to assist us/Government and its partners in thinking through options of how best we could strengthen and accelerate the HIV prevention strategy.

As we know, Lesotho is experiencing a great burden of HIV and AIDS. This situation demands each one of us in our respective capacities to do more, to redouble current efforts, if we are to contain and reverse the epidemic in this country. The existing political commitment and will gives us the strong foundation on which to build and strengthen our long term strategies to scale up the entire range of HIV programmes that cut across prevention, treatment, care and impact mitigation.

Today's Consultation, provides us with the opportunity to seriously discuss the link between male circumcision and HIV prevention and its programme implications. In Lesotho, as most of us know, male circumcision is not a new thing as it is culturally practiced. What is new, however, is that recent studies have found associations between higher rates of male circumcision and lower rates of HIV prevalence.

I am pleased to learn that we will be hearing first hand this morning from one of the researchers involved in a randomized controlled trial of standardized surgical male circumcision among young men in South Africa referred to as the 'Orange Farm Study,' which found 60-75% reduced incidence of HIV among men who had been circumcised during the study. We understand that similar trials of surgical male circumcision are currently underway in Kenya and Uganda.

Despite the strength of epidemiological data, considerable debate remains about the potential role of male circumcision as a public health measure to prevent HIV infection. According to the Demographic and Health Survey of 2004, the relationship between male circumcision and the HIV level in Lesotho does not conform to the pattern seen elsewhere in Africa; the HIV rates are in fact substantially higher among circumcised males (23%) than among males who are not circumcised (15%). There is, therefore, need for more research on this topic in Lesotho.

While we are trying to understand available scientific evidence and waiting for more with on-going trials, the public outside is already talking and demanding male circumcision. Some of them, who get bits and pieces of the information coming out of the studies are jubilating, saying "the magic bullet" against HIV, is here!! As we all know this is not true. It is, therefore, important in the work we do to put the record straight by making it crystal clear that: (a) male circumcision is not the cure to HIV; (b) circumcised men can still become infected and if HIV positive, can infect their sexual partners, and (c) circumcision may lessen the risk of HIV infection, but does not does not give complete protection.

Ladies and Gentlemen, against the background I have painted, it is important that during our deliberations today we view male circumcision as one of "the" elements to be considered in our attempts to accelerate HIV prevention in this country. It should not be misunderstood that we are discussing Male Circumcision as an option to substitute or replace the 'ABC': Abstain, Be Faithful and Condom use.

I wish to end here by making one appeal. I request that this one day consultation come up with specific recommendations to the Ministry of Health and Social Welfare on what needs to be done if Government decides to scale up male circumcision as part of a broad HIV prevention programme.

I declare this consultation meeting open and wish you fruitful deliberations as we strive towards accelerating HIV prevention in Lesotho. I thank you.

2. STATEMENT ON MALE CIRCUMCISION BY WHO REPRESENTATIVE, LESOTHO: Dr Angela Benson

I bring you greetings from the WHO Regional Director for Africa, Dr. Luis Sambo.

Each year more than 2 million people lose their lives to HIV/AIDS in sub-Saharan Africa and more than 3 million new infections occur in the African region. Half of the newly infected individuals in the region are young people aged 15-24 years. In August 2005, 46 Health Ministers met in Maputo as the WHO Regional Committee for Africa and adopted Resolution AFR/RC55/R6 aimed at accelerating HIV prevention in the African region.

The Regional Director of WHO called upon Members States to intensify HIV prevention effort and to declare 2006 as the Year for Acceleration of HIV Prevention. It built on previous commitment by Heads of States, the UN and international partners for example, the Abuja Declaration, the UNGASS and the MDGs.

Many countries in the African Region, including Lesotho, have started implementing these resolutions. The Commission of the African Union declared that HIV prevention acceleration is a noble strategy that should be given high visibility while working towards the goals of Universal Access by 2010. Here in Lesotho, the "Know your Status" strategy (KYS) gives us great opportunity to achieve this goal.

HIV prevention involves a series of elements including, but not limited to the following: abstinence, be faithful to your partner, correct and consistent use of condoms, PMTCT, safe injection practices, blood safety and post-exposure prophylaxis (PEP). The efforts to scaling up these interventions have not yet yielded the desired results. Therefore there is room for concerted effort to ensure access to these proven, cost-effective interventions. Furthermore, there are ongoing efforts to explore other effective interventions like microbicides, vaccines and male circumcision.

As far as MC is concerned, evidence shows that circumcised men have a lower incidence and prevalence of HIV infection than uncircumcised men. There are ongoing research studies to confirm the plausibility of this evidence. While we wait for these results, it is important for countries to start to dialogue in the interest that the results are affirmative. Hence this important meeting in Lesotho.

On behalf of WHO and the UN, we welcome these research findings and would like to state that the UN emphasized that if male circumcision is confirmed to be an effective intervention to reduce risk of acquiring HIV, men and women must understand that male circumcision lessens the risk, but does not give complete protection against the virus. Circumcised men can still become HIV-infected, and if HIV-positive, can infect their sexual partners. It is therefore essential that male circumcision not replace other known effective means of reducing HIV infection, such as abstinence, sex between people who both know they are HIV negative, avoiding concurrent sexual relationships and correct and consistent use of male or female condoms.

