Introducing Early Infant Male Circumcision for HIV Prevention: Considerations for Policy, Safety, Cost, Acceptability and Demand

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Virgile Kikaya, Rajab Kakaire, Elizabeth Thompson, Mareitumete Ramokhele, Tigistu Adamu, Kelly Curran, Emmanuel Njeuhmeli

http://dx.doi.org/10.9745/GHSP-D-15-00231
Sustaining Gains Made in Voluntary Medical Male Circumcision

Chewe Luoa

Introducing early infant male circumcision (EIMC) can sustain voluntary medical male circumcision (VMMC) programs. This Global Health: Science and Practice supplement presents lessons learned, research findings on demand creation, and cost comparisons of various models of EIMC introduction.

Fourteen countries in sub-Saharan Africa with high HIV burden and low prevalence of male circumcision are currently providing voluntary medical male circumcision (VMMC) services in line with the 2007 recommendations from the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS). VMMC, which reduces the risk of heterosexual acquired HIV infection in men by approximately 60%,1–3 is one element of a combination HIV-prevention package that can include correct and consistent use of condoms, HIV testing and counseling, treatment of sexually transmitted infections, behavior change communication, harm reduction for people who inject drugs, community-based interventions for key populations, antiretroviral treatment for people living with HIV, and pre- and post-exposure prophylaxis.

The main thrust of VMMC programs has been to circumcise men ages 15 to 49 years to reduce their risk of HIV infection. Scaling up VMMC to reach the target of 80% coverage among men ages 15 to 49 years in the 13 countries would mean that approximately 20 million circumcisions would need to have been performed by the end of 2015. This would have averted 3.4 million new HIV infections over 15 years, 22% of the total projected infections.4 As of December 2015, more than 10 million circumcisions had been performed, and some regions had already reached the saturation threshold of 80% coverage.5 Settings that reached 80% coverage are starting to plan how to sustain this coverage and maintain the population-level prevention impact and individual-level gains.

A TWO-PHASE APPROACH TO VMMC SCALE-UP

The 2007 WHO–UNAIDS Joint Strategic Action Framework lays the foundation of a two-phase approach to scaling up VMMC: the catch-up phase that focuses on reaching at least 80% of VMMC prevalence among 15- to 49-year-old men and the sustainability phase.6

Three sustainability scenarios have been identified in the framework, depending on whether a country introduces and scales up early infant male circumcision (EIMC). EIMC is medical male circumcision performed between 12–24 hours and 60 days after birth.7

In the first sustainability scenario, the country maintains high circumcision coverage among the adolescent population (ages 10 to 19 years) and does not introduce EIMC. The second scenario is to scale up EIMC while maintaining high coverage among adolescents, and when 80% of the cohort of circumcised infants reaches 10 to 14 years of age, the focus shifts entirely to EIMC. The third scenario is to introduce EIMC but continue circumcision of both adolescents and infants indefinitely. EIMC has several advantages over adolescent and adult VMMC: it costs less, the surgery heals more quickly and has less risk of adverse events, and it can be integrated into routine maternal, newborn, and child health platforms.

INTRODUCING EIMC

Integrating a one-time surgical intervention with long-term benefits into routine health care packages is not straightforward. Although interventions for both the mother and infant delivered at the same time in the same place by the same health care provider or team save more lives and improve health outcomes of mothers and infants better than providing services separately,
there are many policy, programmatic, and logistical issues to consider. The VMMC community needs to act cautiously to avoid negative events and avoid contributing to newborn mortality. Mortality in newborns from all causes currently accounts for 44% of all deaths among children less than 5 years of age.

The Every Newborn action plan was developed in response to country demand, and based on the latest epidemiology and evidence, it outlines specific actions to improve access to and improve the quality of health care for women and newborns within the continuum of care. Although there is no ideal time identified for performing medical male circumcision during infancy, the American Academy of Family Physicians recommends waiting until at least 12–24 hours after birth to ensure the infant is stable. This critical time enables providers to assess the newborn and check for contraindications to circumcision. On the other hand, no added risks of EIMC have been reported. National governments considering introducing medical male circumcision for young infants should look at local data and decide on the optimal time for the intervention.

