



Progress in male circumcision scale-up: country implementation and research update

June 2010



World Health
Organization



UNAIDS
JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS

UNHCR
UNICEF
WFP
UNDP
UNFPA
UNODC
ILO
UNESCO
WHO
WORLD BANK

List of Abbreviations

ACHAP	Africa Comprehensive HIV/AIDS Programme
AIDS	Acquired Immunodeficiency Syndrome
BLM	Banja La Mtsogolo
BOTUSA	Botswana-USA partnership
CDC	Centres for Disease Control
CHAM	Christian Health Association of Malawi
CIDRZ	Centre for Infectious Diseases Research Zambia
DHS	Demographic and Health Survey
DMPPT	Decision Makers Programme Planning Tool
FHI	Family Health International
FLAS	Family Life Association of Swaziland
GFATM	Global Fund for AIDS, TB and Malaria
HCP	Health Communication Partnership
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System
IEC	Information Education and Communication
IMC	International Medical Corps
Jhpiego	John Hopkins Program for International Education in Gynaecology and Obstetrics
KAP	Knowledge, Attitudes and Practice
M&E	Monitoring and Evaluation
MC	Male Circumcision
MCC	Male Circumcision Consortium
MOH	Ministry of Health
MOH&CW	Ministry of Health and Child Welfare
MOH&SW	Ministry of Health and Social Welfare
MOVE	Models for Optimising the Volume and Efficiency of MC services
MSI	Marie Stopes International
NAC	National AIDS Council/Commission
NGO	Non Governmental Organization
OR	Operations Research
PEPFAR	The US President's Emergency Plan for AIDS Relief
PSI	Population Services International
VCT	Voluntary Counselling and Testing
QA	Quality assurance
QI	Quality Improvement
RCT	Randomized Control Trial
RHRU	Reproductive Health and HIV Research Unit
SANAC	Southern African National AIDS Council
SRH	Sexual and Reproductive Health
TOT	Training of Trainers
TRAC Plus	Treatment Research AIDS, TB and Malaria and other epidemics
UNAIDS	Joint United Programme on HIV/AIDS
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
USG	United States Government
UTH	University Teaching Hospital
WHO	World Health Organization
ZNFPC	Zimbabwe National Family Planning Council

Introduction

In 2007, WHO/UNAIDS recommended that male circumcision be included in the HIV prevention package. Thirteen Southern and Eastern African countries with high HIV prevalence, low levels of male circumcision and generalized heterosexual epidemics have been identified as priority countries for male circumcision scale-up, these are: Botswana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Rwanda, South Africa, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe. These countries have been engaged in developing programmes for male circumcision implementation and are at various stages of programme scale-up.

Ten key elements have been identified as critical to male circumcision programme scale-up, these include: leadership and partnerships; situation analysis; advocacy; enabling policy and regulatory environment; strategy and operational plan for national implementation; quality assurance and improvement; human resource development; commodity security; social change communication and monitoring and evaluation. These are outlined in full in the Operational guidance for scaling up male circumcision services for HIV prevention, WHO and UNAIDS, 2008 which can be accessed at http://www.who.int/hiv/pub/malecircumcision/op_guidance/en/index.html.

This report provides an overview of progress in male circumcision programme scale-up in all the thirteen priority countries according to the key elements. Information for each country has been contributed by focal persons from Ministry of Health, UN Agencies within countries, PEPFAR programmes including U.S. Centers for Disease Control, USAID, and other implementing agencies through regular progress reports, collaborative consultations, meetings and discussions. Service delivery statistics have been provided as much as possible from Ministry of Health reports, however, some statistics were provided by supporting agencies. Most of the information has been collected during the month of May 2010.

This report also contains a section on planned and ongoing research in the field of male circumcision for HIV prevention. We would like to acknowledge the contributions of all the study sponsors, investigators, funders and reviewers.

Any further updates, revisions or corrections can be sent to the male circumcision for HIV prevention Clearinghouse Webmaster at webmaster@malecircumcision.org

Botswana

Kenya

Lesotho

Malawi

Mozambique

Namibia

Rwanda

South Africa

Swaziland

Tanzania

Uganda

Zambia

Zimbabwe

SECTION ONE

Country
implementation
update

Botswana

Statistics:

- Population: 1.8m
- HIV Prevalence: 17.6%
- MC Prevalence: 11.2%



Leadership, partnerships & advocacy

- 1. Leadership:** MOH leading the programme. Dedicated MC coordinator appointed and district and facility level focal persons assigned. Safe MC reference group is in place for advisory, policy issues; chaired by Director of Department of HIV/AIDS Prevention and Care. Technical working group in place with all partners represented, STI unit is the secretariat. NAC supports resource mobilization.
- 2. Partnerships:** WHO, UNAIDS, ACHAP, CDC/BOTUSA, I-Tech, Jhpiego, PSI. Partners provide financial, human and technical support resources.
- 3. Advocacy:** Former President Festus Mogae is chairperson of NAC and a leading figure in the 'African champions for HIV prevention initiative'. He led adoption of MC as additional HIV prevention strategy in Botswana. Sensitization of political (Cabinet, MPs) and social leaders, media, civil society organizations, private practitioners, health care providers, medical aid schemes and public done in 2009.

Situation analysis

Rapid situation analysis of health facilities conducted by government and partners in 2007. Results informed the development of the national safe male circumcision additional strategy for prevention of HIV/AIDS.

In-depth needs assessment of 51 public and private facilities ability to expand and strengthen safe MC services conducted in 2008/9 which informed the development of the national operational plan for scaling up safe male circumcision in Botswana: 2011 – 2015. Situation analysis of traditional healers also conducted.

Policy and regulatory framework

MC has been incorporated into existing HIV prevention policy, approved by cabinet.

Strategy and operational plan

Strategy approved by government. Phased scale-up plan to reach MC prevalence rate of 80% among HIV-ve males 0-49 years old by 2016. Six facilities selected to be strengthened as centers of excellence. DMPPT used

to derive costing and impact data. MC included in GFATM application.

Training

Safe MC training curriculum has been developed which includes a video.

By April 2010, 90 health workers trained (medical officers and nurses/social workers). Team of master trainers from I-TECH trained by MOH. Currently decentralized training being conducted in the centers of excellence.

Traditional healers HIV training curriculum has been developed with safe MC.

Quality Assurance

QA framework has been developed, strategy being developed. WHO MC QA guide and toolkit have been adapted and the standards adopted. Team of QA facilitators were trained at a WHO workshop in September 2009. Twenty eight focal persons in centers of excellence trained on QA. External quality assessments conducted at four centers of excellence in February 2010. Internal QA assessments ongoing.

Service delivery

Scaling up of service delivery started in April 2009 with MC services integrated into existing HIV prevention services. Thirty five public health facilities are performing MC including the six centers of excellence, seven public clinics and a few privates.

CDC/ACHAP/WHO supported the MOH to provide mass MC services in July 2009 for initiates in the Kgatleng district. 1321 initiates were counseled and offered HIV testing; 88.5% were tested, 96.2% circumcised, 3.8% excluded with 2% mild to moderate adverse events. All initiates were reviewed 24-48 hrs post-MC.

Service delivery statistics:

MCs done from January 2009 - March 2010= 6,180.

Communication

A short-term communication strategy has been developed to guide implementation and address immediate public information needs. First phase of strategy launched in April 2009 as a six-month multi media campaign; 30 billboards erected country- wide and 32 minibuses branded. TV messages, radio spots, newspaper messages were aired.