Presently, MC in the context of HIV prevention is a product in development; however MC in the tradition of the Basotho is a significant traditional passage of rite from childhood to

manhood. This is an important opportunity to build on, should the protective effects of MC seen in the first trial be confirmed and the demand for services be scaled up. This meeting gives us the opportunity to discuss safe MC and the additional burden that it will place on health services and other related systems should it be scaled up. We need to determine the priority to assign to the intervention in the context of HR constraints on one hand and the risk of unsafe circumcision on the other.

Meeting demands while minimizing post operative complications will require appropriately trained service providers, adequate equipment, close follow-up and care, as well as intensive counseling and support to minimize unsafe sex practice.

From WHO's perspective, we advance the following recommendations; it is time we in Lesotho develop a briefing package for policy makers, program managers, partners and the media.

Secondly, considering that MC is already an entrenched practice in Lesotho, it is important that we enhance the process of developing guidelines that address provision of safe MC services.

Thirdly, we should use this opportunity to assess the level of effective MC in respect to HIV prevention.

Lastly, we should develop tools that would ensure quality of service including monitoring and evaluating circumcision practices, safety and impact on sexual behavior as well as operation research and impact study.

In conclusion, the UN and other international agencies are working together to provide coordinated, consistent, and up-to-date guidance and support to governments and other development partners.

As of now, the position of the UN on the role of male circumcision in HIV prevention programming is as stated earlier on. On behalf of WHO and the UN system/Lesotho, we welcome these research findings and would like to state that the UN emphasized that if male circumcision is confirmed to be an effective intervention to reduce risk of acquiring HIV, men and women must understand that male circumcision lessens the risk but does not give complete protection against the virus. Circumcised men can still become HIV-infected, and if HIV-positive, can infect their sexual partners. It is therefore essential that male circumcision not replace other known effective means of reducing HIV infection, such as abstinence, sex between people who both know they are HIV-negative, avoiding concurrent sexual relationships and correct and consistent use of male or female condoms.

This present position will be reconsidered when the interim analyses of the two research studies ongoing in Kenya and Uganda are concluded.

Summary of Presentations and Discussions

Participants

The meeting attracted a wide range of participants from MoHSW (Ministry of Health and Social Welfare), local NGOs working on HIV, traditional leaders and health providers, academics, UN and other multilateral and bilateral agencies working in Lesotho. More than 70 people were present, more than the number invited. (Please refer to the list of participants in the appendix).

Although the presentations were made in English, given the mix of the audience, the Facilitator/Master of Ceremonies (MoC) and few other individuals offered impromptu translations into Sesotho. They made summaries in English of discussions held in Sesotho.

Opening formalities

Master of Ceremonies: Mr. Peter Phori, WHO, Lesotho

Opening Prayer: Mr. Maraga Ramatlapeng of Christian Health Association of Lesotho.

The MoC outlined the objectives of the meeting as stated in the agenda as follows:
1- Review and discussion of latest evidence on Male Circumcision (MC) and HIV Prevention at global, Africa and country level;
2- Discuss implications of MC within Lesotho context: acceptability; health service delivery; traditional practices; counseling and consent; ethical and regulatory issues; and
3- Discuss strategies for follow-up for programming.

Session 1: Introduction and Current Situation re Male Circumcision (MC) and HIV

Chair: Dr Limpho Maile, Director HIV/AIDS/STI, MoHSW

Official Opening Remarks:

1- Dr Tlhabi Moorosi, Director General, Health Services, MoHSW
2- Dr Angela Benson, WHO Representative, Lesotho

(Please see the previous section on official opening speeches)

'Ground rules'

By Advocate Borenahaborethe Sekonyela, Lecturer in Customary Law, National University of Lesotho

After the initial salutations of giving honour to the King and other dignitaries, he introduced himself as a chief and custodian of the customs of Lesotho. He said that when he had met the organizers of this meeting he noted that:
1- The meeting is important since it deals with HIV and AIDS; it is critical for traditional leaders since people are dying in thousands. It is important for us to get up in arms to deal with the monster.

2- When dealing with MC, there are big problems in the Sotho custom; there is no circumcision but initiation of a Mosotho child into a 'proper person'. "*Baa bolla"* (the initiated) means "cut off all the bad deeds of childhood". We are not just dealing with the surgical part, the symptoms, such as the condom; these alone cannot prevent HIV. The approach is holistic, not just curing the headache.

He pointed out that it was necessary to lay the rules for the consultation meeting for the following reasons:

1. To guide the foreigners who have come with good intentions to help the country not to speak taboos, but use proper language. He cautioned that they would not listen to doctors describe surgical procedures of human anatomy; it is alright for doctors to speak among themselves. He cautioned that otherwise their ancestors would chastise them.
2. He viewed this consultation meeting as just a prelude; the next steps would be to consult the traditional leaders. The discussions at this meeting should be limited to the results of 'the product' [initiation process] and not what goes on inside [MC at initiation schools?]. He commented that he had discussed earlier with his 'sister' Dr Moeteetee, and they agreed that we will not go into the details of MC.
3. We need to discuss the complete person since MC is not the 'magic bullet' for HIV prevention. He commented that traditional initiation schools address internal discipline; however, these values had been destroyed by colonial customs and HIV is increasing. The Government was now making efforts to re-instill these values to build a Mosotho child as illustrated by the draft Initiation Bill.