This supplement to Global Health: Science and Practice, sponsored by the United Nations Children’s Fund (UNICEF) and the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR), brings together several articles on EIMC, including reviews that highlight lessons learned and challenges of providing circumcision services to young male infants; formative research findings on the perceptions of parents, providers, and other stakeholders to inform demand creation for EIMC; and cost comparisons of alternative service delivery models as a result of task shifting and integration into newborn care. The supplement also includes a commentary on an important consideration for successful and sustainable national EIMC programs: service delivery through maternal, newborn, and child health service platforms.

Prevention is a cornerstone of the momentum toward ending AIDS by 2030, following the UNAIDS Fast-Track strategy. VMMC is a proven, effective prevention approach and a component of combination prevention packages. This supplement provides country experiences on scaling up as well as options for sustaining efforts in VMMC and their cost benefits.

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Long-Term Investment for Infants: Keys to a Successful Early Infant Male Circumcision Program for HIV Prevention and Overall Child Health

Tin Tin Sint, Lauren Bellhouse, Chewe Luo

Countries where adult male circumcision has reached high coverage should consider national early infant male circumcision (EIMC) programs where EIMC is feasible and culturally acceptable. Ministries of health that intend to set up a routine offer of EIMC should put systems in place to ensure that its introduction (1) does not compromise adult male circumcision programs, (2) does not weaken routine service delivery platforms, (3) is done safely, and (4) adheres to the rights of the child.

BACKGROUND

Male circumcision involves the complete removal of the foreskin of the penis, the innermost layer of which is highly susceptible to HIV transmission. According to the World Health Organization (WHO), in 2006 about 30% of males globally (665 million infants, adolescents, and adults) had been circumcised. Male circumcision has historically been performed in infancy, adolescence, and adulthood in various regions of Africa for religious and cultural reasons or for ethnic identity. Circumcision is mainly performed using traditional methods, either at birth or to initiate males into adulthood at puberty. Male circumcision also has medical benefits, including the prevention of penile cancer, reduction in the transmission of some sexually transmitted infections (STIs), including HIV, and reduction in vaginal infections and cancer of the cervix in female sex partners.

Scientific evidence and program data show that male circumcision prevents female-to-male sexual transmission of HIV. Three randomized controlled trials conducted by trained health professionals in properly equipped settings concluded that adult male circumcision reduces transmission of HIV from women to circumcised men by up to 60%. Based on these results, WHO and the Joint United Nations Programme on HIV/AIDS (UNAIDS) recommended in 2007 that voluntary medical male circumcision (VMMC) be made available in countries with a high HIV prevalence, generalized heterosexual HIV epidemics, and low levels of male circumcision. Fourteen countries in East and Southern Africa were prioritized for VMMC scale-up as an HIV prevention strategy: Botswana, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Namibia, Rwanda, South Africa, Swaziland, Uganda, the United Republic of Tanzania, Zambia, and Zimbabwe.

Programmatically, VMMC can serve adults (males ages 15 years and older), young adolescents (boys ages 10 to 14 years), and young infants (boys ages 0 to 60 days). Njeuhmeli and colleagues estimated that scaling up VMMC in the 14 priority countries to reach 80% coverage among males ages 15 to 49 years could avert 3.4 million new HIV infections within 15 years. To achieve this goal, countries should first focus on the population in which VMMC is likely to have the most immediate and greatest impact: males ages 10 to 49 years old. This is the catch-up phase to reach the majority of males who may be currently sexually active. The sustainability phase that early infant male circumcision (EIMC) services offer can be introduced slowly to achieve coverage for 80% of males between infancy and 49 years. It is also possible to have a mixed sustainability phase of circumcision for young infants as well as young adolescents, an option that should be explored by stakeholders when exploring the introduction of this second phase of VMMC.