Kenya

Statistics:

- Population: 37.5m
- HIV Prevalence: 7% for the country.
15.3% for Nyanza province.
- MC Prevalence: 85% for the country.
40% for Nyanza province



Leadership, partnerships & advocacy

- 1. Leadership:** Leadership: MOH continues to provide overall technical leadership. Programme now mainstreamed into MOH annual planning process. A national and provincial task force are operational. Focal MC persons at national and district levels. Joint MC inter-ministerial task force working well.
- 2. Partnerships:** The MCC (FHI, University of Illinois at Chicago and EngenderHealth), Nyanza Reproductive Health Society, Impact Research and Development, MSI, IMC, APHIA (EngenderHealth, PATH, PSI), UNICEF, PEPFAR, WHO/UNAIDS, Gates continue to be key partners. World Bank is new partner since January 2010.
- 3. Advocacy:** Ministry of Medical Services called for continued scale up at recent stakeholder meeting. He joins voices from Prime Minister Mr. Raila Odinga who has endorsed the scale up of MC and in 2009 met with the council of Luo elders to promote MC.

Situation analysis

Situation analysis completed for Nyanza, Teso, Turkana and Nairobi provinces.

Policy & regulatory framework

MC policy is in place, called 'National guidance for MC' to enhance acceptance as some groups felt that a formal policy would suggest a mandate of MC for all men. DMPPT training done, data collection being finalized and report available soon.

Strategy and operational plan

The voluntary male MC strategic plan for next 5 years was published in April 2010; to be posted on MC Clearinghouse. Key target: all provinces to have MC prevalence of 80% by 2013. The target groups are 15-49 year olds and newborns.

A phased approach to service delivery underway, with initial programme in Nyanza; Nairobi Province now adding activities; preparatory activities in Western Province.

Training

Nearly 800 providers of various cadres have been trained.

Quality assurance

A quality improvement team has been established. At the national level the M&E team is in charge of QI/QA in the health sector and MC is integrated in this.

WHO MC QA toolkit is being used. Local adaptation underway.

QA strategy is in the strategic plan. WHO supported QI national/provincial training April 2010.

Service delivery

Service delivery scaled up in Nyanza and started in Nairobi.

MC services being offered in prisons.

Service delivery statistics:

MCs Sept 2008 - April 2010 = 110,000.

World Bank funding for pilot of 5000 MC in Teso area.

Communication

Communication strategy published. National harmonized IEC materials developed and being used in field.

Monitoring & evaluation

M&E framework in place. M&E system and forms to monitor MC uptake and adverse events developed and forms being distributed.

M&E indicators developed in line with WHO/PEPFAR recommendations.

MC incorporated into routine Kenya AIDS Information system.

Lesotho

Statistics:

- Population: 2m
- HIV Prevalence: 23.2%
- MC Prevalence: 48%



Leadership, partnerships & advocacy

- 1. Leadership:** MOH is leading the programme. MC Task Force with two sub-committees have been created: the Clinical and the Advocacy and Communications Sub-committee. MC Focal person has been identified in the MOH.
- 2. Partnerships:** PSI, PEPFAR, WHO, UNAIDS, UNICEF, UNFPA.
- 3. Advocacy:** Extensive advocacy has been done with traditional leaders. Traditional task team on MC formed.

Situation analysis

Situation analysis in formal health sector has been completed. Final report printed and ready to disseminate.

Policy & regulatory framework

MC Policy has been approved by MoH & Social Welfare minister. Policy summarized into a brief, translated in Sesotho and ready to be disseminated. MC scale up will be implemented as part of a comprehensive HIV Health Sector Prevention strategy within the health sector; this policy is also ready for dissemination.

Regulations do not allow certain task shifting to nurses.

A review is planned of regulations and processes of task shifting in Lesotho and other countries.

Strategy and operational plan

Strategy and operational plan approved; awaiting a formal launch.

Guidelines on comprehensive HIV prevention service with MC as one component have been elaborated and are now under review. Exploring ways of how to work with traditional providers.

Training

Currently training plans not yet developed.

Quality assurance

QA activities have not been started. Supervision guidelines are being adapted.

Service delivery

Formal scale-up has not started. District assessment on comprehensive HIV prevention service is to be conducted; findings to inform planning for these services. Public-private partnerships being reinforced as NGOs are involved and working in line with the national guidelines.

Communication

Development of IEC materials for HIV prevention services including MC is ongoing within the health sector.

Monitoring and evaluation

M&E framework has not yet been developed. Plans to be developed for operations research.

Malawi

Statistics:

- Population: 13.2m
- HIV Prevalence: 12%
- MC Prevalence: 21%



Leadership, partnerships & advocacy

- 1. Leadership:** The MOH is heading the MC subgroup consisting of national, multilateral & NGO representatives. A focal person for MC has not yet been appointed. High level leadership is still needed.
- 2. Partnerships:** WHO, UNAIDS, UNICEF, UNFPA, CHAM, CDC, PSI, BLM.
- 3. Advocacy:** Planning to identify a local champion for MC. Advocacy is still needed at various political and health provider levels. Advocacy meetings held in 2007; stakeholders meeting held in August 2009.

Situation analysis

Data collection for situation analysis completed. Findings and draft report presented to stakeholders; final version with recommendations awaiting approval by the Permanent Secretary. Main findings: conducive environment exists for establishment of focused MC programme.

Policy & regulatory framework

No policy or regulatory framework exists yet.

Strategy and operational plan

No strategy or operational plan exists yet.

Training

Training activities not yet developed; awaiting government policy and strategy.

Quality assurance

QA activities have not been started.

Service delivery

Formal scale-up has not started.

A local NGO, BLM is providing MC services in their clinics.

Service delivery statistics:

MCs done December 2009 - May 2010 = 1,200

Communication

A communication plan has not been developed.

Monitoring & evaluation

M&E framework not yet developed. Operations research plans to be developed.



Mozambique

Statistics:

- Population: 21m
- HIV Prevalence: 16%
- MC Prevalence: 56%



Leadership, partnerships & advocacy

- 1. Leadership:** MOH leading the programme. A national task force is in place. MC focal person identified in MOH (a surgeon working in the national referral hospital).
- 2. Partnerships:** PEPFAR, PSI, USG, WHO, UNAIDS, UNICEF, JHPIEGO.
- 3. Advocacy:** Former presidents involved in 'African champions for HIV prevention initiative' visited Mozambique in June 2009. A follow up plan of action including continuous advocacy for scaling up access to MC services has been discussed with the government of Mozambique.

Situation analysis

A health facility readiness assessment (facility rapid assessment) has been completed by Jhpiego. A KAP survey is planned for 2010.

Policy & regulatory framework

No formal MC Policy developed. A national strategy for intensifying HIV prevention activities was adopted and launched by the President of Mozambique in December 2008.

Strategy and operational plan

An operational plan for HIV prevention has been developed which includes MC. Five pilot sites have been selected. Scale-up to be initiated in 2010.

Training

A few senior staff of the MOH have been trained on MC. Training plans and materials are being developed with the support of WHO, UNAIDS and Jhpiego.

A 'training of trainers' workshop is planned for 2010 which will be followed by a cascade training of staff in all 11 provinces in 2010-2011.

Training materials for traditional circumcisers are being developed by the National Task Force, to be finalized and tested in 2010.

Quality assurance

QA training materials and methodology are being developed by the MC national task force. The material will be translated into Portuguese and adapted to the national context in 2010. Field testing and implementation of the QA program is planned for late 2010.

Service delivery

No formal scale up has started. MC services are provided on demand and as part of routine minor surgery services. MC services are delivered mainly in government hospitals. There is no known private provider of MC services in Mozambique.