The impact of male circumcision on the female-to-male transmission of HIV: results of an intervention trial: ANRS 1265
Dr Dirk Taljaard, Progressus, South Africa: Investigator, Orange Farm MC Effectiveness Study

Dr Taljaard started his presentation by commenting that he was not sure what lines were appropriate and which ones were not. He apologized in advance if he crosses any lines.

Background: A number of publications as early as 1986 and more recently a systematic review by Helen Weiss had shown possible reduction of risk of HIV infection for those circumcised by 42%.

Objective of study: To study the effect of MC on HIV incidence among young males in a semi-urban area of Orange Farm in South Africa.

Context: Orange Farm is an area with high heterosexual spread of HIV, with 32% HIV prevalence based on antenatal clinic data. MC prevalence was 20%. At the start of the study in 2002 there was no antiretroviral therapy (ART) available in the area, and in 2004 the trial group opened their own VCT centre offering ART.

Design: a randomized intervention clinical intervention trial. Ethics approval was obtained from the University of the Witwatersrand, South Africa, and ANRS (Agence national de recherche sur le sida), France. A total of 3,035 participants (including HIV positive people) were recruited to be followed for 21 months, with visits at month 3, 12, 21 for counseling, collection of information on sexual behaviour, blood tests and clinical examination and treatment of genital ulcer disease (GUD). They had 2% HIV incidence per year. MC was

done by three designated general practitioners in the local area using forceps guided methods. The intervention group was offered circumcision at the beginning and for the control group it was delayed until the last visit. There was blind follow-up and evaluation, i.e., none of the study staff except for the nurse who performed physical examination knew who was in the intervention or control group.

Results: The baseline information showed that about half were Sothos, a third Zulus and the rest 'other' ethnic groups. The sexual behaviour at the beginning was almost similar for the two groups with low use of condoms, multiple partners (47%), and proportion that sought treatment for genital ulcer diseases (10%). Only sixty participants experienced side effects (adverse effects), some of which were: excessive pain (31%); swelling and collection of blood-haematoma (17%); appearance-scaring (15%), which disappeared after time. The trial was stopped because the evidence of the protective effect of MC on male HIV infection was 'strong', with a mean of 18 months of observation.

HIV incidence: There were 20 people who became HIV-positive in the intervention group and 49 in the control group (0.85 per 100 person years). In other words, the MC intervention prevented 6 out of 10 potential HIV infections. It was noted that the gap in HIV infections between the intervention and control group was getting wider with time. In terms of the measure of reported behaviour change, the only significant difference between the two groups is that in the intervention group there was increased number of sexual contacts after controlling for factors such as marital status, condom use, treatment of STI and sexual partners.

Discussion: This is the first randomised controlled trial (RCT) to show a strong protective effect of safe male circumcision on HIV acquisition by males. It was emphasized that that this is only partial protection and that it is a shortterm effect, after a follow-up period of 18 months. He commented that this study was conducted in a sub-Saharan context and the results were consistent with expectation.

Dr Taljaard left the audience with a number of important questions such as: whether this can be used as a public health intervention (where? how? effect?). He referred to a presentation in June made by Prof Veller at the University of the Witwatersrand in Johannesburg who estimated that for South Africa 1,000 circumcision per day would need to be done for a potential demand of 2.5 million males; within five years this intervention would translate into a cost saving per year of R6.75 billion. He challenged the audience about whether we can we afford to ignore this intervention. The implications of offering MC as a standard of care also need to be considered. He wondered whether there were different types of circumcision and whether enough skin removed. What would be the best clinical methods and safety concerns? In terms of the age of circumcision, whether the intervention should target infants (where the results will only be seen in 15-20 years to come, but it is the easiest to do) or young adults (who, for example, are experiencing botched circumcisions, with 20 deaths already in South Africa this season)?

Comprehensive HIV Prevention Programmes and links to MC
David Alnwick, Regional Adviser, HIV/AIDS, UNICEF, ESARO, Nairobi
David Alnwick remarked that some of what he was going to present was based on a meeting on HIV prevention (SADC Expert Think Tank Meeting on HIV Prevention), which took place in this same venue a few months before.

HIV prevention needs to be approached from many fronts:

1- Non-sexual transmission: universal precautions, safe blood, injection safety; and his agency's responsibility, PMTCT. He commented that we know how to do this well.
2- Sexual transmission: the Maseru meeting addressed sexual transmission: knowledge of HIV status, life skills, HIV prevention in and out-of school, ABC, etc.
The meeting was not about what we should not do, but where we should double our efforts. It was agreed that we need to start with young children before they become sexually active through life skills education and also address out-of-school youth, but this is not happening enough.