EARLY INFANT MALE CIRCUMCISION

EIMC is medical male circumcision performed on healthy neonates from 12 to 24 hours after birth, and on young infants up to 60 days of age. It has been noted that the procedure costs less per circumcision and...
the process itself is much simpler in infants than in older males.\(^3\) There is also less risk of complication, faster wound healing, and no loss of time from work or school, factors that have been identified as barriers to acceptability of adult VMMC.\(^4\) Compared with adult VMMC, EIMC has also resulted in fewer surgical and post-operative adverse events.\(^5-7\) It also carries additional child health benefits, including reduced urinary tract infections, especially in the first 6 months of life,\(^8\) paraphimosis, and phimosis.

Although the sustainability phase of circumcision includes providing the services to neonates as well as young adolescents, we only look at issues related to EIMC in this article. We discuss several issues with regard to providing routine EIMC services within the public sector, as a means to sustain the gains made by adult VMMC programs. The issues derive from global meetings, United Nations expert consultations, country assessments, and policy and strategic guidance notes.

**Keys to a Successful EIMC Program**

It is essential that the introduction of the routine offer of EIMC (1) does not compromise adult VMMC programs, (2) does not weaken routine service delivery platforms, (3) is done safely, and (4) adheres to the rights of the child.\(^9,10\) While continuing to provide adult VMMC programs, countries with high HIV and STI prevalence and high coverage of adult male circumcision programs (i.e., at least 80% of the adult male population) should consider a national EIMC program where feasible and culturally acceptable.\(^3\)

**EIMC as a Sustainable Complement to Adult VMMC**

The introduction of EIMC should not necessitate a priority shift away from adult VMMC and should not compete with other health services for children. EIMC can lead to both sustainable prevention programming as well as cost-beneficial impact over the long term.\(^11\)

With any public health program, the key for sustainability is the commitment and investment of national authorities. Donor-funded programs and services face challenges at the end of the funding period and are often hard to sustain nationwide. The uptake of VMMC in sub-Saharan Africa emanates from commitment by ministries of health along with key stakeholders and growing acceptance in communities.\(^12\) With effective leadership at the national level and support from partners and implementing agencies, the same can be done with EIMC. Lessons learned from introducing EIMC services can also be used to expand the knowledge base around pediatric, biomedical HIV-prevention interventions and influence policies and decision making through operations and implementation research.

**Integration Within Routine Service Delivery Platforms**

One of the key considerations for introducing EIMC is integration within routine health services. Most ongoing adult VMMC programs are donor-funded and vertical, providing only male circumcision. Within the broader context of public health and with the interest of sustaining the impact of VMMC on HIV prevention, this should not be the case for EIMC programming. The population benefiting from EIMC is male infants, so a logical platform for EIMC services would be routine services for mothers and their children, such as maternal, newborn, and child health (MNCH) services. The advantages of linking EIMC with other maternal and infant services are multiple: it would enable access to the infant at various times, such as after delivery and before discharge where appropriate, at growth monitoring, during immunization, and during child health days. However, careful consideration must be paid to avoid creating the risk of competition for resources and clients between EIMC and MNCH programs. In addition, stakeholders implementing EIMC programs should coordinate with and bolster established adult VMMC programs, ensuring that EIMC is a complementary intervention and not a diversion of resources. Successful integration of EIMC into routine health services will require strengthened relationships between maternal and child health platforms as well as with HIV programs at all levels of service delivery, and at national and international levels.