Service delivery statistics:

MCs done November 2009 to May 2010: 853

Communication

A communication strategy is being developed with the support of the National task force and PSI.

Monitoring & evaluation

M&E framework for MC has been developed. Nine core MC indicators have been selected and validated.

An operations research agenda is being developed by the national task force.

Namibia

Statistics:

- Population: 2m
- HIV Prevalence: 18%
- MC Prevalence: 21%



Leadership, partnerships & advocacy

- 1. Leadership:** MOH leading the programme. A National Task Force is in place. MC focal person identified in MOH and MC Coordinator hired.
- 2. Partnerships:** WHO, UNAIDS, PEPFAR (IntraHealth, I-Tech, PSI), CDC.
- 3. Advocacy:** The 'African Champions for HIV Prevention Initiative' visited in June 2009. Advocacy done for health workers; advocacy with traditional leaders is required.

Situation analysis

Situation analysis report now available.

Situation analysis needed in terms of understanding traditional circumcisers' practices. Workshop with traditional healers is being planned.

Policy & regulatory framework

Revised draft policy submitted to MOH Management; includes task shifting of surgical tasks to nurses.

This draft policy available and guiding piloting programme.

Strategy and operational plan

Strategy has been developed and being rolled out in a limited number of pilot sites; plans under development. Costing and impact data for the national strategy was derived by using the DMPPT, but DMPPT to be redone given new information.

Training

Task Force developed MC training curriculum & adding to VCT curriculum. Two MC trainings have been conducted in 2009; 1 in 2010. Piloting in selected health facilities. Also MC project management course with hospital management staff at pilot sites.

Quality assurance

QA training will be included in the pilot programme that is underway; trainers follow up trainees.

Service delivery

Formal scale-up not yet started but at pilot sites service delivery underway.

Five pilot sites have been identified. Three sites are in operation. Three dedicated MC teams (MD, Nurse) hired to mitigate HR constraints. Assessment of five facilities to determine feasibility of introduction of volunteer programme done.

Service delivery statistics:

MCs done August 2009 to May 2010=340.

Communication

Communication strategy at final stage of approval.

MC communication materials are being produced. Concerns about matching rise in demand with supply

Monitoring & evaluation

M&E system, database and tools developed, applied and revised based on pilot site experience.

No plans in place yet for operations research.

Rwanda

Statistics:

- Population: 9.3m
- HIV Prevalence: 3%
- MC Prevalence: 12%



Leadership, partnerships & advocacy

- 1. Leadership:** NAC (CNLS) coordinates and leads multi-sectoral approach; MOH responsible for MC as a surgical intervention in health facilities & ensure norms and standards. TRAC plus responsible for MC within HIV. Technical Working Group (TWG) since 2008 as part of National HIV prevention TWG; with sub groups on cost and impact. MC focal person appointed and is located in TRAC plus & CNLS.
- 2. Partnerships:** WHO, UNAIDS, UNICEF. USG, Jhpiego, civil society organizations especially youth.
- 3. Advocacy:** Symposium on cost effectiveness of paediatric MC in 2007. National advocacy campaign conducted in September/October 2008.

Situation analysis

Facility readiness assessment completed. Data is being analysed, report expected December 2009.

KAP survey ongoing - to inform strategy plan development.

One challenge is the mobility of human resources

Policy & regulatory framework

MC integrated in National HIV prevention policy; MC specific policy under discussion. DMPPT meeting planned

Strategy and operational plan

MC draft national strategy awaiting final approval; MC included in National Strategic Plan. Formal implementation strategy not yet available. National guidelines (norms and standards) for implementation developed; awaiting final approval.

DMPPT: Guidelines in the process of development from decision makers based on policy scenarios that consider resources currently available for MC or the prevention key result in the National Strategic Plan; one scenario to be selected and next steps for operational plans to be developed.

One challenge is the development of a scale up plan.

Training

Two programme managers trained; six National trainers; site staff trained: 69 nurse/counsellors, 17 providers.

Training and capacity building of health workers from army health services in Kanombe and Kaduha conducted in September 2009.

Quality assurance

QA framework and structure not yet developed.

Service delivery

Four sites supported by Jhpiego. Ongoing implementation of service delivery in military facilities.

Joint MC implementation planned in 2 districts with UNICEF, WHO UNAIDS.

Service delivery statistics:

MCs done October through to May 2010 = 542.

Communication

Communication through Rwanda Health Communication Centre. TRAC Plus has targeted all 30 district mayors to include MC in their HIV/AIDS control plans.

One challenge is the misconceptions about MC in the general population.

Monitoring & evaluation

National M&E plan for HIV/AIDS (2009-2012) ongoing.

South Africa

Statistics:

- Population: 48.5m
- HIV Prevalence: 18.1%
- MC Prevalence: 35%



Leadership, partnerships & advocacy

- 1. Leadership:** MOH is leading with SANAC and Programme Implementing Committee; Deputy President is Chair of SANAC and there is a MC focal person in MOH. A national multi-sectoral taskforce on MMC, chaired by the Chief Director of HIV and AIDS, will be constituted and serve as the technical and advisory body. Provincial and district MMC Taskforces, under the leadership of the Provincial heads of health, will be formed to spearhead and coordinate the safe male circumcision roll-out in provinces.
- 2. Partnerships:** RHRU, Jhpiego, UNAIDS, UNICEF, WHO, Futures Group, CDC/PEPFAR, SFH. The policy will be implemented in partnership with traditional leaders; faith based organizations, the public and private health sectors and other civil society sectors that should promote MC as part of their comprehensive HIV prevention response.
- 3. Advocacy:** Advocacy with different SANAC groups (men, women). Research task team involved in advocacy.

Situation analysis

A nationwide situational analysis and a review of the existing MMC research & services in South Africa are in progress. Operational lessons continue to be learnt from the MMC Project underway in Orange Farm, as a follow-up to the Orange Farm RCT.

Policy & regulatory framework

The "Male circumcision policy for HIV prevention in South Africa" provides the framework for policy makers and implementers of safe male circumcision activities; in the process of finalization. Prioritizes male 15-49 years old. Priority provinces: Kwa-Zulu Natal, Mpumalanga, Northern Cape. MMC to be provided predominantly at PHC facility in line with policy of decentralization of all public health services. Policy also respects traditional MC and will provide for strengthening of quality of traditional MC as part of public health intervention to reduce adverse events.

Strategy and operational plan

Draft strategy in place and implementation guidelines developed. DMPPT done. Plan is that all provinces should have sufficient capacity and resources to roll-out MMC according to national guidelines. Forceps guided method is primary method for MMC.

Training

Two training centres for MMC which use the Orange Farm model have been established in Pietermaritzburg (Kwa-Zulu Natal): East Boom Community Health Centre and the District hospital.

Quality assurance

Routine program evaluation shall be a component of male circumcision services for quality control and to guide the planning of services.

Service delivery

National/Provincial workshop on MMC, March 2010, including development and implementing partners. MMC guideline & other supporting documents have been finalized. Kwa-Zulu Natal province is to roll out MMC in 11 districts. Mpumalanga and Northern Cape provinces are being assisted to develop plans.

The link between the public and private sector will be improved to provide quality services collaboratively and efficiently.

Service delivery statistics:

MCs through April 2010= 18,100.

Communication

The SANAC communications technical task team has developed a communication framework for MMC that forms the basis for the development of a national communication strategy for male circumcision. Key messages have been developed and posters have been printed.

Monitoring & evaluation

Operations research will be conducted to strengthen male circumcision services and to implement effective, comprehensive HIV prevention programmes in the context of sexual and reproductive health.