Is HIV prevention is working?
It has been observed that the level of HIV infection has reversed in some places such as Uganda, Kenya, Kigali, Addis Ababa, and recently Zimbabwe, the first country in SADC (Southern African Development Community) to register significant change. In other parts of Southern Africa it is working slowly. The SADC meeting asked what to intensify. Some of the most important conclusions were:

1- Agreement to redouble efforts in reduction in multiple partners, especially concurrent partnerships. For example, the Lesotho DHS showed there are a lot of multiple concurrent partnerships.
2- MC is low in southern Africa. At the SADC meeting, the lead researcher of the Orange Farm study, Prof Bertran Auvert, presented the results.
It was noted that multiple partnerships and non-circumcision is a lethal cocktail for HIV infection in the SADC sub-region.
3-ABC: intensify efforts in existing programmes, including life skills for young people.

HIV Prevention and MC
There is the challenge of how to add MC to the range of existing HIV prevention activities. We need to find ways to avoid the risky notion that MC is a 'magic bullet'. If people do not change their behavior, the epidemic can backfire. MC can reduce HIV prevention at individual level, but there is still 40 per cent risk of infection. In Lesotho this is very high risk. MC is also not as good as consistent use of the male condom.

How to link MC and HIV prevention?

- Work with the media right now to make sure that there is responsible public debate on the issue.
- Need to include what MC is in life skills and prevention education with children. What is MC, what it is not, why it is not done? Mr. Alnwick commented that this depended on the discussion later in the day.
- At what age should MC be done? Should we use the opportunities that initiation schools offer?

- Even if MC is neutral, is there an opportunity to doing something more effective with 15-year-olds. What does the traditional rites system offer?

Estimation of the Cost and Impact of Male Circumcision in Southern Africa
Dr Gayle Martin, Futures Group
Purpose of the study: to estimate the cost and model the impact of providing MC for adult males in southern Africa (Lesotho, Swaziland and Zambia). She emphasized that this is not to replace, but to inform other consultations.

Components of the project:
1- Identify likely elements of a MC intervention in each country. MC is more than a surgical intervention, should be part of other interventions.
2- Costing the MC intervention.
3- Modeling the impact of MC. Based on mathematical calculations, to show what would happen to HIV infection rates if MC was added to the existing interventions. This also takes into account behaviour change of people.

In Lesotho, an additional component is to establish whether men who define themselves as circumcised meet the clinical definition of MC associated with protection against HIV infection.

Stages:
1- Identify the likely elements of MC- through key informant interviews with medical and traditional providers (Jul-Nov)
2- Costing of clinical and non-clinical resources (Sep-Jan)
3- Modeling of epidemiological and behavioural data. (Aug-Dec)
4- Assessment of clinical completeness of MC (Oct-Feb??)

Expected outputs:
- Cost per person circumcised under the broad definition
- Behavioural responses after circumcision (different scenarios)
- Discussion of Lesotho results

Conclusion:
In modeling the impact of MC, we also need to include MC in a comprehensive programme of HIV prevention.

Q&A and comments:
Most of the questions and discussion were centred on the evidence of MC from the Orange Farm RCT.

1- Since the follow up was 18 months, what are your concerns what may happen after 18 months?
Dirk Taljaard (DT): Delaying infection. One may argue whether we are delaying the trial long enough to delay infection. This is a common problem with all the trials. This RCT shows MC can show HIV protective effect in the short-term.

2-Was this research done with whites or only blacks? Why was it just Africans? Are there other settings where studies have been done with non-Africans? We know there are other ethnic groups who perform MC at a young age, we would like to know what the best age to perform MC is.
DT: The most important reason for the selection of a study area was to work in an area with high prevalence. If we worked in a low prevalence area, we would need a large number of people. In the trial 100% were African. There are other studies with different ethnic groups, e.g., in India. They are observational studies, so it is hard to tell and whether and how MC prevents HIV infection. For example, the four cities study showed the most important factor for HIV prevalence differences in sub-Saharan Africa was MC.

3- It seems one group was followed up more frequently than the other. What information was given?
DT: The follow up for both arms was the same. In fact, no one in the centre except the nurse who did the physical examination knew who was in which arm.

4- Re 'exit dynamics', at baseline it was obvious what the characteristics were, but not at the end of the study. What was the age of seroconvertors?
DT: The results were controlled for age. So the incidence is not based on any one specific age; the age ranged from 18 to 24 years.

5- Concern about 60% effectiveness, especially given that the study was done in a different context, but conclusions were drawn for the whole of southern Africa.
DT: Dr Taljaard's view was that the study, in fact, underestimates the impact of MC on HIV prevention. Sixty per cent protective effect means 40% were infected. In terms of generalization, there are two more trials in Uganda and Kenya, and if they find the same thing we will know the intervention is working.

6-Were the two groups let go to live as before or was there any change in behavior after circumcision? There is a tendency that participants in trials change due to counseling. How did the behaviour compare with the general population?