Important considerations for program investments that strengthen service delivery platforms include infrastructure support, including for surgical procedures; training, supervision, and mentoring of providers; supply chain management; and human resource investments that facilitate service delivery, such as task shifting.\(^13\) A systematic review in 2012 found that task
shifting of adult VMMC to trained nonphysicians does not increase the frequency of adverse events if performed in a supportive environment. Research is needed, and currently ongoing, to determine if this is also true for EIMC services. The task-shifting approach could have several benefits, including facilitating access to EIMCs since nonphysicians are often the main health care provider at the primary health care level, as well as minimizing costs, as demonstrated by a cost analysis of EIMCs performed by doctors compared with nurse-midwives in Zimbabwe. In addition, integration of continuous quality improvement processes into routine programming will be essential to achieve the full impact of the services. Research on acceptability of EIMC in various locations in East and Southern Africa has shown that fathers are often the final decision makers on when and if their sons should be circumcised. Providing EIMC within routine MNCH services could therefore engage fathers in a stronger way in their sons’ health.

**Quality and Safety Considerations**

As with adult VMMC, the introduction and expansion of EIMC requires measures for the procedure to be carried out safely, with informed consent, and without discrimination. WHO, in collaboration with Jhpiego, has produced a manual on providing EIMC under local anesthesia to help providers and program managers deliver high-quality and safe infant male circumcision services for HIV prevention and other health benefits. This manual complements the WHO manual for adolescent and adult VMMC and focuses on the considerations and clinical best practices of circumcision for male infants under 60 days of age.

Neonatal and infant mortality rates are high in many of the male circumcision focus countries; for example, the infant mortality rate ranges from 33 infant deaths per 1,000 live births in South Africa to 73 deaths per 1,000 live births in Lesotho. Adding a routine surgical intervention to MNCH services in countries with high neonatal mortality may raise concerns. A systematic review from 2010 found few reported severe complications, but mild or moderate complications have been seen. Child circumcision tended to be associated with more complications than circumcision of neonates and infants; more complications were also associated with circumcisions performed by inexperienced providers or in non-sterile conditions. For complications, a system of referral should be in place suited to the local setting.

**Patient and Parent/Guardian Rights**

According to the United Nations Convention on the Rights of the Child, social welfare institutions must make the best interests of the child the primary consideration in all actions concerning children. Accurate and age-appropriate information on the protective effects of VMMC, and the risks and benefits associated with the procedure should be accessible to everyone; and the best interest of the child should be determined by taking into account diverse health, religious, cultural, and social factors—both positive and negative.

When considering the routine offer and delivery of EIMC services, national governments should weigh the issues of parental consent, the rights of the child, the health of the child, and the benefits for the wider population. It should be noted that VMMC, and the routine offer of EIMC, is appropriate in some contexts but not all. No agency recommends medical male circumcision universally, and all denounce male circumcision carried out with unsafe methods by nonmedical professionals, which can lead to infection, disfiguration, and even death.

Policies covering the issues of consent and authorization for EIMC services must be discussed and decisions made within a nation’s legal and regulatory framework. It is critical that national authorities address informed consent in EIMC programming and incorporate procedures that ensure informed consent, as should be done for all child health services. This includes prohibiting coercion, providing all information needed for decision making, giving adequate time for parent or guardian consideration, offering the option of written consent, and ensuring appropriate follow-up.

Education and information on the benefits and risks of EIMC services for both providers and clients must be offered, with an emphasis on parental rights and choice. Governments and stakeholders must ensure that parents/guardians are fully informed before they provide consent. The decision for a parent to have his or her son circumcised is a personal one, and parents/guardians should make the decision after carefully weighing the health status of the neonate and regulatory framework. It is critical that national authorities acknowledge and address the issue of informed consent and incorporate procedures that ensure informed consent into EIMC programming.
and the risks and benefits, as well as religious, cultural, and personal preferences.

Information and educational materials provided during routine antenatal or child health visits should be tailored to the concerns of the caregivers and the community. This may require additional research before full EIMC service provision, including situational analysis of the target audience and testing the educational messages. EIMC may not be feasible in some settings, for example, where adolescent and adult circumcision is preferred for cultural reasons. Education and counseling will avoid reduced attendance at MNCH services due to fear of adverse events of EIMC, coercion, or not having the information to make informed decisions.