Swaziland

Statistics:

- Population: 1m
- HIV Prevalence: 26%
- MC Prevalence: 8%



Leadership, partnerships & advocacy

- 1. Leadership:** MOH leading the programme. National task force includes all partners who are working on MC. Deputy director clinical services is the MC focal person and chair of the MC task force. A dedicated MC coordinator now in place in MOH.
- 2. Partnerships:** Supporting partners: WHO, UNICEF, UNAIDS, PEPFAR, FLAS, MC partnership (PSI, Jhpiego, MSI, Population Council).
- 3. Advocacy:** Current Prime Minister is strong supporter of MC.

Situation analysis

Parts of situation analysis done to inform policy development.

Policy & regulatory framework

Finalized policy on safe male circumcision for HIV prevention adopted by cabinet, official launch pending; posted on male circumcision Clearinghouse website.

Strategy and operational plan

Strategy and Implementation Plan for Scaling up Safe Male Circumcision for HIV Prevention in Swaziland finalized and printed. Posted on the male circumcision Clearinghouse website.

Training

Training is ongoing. Jhpiego/PSI have done five trainings in 2010. A total of 79 providers, 20 doctors and 59 nurses have been trained.

Quality assurance

In 2010 WHO and Jhpiego QA/QI tools merged and are to be implemented in all health facilities.

Service delivery

Additional government sites (now total six) identified to provide integrated MC services. The MC Task Force Coordinator ensures the work plans of NGO implementers are shared with the MOH. Cabinet approved MOH Accelerated Saturation Initiative. MC service delivery model piloted using volunteer physicians from American Urological Association, April-May 2010. Four volunteer physicians were placed at health facilities.

Service delivery statistics:

MCs done 2006 - March 2010 = 9,309.

Communication

The MC Programme Coordinator is increasing awareness in other sectors and has begun giving presentations to the Ministry of Education, faith-based organizations, and private sectors. From February 2010, a media campaign about MC occurred that included weekly newspaper articles and national radio spots. HPI facilitated dialogue with parliamentarians on MC. MOH worked with both Houses of Parliament who adopted a Resolution to commit to "the objective, mission and vision of Male Circumcision for HIV Prevention" in Swaziland.

Monitoring & evaluation

M&E framework is in draft form.

MC task force Sub-Research Committee which consists of programme planners, senior government officials and higher institutions of learning will be overseeing ongoing research.

Tanzania

Statistics:

- Population: 40m
- HIV Prevalence: 5.7%
- MC Prevalence: 70%



Leadership, partnerships & advocacy

- 1. Leadership:** MOH leading the programme. MC Task Force was formed in October 2007 with 25 members. MC responsibility added to IEC Head within National AIDS Control Programme in the MOH&SW
- 2. Partnerships:** NIMR, WHO, CDC, UNICEF, USAID, Jhpiego, Association of Private Hospitals.
- 3. Advocacy:** MC has been widely practiced in regions for traditional and religious purposes. There is no evidence of opposition to MC.

Situation analysis

Situation analysis has been completed. Final report available.

Traditional providers study completed. Report available.

Policy & regulatory framework

Development of specific MC policy still being discussed.

Strategy and operational plan

Draft national strategy awaiting final approval of the government. MC included in the 5 year national multi-sectoral HIV/AIDS strategic framework 2008-2012 and the health sector HIV/AIDS strategy 2008-2012.

Training

Adaptation of the WHO Manual for Male Circumcision for HIV Prevention under Local Anesthesia and the Training Manual: Counseling for Male Circumcision; it is being utilized in demonstration sites.

Total 49 MC providers trained (additional 45 to be trained in May 2010).

Quality assurance

Standards for services providing male circumcision under local anesthesia, a site start-up guide, a 3-day facility orientation and operations guide developed for demonstration sites; to be adapted for country use.

Service delivery

An additional demonstration site providing MC services set up (total four).

MOVE gradually being introduced at these four sites.

Service delivery statistics:

MCs done October 2009 through March 2010 = 3,148.

Communication

Client education materials (flip chart, brochure, poster, flyer) developed; demand creation materials still in draft but will target men, adolescents and their guardians, female partners.

Monitoring & evaluation

M&E tools for male circumcision have been developed for demonstration sites; to be adapted for country use.

Uganda

Statistics:

- Population: 32m
- HIV Prevalence: 6.4%
- MC Prevalence: 25%



Leadership, partnerships & advocacy

- 1. Leadership:** National Task Force for MC is in place.
- 2. Partnerships:** Supporting partners: WHO, UNAIDS, UNICEF, UNFPA, PEPFAR (USAID and CDC), FHI and Makerere University School of Public Health. Multiple development partners available but awaiting firm plans to become active.
- 3. Advocacy:** No local champions identified. There is increasing acceptance for MC for HIV prevention but advocacy still needed with parliament members.

Situation analysis

Situational analysis to determine the acceptability and feasibility of medical MC promotion in Uganda has been completed and disseminated. Mapping survey of medical MC services completed.

Policy & regulatory framework

Policy approved in March 2010.

Strategy and operational plan

Planning for strategy development. Consultations ongoing on which MC surgical technique to adopt and which cadres to do surgery. Results of DMPPT under discussion to inform target group in strategy.

Training

Nationwide training not yet initiated. Health workers from a selected number of facilities are being trained at the Rakai Health Sciences Research Project.

Quality assurance

QA activities have not yet initiated.

Service delivery

Formal scale-up not yet started. Scale up expected after the launch of the Policy in 2010.

Military willing to offer services.

Communication

Communications strategy approved, May 2010. MC awareness campaigns ongoing. IEC materials developed.

Monitoring & evaluation

Monitoring and evaluation framework has not yet been developed. Operations research is ongoing in specific sites.

Zambia

Statistics:

- Population: 12m
- HIV Prevalence: 14.3%
- MC Prevalence: 13.1%



Leadership, partnerships & advocacy

- 1. Leadership:** MOH leading the programme. National Task Force in place. A dedicated National MC Coordinator has been appointed.
- 2. Partnerships:** Supporting partners: UTH, MC Partnership (PSI, Jhpiego, MSI, Population Council) and CIDRZ.
- 3. Advocacy:** Ongoing advocacy. High level meeting July 2009.

Situation analysis

Situational analysis including acceptability and health facility readiness assessment has been completed; due to be printed.

Policy & regulatory framework

Cabinet memo incorporating MC in HIV prevention has been approved. The agreement is not to have a stand alone policy but rather part of comprehensive HIV policy.

Looking at task shifting and working with traditional providers.

Strategy and operational plan

Dissemination of the national MC strategy and implementation plan 2010-2020 to all districts in North Western, Copper Belt and Eastern Provinces.

DMPPT data collection completed and due for analysis.

Training

Partnership with Jhpiego and UTH for training. Approximately 350 providers trained.

Training of providers ongoing. MC training manuals adapted; national MOH MC training manuals finalised.

Quality assurance

QA strategy in place. QI team present at national level. WHO QA guide and toolkit to be implemented.

MC health worker certification framework developed with Medical Council of Zambia.

Service delivery

Service delivery sites adopting MOVE principles

Service delivery statistics:

MCs to January 2010= 20,779:

Public - 10,476

NGO - 9,566

Private - 737.

Communication

Communication activities being implemented. Media programmes incorporating MC; men's health kit.

Monitoring & evaluation

Reporting tools and system put in place to allow MC implementers to report to MOH.

Provincial and district disaggregated annual targets made and provided to provincial medical officers

Ongoing OR through university teaching hospital.