DT: HIV testing and counseling was offered to men in both groups, and they both received the same standard of care.
It is possible that there could have been behavioural change for trial participants making them different from the general population. The research team had done previous studies on sexual behaviour before. The Orange Farm population was not any different to other areas, e.g. Carletonville (a mining town 80 km southwest of Johannesburg), except that their HIV prevalence was higher.

7-Are there other factors that would influence the results, e.g., the group that was circumcised was not sexually active for some time?

DT: In the RCT, the only factor that changed was the number of sexual acts for the MC group, not the number of partners. In other words even with more sex they were more protected.

8- What was the relevance of the information that about a third [half in the presentation] were Sothos? We know Zulus do not circumcise; who were the 'others'? We cannot paint all people with the same paint brush.

DT: In the RCT, there was random assignment of participants regardless of age, ethnic group… Therefore, the differences in the end can be attributed to the MC intervention only. A third of the sample were Sotho (including Pedi, Tswana)

9- Comment on the Futures Group presentation: what does adult MC mean? Hope it does not pre-judge the conclusion that MC only happens in a clinic.

Session 2: Country context of MC

Chair: Advocate Borenahaborethe Sekonyela

He echoed his warning about the sensitivity of MC in Basotho culture. He was pleased that the presentations he had listened to looked at the results rather than the practicalities of male anatomy. He further commented that a man cannot describe female anatomy in the presence of woman. At this point a Mosotho woman objected to these sentiments and remarked that she, like many people had come to listen to topic of MC and HIV prevention, and that people were interested in freedom of expression. She cautioned that his warning would hinder open discussion. The Advocate retorted that every situation has rules. The focus of this meeting was not to discuss the surgical part. He commented that as David Alnwick mentioned, we need to focus on a comprehensive strategy. He argued that within initiation, MC is comprehensive.

One of the traditional leaders stood up and insisted that under Basotho custom they talk about one initiation process; what happens in hospitals is a different thing, which they were not concerned about. He concluded that we were trying to build up on what already exists.

Cultural Practices and acceptability

Dr T. Letsie, Retired Private Practitioner (works with traditional health providers)

He introduced himself as a Mosotho and from the royal family. He said he is entrusted by King Letsie II to look after the Basotho culture. His oral presentation can be summarized as follows:

- He was asked to talk about acceptability which assumed that a study has been done in Lesotho. He noted that there are no acceptability studies done in Lesotho.
- He remarked that he and Advocate Sekonyela had a royal commission to preserve Basotho culture. He emphasized as 2006 was declared the year of accelerating prevention of HIV infection, the consultation involving traditional leaders is part of that effort.
- He commented that people may wonder why there is secrecy surrounding initiation. His view is that this was part of the liberation struggle from colonialism. He noted, however, that now we can use initiation to liberate ourselves from the HIV scourge. As part of this 'liberation struggle' the Cabinet resolved in 2003 to scale up the fight against AIDS; a resolution which recognizes the role of initiation schools. It mentions that all chiefs need

to be 'HIV/AIDS competent' [was not clearly defined]. There are 1,600 chiefs, and 12,000 registered traditional practitioners (2001), and it is estimated that 10,000 young men attend at initiation schools each year.

- Whatever we do should invoke good virtues in the Basotho culture. At initiation schools boys are taught virtues such as respect for elders and caring for each other
- Initiation schools are critical in the fight against AIDS. He argued that if we are to bring in initiation schools in the mainstream fight against HIV/AIDS, we can remove the old elements of and modify them to conform to the 21st century. For example, they need to deal with the greed for money of some of the initiation schools. (At this point he said he hoped he was not stepping the line.)

Clinical/surgical MC services and Ethical and Regulatory Issues
Dr Palesa Mohaleroe, QEII Hospital

Dr Mohaleroe, (a young female doctor from QEII and involved in developing the assessment tools by WHO) first made an apology, hoping that she would not cross the line given the 'ground rules' that had been laid.

She remarked that there were challenges to providing safe MC in hospitals in Lesotho such as: the lack of competent health workers resulting in long waiting period (up to 6 months), inadequate sterile space for surgery and a general lack of financial resources. She gave the clinical definition of MC as the removal of the foreskin. She outlined the benefits of MC (hygiene, reduction of risk of penile and cervical cancer, UTI in children, STIs) and its risks (pain, sensitivity of the penile glands and risk of injury to the urethra). She stated that every parent or client has a right to correct information on MC, and the decision is based on the individual (or legal guardian of children).

Dr Mohaleroe described the process of obtaining informed consent from MC clients in a resource-limited setting: starting with group education before individual counseling in order to save time. The session includes: giving basic facts about MC and HIV counseling, cautioning against possible risk of infection after MC, emphasis on condom effectiveness and promoting HIV testing. Men are told they have a right to have their sexual and reproductive health needs met. She stressed that counselling is not about forcing clients about what to do or make decisions for them. All clients have a right to pre- and post-operational counseling and referral to other sexual and reproductive health services. The approach was to let them know about the importance of MC and HIV prevention.