CONCLUSION

VMMC is an effective method to prevent heterosexual transmission of HIV, and can be provided to adults, young adolescents, and young infants. Scale-up of adult VMMC in the 14 priority countries remains the focus; introduction of EIMC as a sustainability phase is recommended once adult programs have reached high coverage. EIMC programs are not replications of adult and adolescent services, but require thoughtful consideration of many infant-specific issues. EIMC service provision should be context-specific, and led by national authorities with support from implementing agencies.

EIMC services should be offered as part of routine MNCH services and used as an opportunity to strengthen newborn and child health services overall. The quality and safety of the services remain paramount: the rights of the child should be protected at all times by providing complete information to parents and guardians to inform their decisions, giving them adequate time to consider their options, offering the option of written consent, and ensuring appropriate follow-up.

Although the impact of EIMC on HIV incidence and overall prevalence will not be realized immediately, the routine offering of EIMC services will provide longer-term impact, benefiting the health of the child as well as protecting against heterosexual transmission of HIV at both the individual and population level. Performing medical male circumcision in infancy will provide lifelong benefits for the child and contribute to sustaining the gains made from adult VMMC programs.

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COMMENTARY

Scaling Up and Sustaining Voluntary Medical Male Circumcision: Maintaining HIV Prevention Benefits

Emmanuel Njeuhmeli, a Marelize Gorgens, b Elizabeth Gold, c Rachel Sanders, d Jackson Lija, e Alice Christensen, f Francis Ndewiga Benson, g Elizabeth Mziray, b Kim Seifert Ahanda, a Deborah Kaliel, a Tin Tin Sint, b Chewe Luo h

To maintain high circumcision prevalence, voluntary medical male circumcision programs in Eastern and Southern Africa need to plan for sustainability and conduct transition assessments early on, rather than waiting until the saturation of priority targets at the end of the program.

INTRODUCTION

The changes in the AIDS financing landscape and in the architecture of health financing under the post-2015 sustainable development agenda have highlighted the need to ensure that HIV and AIDS programs continue to yield health benefits regardless of funding sources, implementation mechanisms, and governance structure. Further highlighting this need are the changes in the nature of institutions implementing HIV services and the number of people who will need HIV services to end AIDS by 2030. Thus, donors in the international development arena have increasingly mandated that the interventions of their funded programs be sustainable.

Yet sustainability—sometimes called institutionalization—can mean different things in different contexts. According to the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR), “a sustainable response can only be achieved when the epidemic is under control and no longer expanding and the response is constantly adapting to the evolution of the epidemic to maintain control.” In the context of voluntary medical male circumcision (VMMC), this article defines a sustainable VMMC program as one whose local stakeholders maintain high circumcision prevalence after the initial scale-up—generally by incorporating either early infant male circumcision (EIMC), early adolescent VMMC, or both, into routine newborn and adolescent service delivery systems. (EIMC is performed during the first 60 days of an infant’s life and early adolescent VMMC between the ages of 10 and 14.)

In December 2011, the “Joint Strategic Action Framework to Accelerate the Scale-Up of VMMC,” launched by the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS), articulated a 5-year strategy to achieve at least 80% circumcision coverage (i.e., saturation) among males ages 15 to 49 in 14 priority countries in Eastern and Southern Africa with generalized HIV epidemics, high HIV prevalence, and low prevalence of male circumcision. By the end of 2014, the 14 countries had reported nearly 9 million VMMCs, with some countries about halfway toward reaching their targets and others lagging behind. However, the number of circumcisions and total coverage do not provide the whole picture. In some countries, progress has been uneven, and certain age groups and certain districts are reaching saturation before others.

Based on the initial targets, these regions will need to start planning for sustainability sooner than originally thought. Tanzania, which has prioritized 11 regions for VMMC, is an example of this unevenness. The Iringa and Njombe regions are close to saturation among males ages 15 to 24, while other regions lag behind. As Iringa and Njombe regions achieve their targets for saturation, the time is now to consider planning for sustainability: preparing to transition the regions’ male circumcision activities to local stakeholder design, management, and funding and to include young adolescents and infants as part of the target age range. Transition planning includes VMMC becoming institutionalized into the health care...
In a sustainable VMMC program, local stakeholders maintain high circumcision prevalence by incorporating EIMC, early adolescent voluntary medical male circumcision, or both into newborn and adolescent service delivery.