Zimbabwe

Statistics:

- Population: 12m
- HIV Prevalence: 13.6%
- MC Prevalence: 10%



Leadership, partnerships & advocacy

- 1. Leadership:** Ministry of Health and Child Welfare is providing leadership with an appointed Focal Person leading the MC programme. MC Task Force with subcommittees formed. Steering Committee and three Technical Working Groups are in place. The Ministry continues having MC Steering Committee meetings comprising of different partners. Focal person for MC and condom programming identified in the MOH&CW.
- 2. Partnerships:** Supporting partners: ZNFPC, WHO, UNFPA, PSI, church organizations.
- 3. Advocacy:** Ongoing sensitization and involvement of traditional circumcisers, medical practitioners, provincial health teams and community stakeholders. A one day workshop was conducted in February 2010 with Provincial Medical Directors to advocate for the service delivery models for the roll out phase of male circumcision. Two stakeholders meetings were held to sensitize the key stakeholders in two provinces.

Situation analysis

MC situation analysis conducted and results disseminated to stakeholders.

Policy & regulatory framework

MC policy finalized in October 2009. Launched in November 2009.

Strategy and operational plan

The country is in the process of developing a male circumcision 5-year Strategy and Implementation Plan. The Strategy is expected to be complete by June 2010.

The DMPPT is in progress and expected to be completed by end May 2010.

Training

No trainings undertaken in this quarter. Established central level training site at ZNFPC Harare & 2 other training sites have been set up. National TOT was conducted previously for 18 national trainers consisting of surgeons, nurses and counselors. One hundred and four nurses and doctors trained. Training materials have been adapted from WHO training guidelines.

Quality assurance

Developed a quality assurance MC counselling tool to improve the quality of MC services.

Service delivery

Service delivery statistics:

MCs done to March 2010 = 4,361.

Communication

Developed 10 billboards to increase awareness and visibility of MC services. Developed flyers targeting youth, parents and guardian in an effort to increase awareness of the services to youth and parents.

Monitoring & evaluation

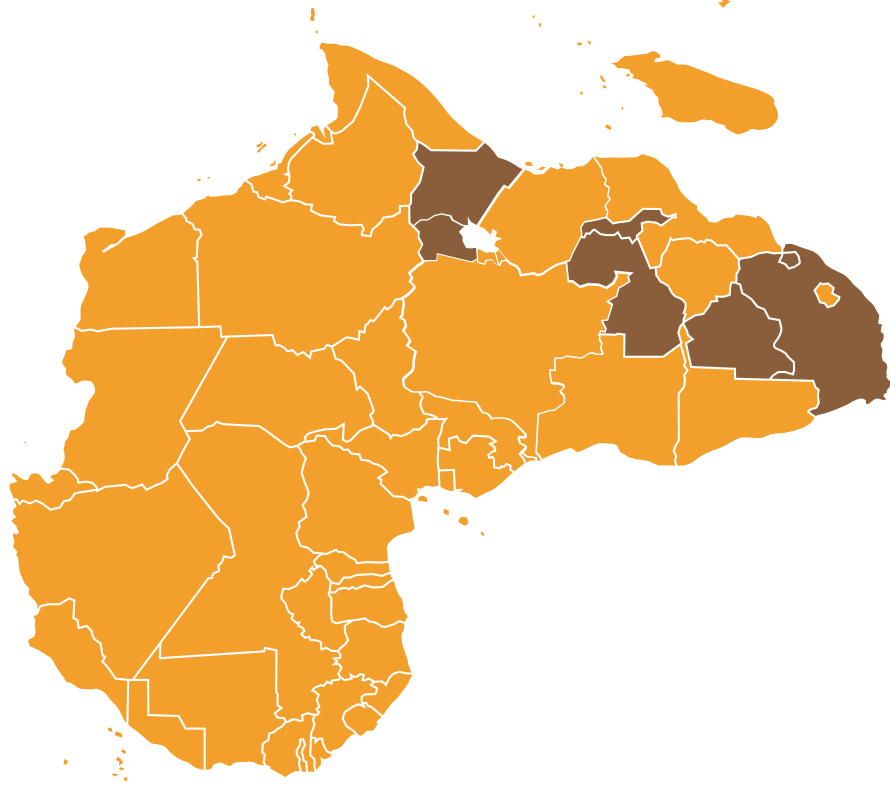
Evaluation of the pilot phase of MC was conducted and this will inform the strategy.

SECTION TWO

Planned and ongoing research on male
circumcision for HIV prevention

Introduction:

Since the three randomized controlled trials demonstrated reduced risk of female-to-male transmission of HIV, a variety of research has been undertaken or is planned, to continue to inform the scale-up of male circumcision services. This section provides a summary of research related to male circumcision as of June 2010. The contributions of all the study sponsors, investigators, funders and reviewers of this overview are gratefully acknowledged.



Title of study	Location	Sponsor/funder	Type of study	Aim/objectives	Study population	Status
Behaviour, knowledge/attitudes/beliefs						
A prospective study of behavioral risk compensation related to male circumcision (MC) as an HIV prevention method	Kisumu East, Kisumu West and Nyando Districts, Kenya	University of Illinois at Chicago & Nyanza Reproductive Health Society (The Bill and Melinda Gates Foundation through the male circumcision Consortium)	Observational prospective study. Follow up at 6, 12, 18, and 24 months after circumcision/enrolment.	Evaluate sexual risk behaviour 1a) changes in sexual risk behaviour b) sexual function and satisfaction c) perception of HIV risk; 2) evaluate perceptions of circumcision in long-term female partners of circumcised participants.	1600 Circumcised and 1600 matched uncircumcised males aged > 18 years; long-term female partners of circumcised males	Recruitment completed. Follow-up ongoing
Impact of male circumcision on sexual risk behaviours	Kisumu Municipality, Kenya	University of Illinois at Chicago & Nyanza Reproductive Health Society (The Bill and Melinda Gates Foundation through the male circumcision Consortium)	Series of 3 cross-sectional random-household studies conducted every 2 years	Changes in perceptions, knowledge and beliefs about male circumcision and HIV over time. HIV and male circumcision prevalence following introduction of male circumcision services in general population over time.	Men and women aged 15-49 yrs, 1,000 male and 1,000 female participants in each study cycle (total n=6,000)	Baseline survey completed
Prospective study of behavioral risk compensation post male circumcision	Zambia	The population council (Bill & Melinda Gates foundation through male circumcision partnership)	Observational prospective study at baseline, 6, 12 and 24 months post enrollment.	Evaluate: a) changes in sexual risk behavior over time among men and women b) changes in age and use of condoms at first sex c) changes in women's ability to negotiate safe sex.	Random sample of 1750 males and 1650 females 15-29 years; oversample of males 15-24 years and females 15-19 years will be obtained to assess changes in risk behavior among young adults specifically. Qualitative samples of 30 male and female study participants.	Recruitment July/Aug 2010
Evaluation of the timing of the resumption of sexual activity post-male circumcision	Zambia	The population council (Bill & Melinda Gates foundation through male circumcision partnership)	Observational: Baseline and 6 weeks post-male circumcision	Measure the prevalence of unprotected sexual behavior during the healing period post-male circumcision.	225 men interviewed immediately prior to male circumcision and 6 weeks post male circumcision; validation of reporting of sexual activity with marital partners of male participants	Recruitment June/July 2010
Evaluating methods for improving outcomes for women of male circumcision clients who are HIV+ or clients who refuse HIV VCT	Zambia	The population council (Bill & Melinda Gates foundation through male circumcision partnership)	Observational formative assessment	To reduce women's HIV risk from HIV+ men who have recently have undergone male circumcision by 1) assessing and improving knowledge of HIV risk 2) improving adherence to sexual abstinence among partners of male circumcision clients during post-operative healing period and 3) evaluate methods for improving HIV VCT among male circumcision clients.	Male circumcision clients and their sexual partners	Protocol under development