She explained the importance of health workers to be able to understand issues of informed consent and confidentiality regarding MC services for adolescents. Dr Mohaleroe emphasized that MC cannot be done without informed consent. She stated that before the "age of majority" (18 years old), a parent or a responsible caregiver needs to give consent. She observed that the age of consent for MC was older that that for an HIV test. Health workers should work in the best interest of the adolescent and judge for themselves whether they can let the adolescent give informed consent.

Q&A and Comments
Q: (Mosotho lady participant) Dr Mohaleroe was thanked for taking the audience back on track regarding male circumcision and HIV prevention, given the rules. How many MCs are done at QEII?
Palesa Mohaleroe (PM): Hardly any [one per week]; currently the waiting period is 6 months. At the private doctor's office, you can have it done on demand for over R1,000.

Comment: (Traditional leader) thanked Dr Letsie for describing *'lebollo'* in the Lesotho context. While tests are in progress let us not let scientists take advantage of Sesotho culture. This is not the venue to discuss *'lebollo'*.

Q: Can the elders of Lesotho propose terminology in Sesotho that will allow us not to confuse MC and *lebollo* (initiation school) in order to approach MC and HIV protection in a culturally appropriate manner?

Advocate Sekonyela: We need to address two views: in Sesotho for the operation, it's not *lebollo*, it will be confusion. *Lebollo*, the initiation is a rite of passage. This can prevent AIDS since it addresses abstinence. Dr Lestie's question is how we can use the initiation schools to address HIV prevention. Should we call MC 'operation'?

A traditional leader: Colonialism had an impact on destroying some of the Basotho customs, e.g., traditionally if a child is sick, you just don't give a sick child Panadol, you approach the sickness in a broader way. We need to go to the core of the issue and not only look at the symptoms of HIV.

There are two groups here: the *lebollo* initiation team and the modern medicine people. They need to first meet separately and come up with strategies, and then meet together and compare their solutions.

Mosotho lady participant: With due respect, we should divorce MC and initiation; we appreciate that we should not taint our culture. At the same time we [as in Westernised people?] need to be given a chance to move forward.

Session 3: Strategies for follow up

Chair: Chief Sempe Lejaha, President of the Senate

He commented that he had nothing to say. As a chief he would listen to the people and put together his comments at the end, based on what the people have said.

Programmatic approach: some questions to be considered
David Alnwick, Regional Adviser, HIV/AIDS, UNICEF, ESARO, Nairobi
David Alnwick commented that so far there is no programmatic framework on MC among UN agencies. He issued a disclaimer that what he was going to say were his own thoughts and not UNICEF views.

He stressed the importance of the role of government in direction and leadership re: MC. The Lesotho Government has to make a decision. He commented that the debate in the morning was healthy between the traditionalists and modern people. However, there is no time to delay. He stated that his own opinion is that the trials in Kenya and Uganda will close in early 2007 and will confirm the Orange Farm study results. When that happens, the UN position will be very clear. He remarked that this is a great opportunity for HIV prevention in this region where the HIV epidemic has been serious. By the second half of 2007 the press will be full of MC, and people will demand it. The lack of a policy will be the policy (*laissez faire*) BUT doing nothing is risky. This would give room to quack MC providers without any guidance or regulation; for example, at what age to circumcise; it will have a lot of damage. He reiterated that the UN position is to get governments to think ahead of the game so that by July/August 2007 we are ready with guidelines, training, equipment…and parts of this plan can be done this year.

Programmatically, Mr Alnwick explained that a draft manual on MC has been prepared. It describes MC under local anaesthetic (LA) only, which restricts MC patients to certain ages, e.g. infant boys who can be held by a nurse; boys older than12 years old who can cooperate; and, it excludes boys aged about 2-11 years old. He further discussed what age group should be given priority in a possible MC intervention. He commented that although infant circumcision may be technically the simplest, the impact on HIV transmission will only be realized in 15-20 years. For adolescents (13-18 years old) it may be ideal to circumcise them before sexual debut. He argued that they are an age group that is likely to be receptive to behavioural change communication messages. They can also be mobilized in large numbers and potentially have high levels of acceptance. For those 18 years and older, they are likely to be already sexually active, exposed and some infected. This may reduce the public perception of the impact.

He then discussed strategies to service delivery. This could be routine, demand driven or walk-in or appointment-based. He reflected on a campaign approach to MC, where we could set a day or a week, and get local and international health workers to perform MC on a number of boys. He explained that in addition to the surgery, the male patients should also be provided with HIV prevention education and address issues of gender sensitivity and gender-based violence. This would also be an opportunity to provide other life skills. He stated that the camp approach seemed appealing where young men are sensitized about what would happen.

He observed that in Africa mass campaigns have worked in the past, e.g., with polio eradication and measles control. However, MC was more complex. Since Lesotho is committed to the Know-Your-Status campaign, people need to ask what could be the link to this campaign. He shared an example from Central Province of Kenya (Chogoria Hospital in Meru district), where they managed to provide safe MC to boys in a hospital as part of a rite of passage: "Climbing to Manhood". Boys are secluded in a hospital ward for six days and are taught about: changes in adolescence, drugs and alcohol abuse, community expectations of men, how to survive secondary education… The talks are provided by role models (both traditional and modern), peers, videos and booklets. He quoted a report by a Dr Judith Brown written in Sept 2002, who contended that their model had shown how Meru traditional circumcision teaching can be adapted to modern situation. It was concluded that

other African ethnic groups can re-examine their circumstances and modify the traditional circumcision practices to current needs.