The 4 domain areas of the PEPFAR Sustainability Index are governance, leadership, and accountability; national health system and service delivery; strategic investment, efficiencies, and sustainable financing; and strategic information.

infrastructure of Tanzania. In this article, we discuss critical considerations for VMMC sustainability and highlight sustainability approaches taken by 2 countries—Kenya and Tanzania.

**SUSTAINING HIV/AIDS PROGRAMS: FINANCING AND SERVICE DELIVERY**

Core to all definitions of sustainability is the notion that the ongoing program will continue to yield an agreed-upon set of health benefits, and those programs will be planned, managed, and eventually funded by local stakeholders, including government, private sector, civil society, and others. Current thinking and lessons learned from transitions in other programs (such as U.S. Agency for International Development [USAID] graduations in family planning and the Bill & Melinda Gates Foundation’s transition of the Avahan HIV prevention program in India from donor to government financing) offer the following lessons about sustainability (or continuation):

- Early planning is critical to successful transitions—planning for sustainability and transition needs to be factored in from program inception, not just when financing is shifting or phasing out.
- Sustaining the status quo is not a prerequisite. Transition could also involve moving to more efficient and effective service delivery modalities and better targeting programs to populations and geographical areas that are most important to the HIV response for a particular context. It is a dynamic process and plans should be adjusted as needs shift.
- Clear communication among all related stakeholders is critical for success.
- Technical and managerial support is often needed to build domestic capacity and ensure the institutionalization of support mechanisms.
- A systematic, phased approach to transition planning allows for course corrections and helps ensure that critical elements are considered.
- Post-transitional support is important to ensure quality as well as to assess transition effectiveness.
- Transition planning might result in changes in implementing agencies (moving from service delivery by an NGO to government service delivery, for example) or changes in governance approaches (moving from coordination and budgeting by donors to coordination by government departments).

**Donor Focus on Sustainability of HIV Programs**

Building on these lessons, several partners, including the World Bank, PEPFAR, and the Global Fund to Fight AIDS, Tuberculosis and Malaria, have embarked on efforts to support countries in planning for and improving their programs’ sustainability. As PEPFAR enters its third phase, there is a new “Sustainability Action Agenda,” which includes, among other strategies, implementing the “Sustainability Index and Dashboard” (a tool designed to measure the sustainability of national HIV responses across 4 domains with approximately 80 indicators) in PEPFAR country programs; building on health systems strengthening and human resources for health programs; and engaging with multilateral institutions and civil society for greater coordination on sustainability. The World Bank is supporting countries to identify the constraints to and opportunities for developing health financing systems to accelerate and sustain progress toward universal health coverage. The Global Fund has just released a policy paper on sustainability, transition, and co-financing.

**HIV Sustainability Frameworks and VMMC Sustainability**

To ensure the sustainability of HIV/AIDS results, certain factors are important to assess, plan for, and strengthen. Drawing on the 4 domain areas of the PEPFAR Sustainability Index and Dashboard as a way to frame the discussion, we note these areas as critical for VMMC sustainability:

- **Governance, leadership, and accountability**: Coordination, led by government, across all donors and stakeholders is essential for long-term program success and sustainability. New policies may be needed, such as national or subnational strategies and implementation plans, or legal actions may be needed (e.g., formation of new institutions or bodies, or enabling laws) to ensure that practices are formalized and changes in governments or leadership do not mean gains are lost. In some cases, policy changes affect the institutions responsible for managing the HIV/AIDS
response or the governance structure more broadly. In addition, ensuring engagement from civil society and the private sector as program planners, implementers, and monitors is key, with the assurance that all stakeholders have access to information in a transparent manner that allows for holding each other accountable for results.