Title of study	Location	Sponsor/funder	Type of study	Aim/objectives	Study population	Status
Information, Circumcision and HIV Prevention	70 Villages in Kuntamanji, Malawi	University of Michigan with the University of Malawi Chancellors College.	Randomized controlled trial	Estimate behavioural responses to information about male circumcision protective effect and HIV.	1,200 circumcised and uncircumcised men	Ongoing
Communications						
Text messaging to improve adherence to postoperative clinic appointments and reduce early resumption of sexual intercourse	Kisumu East, Kisumu West and Siaya, Kenya	University of Washington, Fogarty through University of Illinois Chicago & Nyanza Reproductive Health Society	Randomized controlled trial	Assess the efficacy of text messages for increasing adherence to 7 day post surgical follow up visit and for reducing the proportion of men who resume sex before 42 days post-operatively.	Men aged 18 years+ who get circumcised at any of four study clinics	Submitted to Institutional Review Boards (IRBs)
SMS messaging to Improve adherence to postoperative clinic appointments and to reduce early resumption of sexual intercourse after male circumcision	Zambia	The population council (Bill & Melinda Gates foundation through male circumcision partnership)	Randomization to different doses of SMS messaging, including to sexual partners	Assess the efficacy of text messages for increasing adherence to the 7 day post-surgical follow-up visit and for reducing the proportion of men who resume sex before 42 days post-op.	Male circumcision clients and their sexual partners	Protocol under development
Communicating partial protection of male circumcision	Kisumu East and Kisumu West districts in Nyanza Province, Kenya	Family Health International (The Bill and Melinda Gates Foundation through the male circumcision Consortium)	Phase 1: formative qualitative in-depth interviews Phase 2: qualitative interviews/focus groups to test and refine initial messages Phase 3: quantitative message testing using post-test only randomized design	1) Insight into men's and women's understanding of partial protection of voluntary medical male circumcision 2) Messages that effectively communicate partial protectiveness of voluntary medical male circumcision that can be incorporated into male circumcision communication strategies in Nyanza Province, Kenya.	- circumcised and uncircumcised men aged 18-39 years - women of reproductive age 18-39 years	Underway, completion December 2010

Title of study	Location	Sponsor/funder	Type of study	Aim/objectives	Study population	Status
Community impact						
Effect of male circumcision on HIV at population level: demonstrate that the roll-out of male circumcision (MC) has an impact on the spread of HIV at a community level.	Orange Farm township, South Africa	Agence nationale de recherches sur la sida et les hépatites virales (ANRS)	Phase 4 study, with 3 cross sectional surveys among the general population	Assess the impact of the rollout of a male circumcision intervention in the community on: a. knowledge, attitudes and practice regarding male circumcision b. sexual behaviour and condom use c. the spread of HIV, HSV-2 and Human papilloma virus.	Males 15 years and older in Orange Farm township	Underway: Completion in 2013
Effects of rapidly achieving high level male circumcision coverage on HIV incidence	Swaziland nationally	CDC/PEPFAR and Ministry of Health	Longitudinal cohort(s)	1) Acceptability/feasibility/uptake of accelerated saturation approach; 2) risk compensation; 3) reduced HIV incidence.	Groups for incidence monitoring being determined	Protocol under development; baseline expected to be initiated before year-end 2010
Community effects of male circumcision on HIV Epidemic	Uganda	The Bill and Melinda Gates Foundation and National Institutes of Health through Rakai Health Sciences Institute	Phase 4 longitudinal study, 5 years follow-up	Assess acceptability, sexual risk behaviours and attitudes towards and comprehension of male circumcision. Assess the long term effectiveness of male circumcision for HIV (incidence) and STI prevention at the population level.	1) 15,000 community cohort participants age 15-49 years	Ongoing
Costing						
Costing and impact of male circumcision in Uganda and South Africa	Health facilities throughout Uganda, South Africa	USAID through the Health Policy Initiative	Costing analysis and modelling with primary data collection	Calculate the unit cost of delivering male circumcision and estimate the impact of various policy approaches to scaling up male circumcision.	27 health facilities in Uganda and 20 health facilities in South Africa	Data collection completed, initial analysis of data underway
Estimating the costs, cash flow analysis and impact of male circumcision in Kenya and Zimbabwe	Health facilities throughout Nyanza province, Kenya and Zimbabwe	USAID via Health Policy Initiative and UNAIDS through the Technical Support Facility, South Africa	Costing analysis and modelling with primary data collection	Calculate the unit cost of delivering male circumcision and estimate the impact of various policy approaches to scaling up male circumcision.	30 health facilities in Nyanza province and 5 facilities in Zimbabwe	Data collection completed, initial analysis of data underway
Scaling up male circumcision programs: demand responses to prices	Kawale (Lilongwe) Malawi	University of Michigan and Marie Stopes International with the University of Malawi College of Medicine	Randomized controlled trial	Estimate the elasticity of demand to prices of adult male circumcision.	1800 uncircumcised adult men	Ongoing

Title of study	Location	Sponsor/funder	Type of study	Aim/objectives	Study population	Status
Devices						
The ShangRing: A novel male circumcision device for HIV prevention	Homa Bay District Hospital, Kenya	EngenderHealth and Weill Cornell Medical College; Kenya National AIDS Control Programme and Ministry of Health.	Non-comparative pilot study	1) Assess safety & efficacy of the Shang Ring for adult male circumcision in Kenyan men to determine if safe for use in larger studies in Africa; 2) assess acceptability among providers and satisfaction among men being circumcised.	40 HIV-negative men aged 18 to 54 years seeking male circumcision	Completed. Data analysis & manuscript writing are underway
The ShangRing: Evaluation of healing at three time intervals and potential for spontaneous detachment	Homa Bay District Hospital, Kenya	Bill & Melinda Gates Foundation through FHI with EngenderHealth and Weill Cornell Medical College, University Teaching Hospital, Lusaka, Kenya National AIDS Control Programme and Ministry of Health.	Non-comparative safety and acceptability study	1) Assess healing after removal of the Shang Ring at three different time points, 7, 14 and 21 days; 2) determine whether the device will spontaneously detach if removal is delayed for longer than the currently recommended time of 7-10 days, up to a maximum of 21 days.	50 HIV-negative men aged 18 to 54 years seeking male circumcision	Submitted for IRB review.
Comparison of the Shang Ring with conventional surgical methods	1) Zambia: Lusaka, University Teaching Hospital / Society for Family Health, Lusaka; 2) Kenya: Homa Bay District Hospital, Kenya	Bill & Melinda Gates Foundation through Family Health International with EngenderHealth and Weill Cornell Medical College; University Teaching Hospital, Lusaka, Kenya National AIDS Control Programme and Ministry of Health.	Randomized controlled trial	1) Compare the pain and acceptability of the Shang Ring procedure with the forceps guided surgical circumcision technique (Kenya) and the dorsal slit technique (Zambia); 2) compare the safety and the course of wound healing, including the time to complete healing, between the Shang Ring adult male circumcision procedure and the standard surgical circumcision procedures; 3) compare the ease of the Shang Ring method versus standard circumcision surgical procedures.	400 HIV-negative men aged 18 to 54 years seeking male circumcision: 200 Shang Ring and 200 standard surgical procedures	Submitted for IRB review.
Shang ring	Uganda	National Institutes of Health	Safety and acceptability	To assess Shang Ring safety and acceptability compared with dorsal slit.	250 HIV-negative men, 15-49 years old	Planned