Assessment Tools
Dr George Schmid, Department of HIV/AIDS, WHO, Geneva
In his opening remarks Dr Schmid said his first visit to Maseru was in 1989 and he was working on MC, and this time he is back to discuss MC! He commented that during that visit he was working in hospital and when he physically examined men who said they were circumcised, it was not the case.

He restated the UN position on MC for HIV prevention, that it is to prepare now while we wait for the other trial results. Like David Alnwick, his personal view was that this may be early next year. In summary: the UN is not promoting MC; it should be done with assent/consent; and wherever it is done, it should be in a safe manner. He explained that once the results of the remaining two trials are known, the UN will review the evidence with UN agencies, countries and expert consultants. Then the UN will issue guidance; if the guidance is helpful, countries will decide what to do with this information.

He asked the participants "tell us what you want as a country" if they were to scale up MC services. He then outlined the assessment tools that are available to aid this process:

1- A means of guiding safe circumcision practice: i.e., a manual which describes the MC surgical technique and pre-test, information on testing, and post-surgical follow up.
2- A means of assessing the need for, determinants (acceptability), and ability of health care services to meet the demand for safe MC: i.e., a situational analysis toolkit, which collects and analyses information collected through desk review, interviews and workshops.
3- A means of assessing the results to scale up MC: i.e., a programmatic toolkit which assesses two broad areas: health care (number of MCs, adverse event rate, HIV testing and counseling) and clients (acceptability of MC and sexual behaviour).
4- A means of assessing the impact of a decision to scale up safe MC: e.g., DHS and other surveys.

He explained that as part of the situational analysis toolkit the Service Availability Mapping (http://www.who.int/healthinfo/systems/serviceavailabilitymapping/en/) is a technique developed by WHO to evaluate the health care facilities of countries or districts: type of staffing, services and availability of equipment. Some of the data collected are: the number of staff who work at a facility and present on the day of the visit; HIV testing and provision of Nevirapine to pregnant women; if the facility offers emergency Caesarean sections; and, if it performs MC? It uses PDA (Personal Data Assistant) technology, so information is available in a timely way for analysis. A team can be trained to collect data in all health facilities, and the whole process can take about four months. For a country like Lesotho it would cost $60,000.

Dr Schmid outlined some of the challenges with operational research as follows:

- How to work with traditional male circumcisers. He pointed out that WHO only works with healthcare systems. It would be hard to regulate the traditional systems. However, he argued that there is a need to work with them to provide safe MC.
- How to scale up services: e.g., Model Centres of Excellence? How effective are some of the current programmes, e.g., Chogoria Hospital in Kenya that David Alnwick had cited. Can we use this as a model?
- He cautioned that it is unethical to increase demand and not be able to meet services.
- What will happen 'in the real world' as opposed to what happens in scientific trials: e.g., in Swaziland men come back for follow up visits after 2 days, 7 days, but do not come back after 30 days; yet this visit is important for behavioural change counseling.

Finally, he summarized the UN work plan on MC and HIV transmission, which includes:

1- Briefing packs
2- Technical guidance on clinical approaches to MC (manual)
3- Stakeholder consultation meetings (Lesotho is the first country!)
4- Develop and conduct operational research
5- Model impact of MC at population level
6- Estimate resources
7- Situational analysis survey toolkit
8- Monitoring and evaluation programmatic toolkit
9- Guidance for standard setting and accreditation.

Support for the UN work plan is provided by: US National Institute of Health (NIH); Agence national de recherche sur le sida (ANRS); UNAIDS; Bill and Melinda Gates Foundation. The programmatic support from UNAIDS, WHO, UNICEF, UNFPA headquarters and regional offices.

He concluded by again asking "Tell us what you want we will help you and guide you."

Q& A and comments

Comment: David said "if the government decides to do nothing". It is already doing something re prevention. MC is an opportunity to accelerate the proven HIV prevention methods.

David Alnwick clarified that he was not saying that the Government of Lesotho is doing nothing. He emphasized that the Government is doing something. He gave an example that if Lesotho could only circumcise 60% of 15 years olds; they would need to do about 100 operations a day. We need to start now.

A local doctor: We understood the context and did not feel that our sovereignty was undermined.

Key follow-up steps

Facilitator: Dr Limpho Maile, Director HIV/AIDS/STI, MoHSW

Although it was late in the day there was active participation from across the spectrum of the audience. It was acknowledged that although at the beginning things seemed tense ("like mixing oil and water" as one traditional leader remarked) the participants congratulated themselves for holding fruitful discussions to help fight the common problem HIV. There were many points raised, often confirmed by a number of participants. Some of the key points identified include:

1- **Synergistic collaboration of modern and traditional health practitioners in addressing MC and HIV prevention in Lesotho.** It is clear that "AIDS is killing our people" and the current prevention strategies are not entirely effective; it is important to unite and take a wholistic approach to HIV prevention and not just address "the symptoms". It was strongly agreed that both sectors have something to learn from each other and this consultation meeting was hopefully a start of a process. One traditional leader used a Sesotho expression which translates as: to make a new loin cloth you use old pieces and add new ones; which suggests the need to build on old knowledge when introducing new strategies. It was also acknowledged that a high proportion of Basotho use both modern and traditional health services.