Title of study	Location	Sponsor/funder	Type of study	Aim/objectives	Study population	Status
Formative research						
Assessing methods to improve the self-reporting of male circumcision status among men and their partners	Zambia (Lusaka and rural sample) and Swaziland (Mbabane, Manzini)	The population council (Bill & Melinda Gates foundation through male circumcision partnership)	Randomized to 3 study arms: (1) verbal description (2) verbal description + illustration, (3) computerized self-administration with verbal description and illustration	To evaluate methods for improving the reporting of circumcision status: a) assess the validity of self-reports and partner-reports of MC status; b) investigate whether illustrations of a circumcised & uncircumcised penis improves accuracy of MC reporting.	Men aged 18–34 years and their female partners, & adolescent boys aged 13–17 years.	Completed May 2010
Assessment of informed consent process and participant understanding	Zambia, Swaziland	The population council (Bill & Melinda Gates foundation through male circumcision partnership)	Qualitative and quantitative assessment of client comprehension	(1) Make recommendations for standardizing and streamlining the informed consent process while adhering to WHO, UNAIDS, and other accepted informed consent guidelines; (2) to assess male client's comprehension of key concepts in the informed consent process.	Key informants; parents/guardians; adult and adolescent males; adult and adolescent males undergoing male circumcision	Zambia completed April 2010. Swaziland underway
Healing						
A study of post-surgical wound healing	Universities of Nairobi, Illinois, and Manitoaba Research and Training Center, Kisumu	University of Illinois at Chicago & Nyanza Reproductive Health Society (The Bill and Melinda Gates Foundation through the male circumcision Consortium)	Longitudinal follow-up of clients post-surgery to 6 months	To assess progression of wound healing and keratinization; differences in wound healing by HIV status, CD4 count, age, resumption of sex, condom use and other factors.	Men >15 years circumcised at the UNIM Research and Training Center, Kisumu	Protocol under development
Healing and keratinization	Rakai District Uganda	The Bill and Melinda Gates Foundation through the Rakai Health Sciences Project (RHSP)	Prospective research. Weekly visual and dermoscopic examination of the surgical wound	To determine the time required for complete healing and keratinization of scar tissue by HIV status. In HIV-infected men, determine if viral load is increased by stress/ inflammation of surgery and measure HIV shedding from surgical wound.	100 HIV-positive and 100 HIV-negative men	Underway

Title of study	Location	Sponsor/funder	Type of study	Aim/objectives	Study population	Status
Human resources						
Responding to the human resource capacity development and training needs	Homa Bay, Rachuonyo, Rongo and Nyando districts in Nyanza, Kenya	EngenderHealth (The Bill and Melinda Gates Foundation through the male circumcision Consortium)	Desk review; facility assessments; in-depth interviews with key informants; focus group discussions with sexual and reproductive health and HIV program managers & health workers	1) Determine gaps in human capacity and training needs related to male circumcision; 2) identify human resource and training barriers/facilitating factors to introducing male circumcision services; 3) recommendations regarding strategies to address current human resource and training gaps to support male circumcision roll-out.	Not Applicable	Finalizing study report.
Private sector health providers assessment	Nyanza Province, Kenya	Family Health International (The Bill and Melinda Gates Foundation through the male circumcision Consortium)	Cross-sectional study	1) Description and clear understanding of costs associated with bringing facilities and employees to minimum standards for male circumcision provision; 2) actual costs associated with providing male circumcision services according to WHO minimum package; 3) recommendations for strategies to integrate private male circumcision service provision with MOH services.	Survey and observations of private-for-profit, non-governmental and faith-based organization health facilities	Completed
Assessment of non-physician clinicians performing male circumcision	Homa Bay, Rachuonyo, Rongo and Nyando districts in Nyanza, Kenya	EngenderHealth (The Bill and Melinda Gates Foundation through the male circumcision Consortium)	Prospective study	1) Male circumcision surgical and post-operative procedures performed by trained non-physician clinicians at regular facilities workplace; 2) male circumcision surgical outcomes at 7-days and 60-days post-surgery; 3) patient satisfaction with male circumcision services provided by non-physician clinicians at 7-days and 60-days post-surgery; 4) costs associated with providing male circumcision by non-clinician physicians.	2,530 male circumcision procedures - males aged 13-54 years	Underway, completion September 2010
Assessment of training	Uganda	PEPFAR	Observational study	Process assessment with pre and post training evaluations and monitored surgeries.	Trainees	Ongoing (280 completed)
Assessment of physicians and clinical officers	Uganda	Center for Communication Programs/USAID	Observational study	Safety and time required for surgery.	Men 15- 49 years old	Ongoing

Title of study	Location	Sponsor/funder	Type of study	Aim/objectives	Study population	Status
Infant male circumcision						
Infant male circumcision in Gaborone, Botswana, and surrounding areas: Feasibility, safety and acceptability	Gaborone, Mochudi and Molepolole, Botswana	PEPFAR / Centers for Disease Control Botswana-USA Partnership (BOTUSA)	Prospective randomized trial of two methods for infant male circumcision.	Ascertain: 1) actual uptake / acceptance of infant male circumcision and determine parental factors associated with uptake; 2) feasibility (including cost) and safety of infant male circumcision using Mogen clamp versus Plastibell; 3) parental satisfaction with the results of circumcision.	300 male infants (150 in each arm) in Botswana	Enrolling with approximately 190 of the 300 infants enrolled.
Evaluation of safe voluntary infant medical male circumcision in selected facilities in Nyanza Province, Kenya (The Mtoto Msafi Project)	Kisumu East, Kisumu West and Siaya districts in Nyanza Province, Kenya	University of Illinois at Chicago & Nyanza Reproductive Health Society (The Bill and Melinda Gates Foundation through the male circumcision Consortium)	Case control study	1) Compare beliefs and attitudes about circumcision between parents choosing infant male circumcision and those declining the procedure; 2) identify facilitators and barriers to uptake of infant male circumcision; 3) measure adverse event rates associated with infant male circumcision.	Consenting parents in selected health facilities. Recruiting 300 parents accepting infant male circumcision and 300 parents declining infant male circumcision	Underway
Evaluation of safety and acceptability of neonatal circumcision using Gomco, Plastibell, and Mogen methods	Lusaka, Zambia	Centers for Disease Control, Centre for Infectious Disease Research in Zambia and the University Teaching Hospital Department of Urology	Prospective randomized trial	To test the hypothesis that the Gomco and Mogen clamps methods will be safer than the Plastibell method in Zambia.	600 neonates (450 from the University Teaching Hospital, Lusaka and 150 from a Matero reference clinic)	Underway
Molecular microbiology, immunology						
Genital anaerobes, inflammation and HIV risk	Rakai District Uganda	USA National Institutes of Health / National Institutes of Allergy and Infectious Diseases	Molecular microbiology, immunology and epidemiologic observational study	AIM 1. To assess the correlation between the burden of genital anaerobes and inflammatory markers in HIV-uninfected men and their female partners.	100 HIV-negative married men in the intervention arm who received circumcision at enrollment and 100 men in the control arm who received circumcision delayed for 24 months, and their linked female partners (n = 200)	Specimen analysis to start in July, 2010

Title of study	Location	Sponsor/funder	Type of study	Aim/objectives	Study population	Status
Genital anaerobes, inflammation and HIV risk	Rakai District Uganda	USA National Institutes of Health / National Institutes of Allergy and Infectious Diseases	Case-control design	AIM 2. To assess the associations between genital anaerobes, inflammatory markers and risks of HIV acquisition in men and women. AIM 3. In HIV-discordant couples assess the associations between genital anaerobic burden/inflammatory markers and the risk of HIV transmission/acquisition. AIM 4. Estimate the mediating role of genital anaerobes/inflammation in the efficacy of circumcision for HIV prevention in men (if MC is shown to decrease genital anaerobes and inflammation and they are associated with acquisition/transmission.	AIM 2. Among the 194 HIV-seroconverters (cases) and a randomly selected group of persistent HIV-seronegative controls. AIM 3. 310 HIV-discordant couples. AIM 4. N/A	Specimen analysis to start in July, 2010
Circumcision: HIV, STIs and Behaviours in a RCT and Post-RCT surveillance: In situ analysis of HIV transmission in foreskin	Johns Hopkins University Laboratory, Baltimore, MD, USA	USA National Institutes of Health / National Institutes of Allergy and Infectious Diseases	Basic science	1) To envisage the earliest events and virus-host cell interactions in transmission by analyzing foreskins from apparently HIV-uninfected men enrolled in Rakai circumcision trials; 2) to determine the bases for observed low rates of female-to-male transmission by in situ studies of foreskins from men who are in discordant relationships with HIV positive women and are highly exposed but remain serologically and PCR negative to HIV.	Foreskins from 14 men with a new HIV+ serology at the first visit post-circumcision, 6 men who are PCR+ but serologically negative at male circumcision, and 50 men who are highly exposed but serologically uninfected.	Underway
Community effects of male circumcision on HIV epidemic: Foreskin inflammation and mucosal immunology studies	Rakai District Uganda	The Bill and Melinda Gates Foundation through the Rakai Health Sciences Project (RHSP)	Basic science	Foreskins removed during male circumcision provide mucosal tissue and a new model for the investigation of mucosal barriers and susceptibility to HIV infection and transmission.	Consenting HIV negative adult males, age 15-49 years, undergoing elective male circumcision at the RHSP	Underway
Monitoring						
A monitoring and evaluation study to assess the implementation of male circumcision as an HIV prevention strategy	Kisumu East, Kisumu West and Nyando Districts, Kenya	University of Illinois at Chicago (The Bill and Melinda Gates Foundation through the male circumcision Consortium)	Prospective study	1) Evaluate monitoring and evaluation system; 2) adverse event rates (by severity, type, clinician cadre, etc.); 3) identify factors that facilitate and act as barriers to the uptake of male circumcision; 4) evaluate time to onset of sexual activity; 5) assess satisfaction (appearance, sexual, health facility, etc).	Circumcised males aged > 12 years recruited at selected health facilities; using the passive system (n≈4,000) and a sub-sample of clients through 30-40 days post-surgery using the active system (n≈2,000).	Data collection completed
Home-based study of post-operative adverse events	Nyanza Province, Kenya	PEPFAR/Westat	Prospective study	1) Adverse events rates; 2) loss to follow-up rates; 3) barriers to adherence to routine follow-up; 4) other sources of post-op clinical care.	Sub-sample of circumcised males aged >12 years recruited at selected health facilities to receive home-based assessment at 20 days.	Protocol being finalized

Title of study	Location	Sponsor/funder	Type of study	Aim/objectives	Study population	Status
Service delivery						
Assessment of the 'Models for Optimising the Volume and Efficiency of MC Services (MOVE) methods	Kenya, Zimbabwe and potentially South Africa and Zambia	USAID Project SEARCH through Johns Hopkins Bloomberg School of Public Health - Research 2 Prevention Project with PSI, Jhpiego & MOH.	Facility-based, multi-country operations research study	Track adoption of MOVE elements and determine benefits in terms of improved productivity and cost efficiency, with equivalent safety.	A sample of selected fixed site health care facilities, and possibly a random sample of outreach/mobile sites in each participating country	Protocol submitted
Assessment of male circumcision services at outreach health care facilities	Homa Bay, Rachuonyo & Rongo districts in Nyanza, Kenya	EngenderHealth (The Bill and Melinda Gates Foundation through the male circumcision Consortium)	Prospective study of male circumcision performed by trained medical officers working at outreach health facilities.	1) Male circumcision surgical and post-operative procedures at outreach service sites; 2) male circumcision surgical outcomes at 7-days and 60-days post-surgery; 3) patient satisfaction with male circumcision services received at outreach sites at 7-days and 60-days post - surgery; 4) costs associated with providing male circumcision through outreach services.	800 male circumcision procedures on males aged 18-54 years	Underway, completion Sept 2010
Comparing Outcomes: Physicians, Nurses and Clinical Officers	Zambia	The population council (Bill & Melinda Gates foundation through male circumcision partnership)	Prospective at MC and 6 weeks post-MC; randomize clients to different provider types	Evaluate clinical, post-operative and client satisfaction male circumcision outcomes for different provider types. Assess physician, nurse and clinical officer attitudes and job satisfaction as well as provider programme drop-out; assess impact on other services provided.	Male circumcision clients and providers	Protocol under development
Assessing different suture types on male circumcision client outcomes	Swaziland	The population council (Bill & Melinda Gates foundation through male circumcision partnership)	Randomization to standard and quick absorbing sutures	Assessing different suture types on male circumcision client outcomes: 1) clinical and post-operative adverse events rates; 2) client satisfaction; 3) timing of resumption of sexual activity post-male circumcision.	Male circumcision clients	Protocol under development
Assessment of post-operative adverse events rates among compliant and non-compliant clients who do not return for follow-up visits	Swaziland	The population council (Bill & Melinda Gates foundation through male circumcision partnership)	Observational and experimental	Measure post-operative adverse events rates among a full sample of male circumcision clients, including those who are compliant and non-compliant with follow-up visits; evaluate predictors of adverse events and non-compliance with follow-up visits; evaluate methods for improving follow-up visit rates	Male circumcision clients	Protocol under development

Title of study	Location	Sponsor/funder	Type of study	Aim/objectives	Study population	Status
Sexually transmitted infections and reproductive tract infections						
HIV and STI Incidence	Kisumu, Kenya	University of Illinois-Chicago and Nyanza Reproductive Health Society (The Bill and Melinda Gates Foundation through the male circumcision Consortium)	Cohort study, post-RCT	Estimate the differences in HIV and other STI incidence between circumcised and uncircumcised men.	Men ages 18 - 34 years	Continuing follow-up
Male circumcision: HIV, STIs and behaviors in a RCT and post-RCT Surveillance; Human papilloma virus (HPV) testing	Rakai District Uganda and Johns Hopkins University Laboratory, Baltimore, MD, USA	USA National Institutes of Health / National Institutes of Allergy and Infectious Diseases	Randomized clinical trial with 6, 12 and 24 month follow up visits.	1) Assess the efficacy of male circumcision for high risk HPV prevention and to determine the prevalence, incidence and clearance of HPV ; 2) assess the efficacy of circumcision for reduction of genital high risk-HPV infections in female partners of HIV-infected and uninfected male trial participants by comparing HPV prevalence and incidence in female partners of circumcised and uncircumcised married men.	Samples from 609 HIV-negative and 530 HIV-positive men, and female partners	Underway
Circumcision: HIV, STIs and behaviors in a RCT and post-RCT Surveillance	Rakai District Uganda	USA National Institutes of Health / National Institutes of Allergy and Infectious Diseases	Phase IV, post-trial surveillance study of male circumcision effectiveness	1) Conduct STI assays on stored samples to determine the efficacy of circumcision in preventing selected STIs; 2) assess the long-term effectiveness of circumcision for HIV/STI prevention, and effects on sexual risk behaviors, by conducting an additional 5 years of annual follow up among men who had enrolled in the NIH trial.	5,000 men aged 15-49 years originally enrolled in the male circumcision trial.	Underway