   Although there were many nuances of the nature of this collaboration, the key points can be summed up as:

   a. Hold follow up national consultations on MC involving traditional practitioners, MoHSW, Ministry of Culture and other key stakeholders. It was agreed that the subsequent meetings should plan rather than debate on issues because during this consultation meeting time was limited and most of it was spent on presentations.
   b. Identify 'initiated' health workers who can perform MC within the initiation school setting. It was emphasized that this step needed cooperation from the traditional sector.
   c. Conduct study tours to see models of how traditional and modern branches of health services work together to ensure safe MC in other countries. Some of the participants shared their experiences of visits with Chinese counterparts (both in China and Lesotho); and Advocate Sekonyela and Dr Letsie also cited their involvement in the provision of safe MC services within the traditional initiation schools in Eastern Cape Province in South Africa. Another example is the one that David Alnwick presented on how well the collaboration between a hospital and initiation institution has worked in Meru district in Kenya.

2- Improve health service delivery and provision of safe MC.

   a. It was stressed that there is a need to improve health service delivery since currently hospitals are not coping with demand; for example, QEII does not perform MC because of the lack of capacity despite the demand.

b. It was agreed that it is urgent that capacity needs are assessed now. We need to start looking at the assessment tools presented by Dr George Schmid now. WHO is available to give training and resources to support these efforts.
c. Training in safe MC for traditional providers. For example, Advocate Sekonyela mentioned he has been to Mount Fletcher in Eastern Province, where there is a government-sponsored monitor to ensure that MC is done in a safe way at traditional circumcision camps.

3- Conduct further research on the nature of MC in Lesotho

a. It was remarked that there is evidence to show that MC works in reducing risk of HIV infection. However, with reference to the latest Lesotho DHS (Demographic and Health Survey), HIV prevalence for the circumcised was higher. A local doctor commented that respondents were not asked when the MC was done. She argued that it was possible that men had MC done when they were already infected. It may also be possible that the circumcision that was performed on them was not the total removal of the foreskin with no protection against HIV infection. We need evidence-based results to see where the difference comes from.
b. In her presentation on Futures Group studies in southern Africa, Dr Gayle Martin mentioned a study proposed uniquely for Lesotho to assess the completeness of MC. It was felt that such a study would provide important data to base decisions on.

Closing remarks

Chief Sempe Lejaha, President of the Senate

The Chief switched between Sesotho and English. He lamented that the AIDS pandemic has reached unprecedented levels in Lesotho. It is therefore time for all people who love this country to come together and fight the spread of HIV; unity is strength. He encouraged everyone to join the initiates in this fight. He commented that *lebollo,* MC is a covenant between God and His people, and therefore there is no secrecy. He asked Western medical scientists to share their research findings so that they [the Basotho traditionalists] would know the latest developments. He wholeheartedly thanked everyone for their contributions.
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Closing Prayer: Mr. Teboho Mohlabi, Lesotho Network of People Living With HIV/AIDS (LENEPWHA)

Appendix: ATTENDANCE LIST

Male Circumcision & HIV Prevention Consultation Meeting

Lesotho Sun Hotel - 25 July 2006

NAME	ORGANISATION and EMAIL ADDRESS
1. Mathabo Ntai	STI/HIV and AIDS Directorate, ntaibm@yahoo.com
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5. 'Machaka Mahoholi	STI/HIV & AIDS Directorate
6. L.C. Moholi	Consultant
7. M. Lebeko	Cabinet
8. H. Mathealira	GTZ
9. Palesa Mohalaroe	Q.E. II Hospital
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30. M. Teketsi	Lekhotla la Moetlo
31. Dr. M. Liau	Lekhotla la Moetlo

32. M. Hlobotsi	Lekhotla la Moetlo
33. M. Qothelo	Lekhotla la Moetlo
34. L. Malebapo	Lekhotla la Moetlo
35. M. Kobohoroana	Lekhotla la Moetlo
36. C. Annor-Frempong	World Bank
37. M. Ramatlapeng	CHAL
38. N. Nkuebe	Royal Palace
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40. Lineo Hotane	Multi Media Communications
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43. Litaba Rapeea	Ha-Ts'osane (Babolotsi)
44. 'Mamoliboea Tau	Berea DHMT
45. 'Mamokhosi Maqekoane	Masite – Mokhatlo oa Moetlo
46. 'Mamonkoe Nkhahle	Masite – Mokhatlo oa Moetlo
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51. Anne-Marie Fonseka	UNICEF
52. Abraham Opito	ActionAid
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75. Dr George Schmid	WHO- Geneva
76. Dr Dirk Taljaard	Progressus