- **National health system and service delivery:** Changes in financing sources may result in the need to change service delivery modalities (e.g., to shift from service delivery by an NGO to public-sector service delivery). Before planning the transition, it is important to understand which services are essential, and for which populations, in which geographical areas, and at what intensity. For example, as targets are reached for VMMC coverage for men 15 to 49 years old, there may be a need to consider targets for other age ranges. Along with direct service delivery, systems support is critical to successful service delivery, for instance, ensuring sufficient numbers of health care providers are trained, commodities and logistics systems are reliable, and laboratory systems are functioning. For long-term success, high-quality and responsive service delivery is also key to meeting the demand of clients and should be assessed.

- **Strategic investment, efficiencies, and sustainable financing:** Shifts in the source or level of financing may have implications for the type and level of services to be delivered and their sustainability. Planning transitions necessarily involves understanding the current and future financial landscape, including the possibility of assigning public resources for specific priority services, and the opportunities for diversified funding through resource mobilization and innovative financing from both public and private sources. The landscape may require advocating inclusion of VMMC in the national health insurance basic benefit package. In the context of reduced financing, and because of the need to focus on more efficient HIV responses, it is also important to look at allocating resources across populations, programs, and geographical areas to achieve the highest impact at the lowest cost. The potential for integrating services should be considered.

- **Strategic information:** Institutionalized, regular data collection is needed to monitor the progress of programming. Data should include specific surveys and surveillance, expenditures, and performance measures. Data should be made available in a timely manner so they can be used to better inform and target programming.

### WHAT DOES VMMC SUSTAINABILITY ENTAIL?

As noted above, VMMC sustainability involves local stakeholders maintaining high circumcision prevalence through EIMC and/or early adolescent VMMC and integration into service delivery systems. Two considerations are critical to ensuring VMMC sustainability:

- VMMC age-group prioritization after adult saturation
- The status of the national VMMC response for sustainability

#### VMMC Age-Group Prioritization

Depending on the context and desires of the local government, it may make sense to focus on different populations as there is near-saturation of the 15 to 49 age range during or after scale-up and the program transitions to local stakeholder ownership. In the scale-up phase, the country circumcises males across the entire target age group, requiring a large number of annual circumcisions. After the target coverage is achieved, males are circumcised only as they move into the focus age group to maintain coverage. But once the infants reach adolescence, it is no longer necessary to continue circumcising adolescents, and the country can focus entirely on EIMC.
• **Adolescents and infants (mixed focus):** The country focuses on both infants and adolescents, since high coverage among infants is never achieved and both adolescents and infants will need to be circumcised indefinitely to maintain the target coverage across the population.

**The Sustainability Status of the National VMMC Response**

To plan for a responsible transition and long-term sustainability, an assessment is suggested that includes 15 elements drawn from the PEPFAR Sustainability Index and Dashboard. The 15 elements are:

- Policy
- Planning and coordination
- Civil society engagement
- Private-sector engagement
- Public access to information
- Quality
- Service delivery
- Human resources for health
- Commodity security
- Laboratory
- Financing
- Efficiencies
- Surveys and surveillance
- Expenditure data
- Performance data

After an assessment of these elements, weak elements should be strengthened before a program is transitioned. Financing and tracking domestic expenditure on VMMC programs is important, although hard to monitor because of the way government charts of accounts are developed, and because VMMC delivered in primary care settings would not necessarily be listed as a separate line item in a budget or district hospital expense report.

We discuss below some of the elements that have been considered for VMMC transitions.

**Human Resources and Commodities**

Human resources, commodities, and supplies are as important as financial resources for health care services. A preliminary analysis by the USAID-funded Project SOAR (Supporting Operational AIDS Research) explored the human resources and commodity costs in Tanzania for the focus populations described earlier. Project SOAR calculated the human resource requirements to achieve service goals based on the number and age of people to be circumcised and on provider time required per person (based on country costing studies). The need for doctors and nurses depends on both client numbers and treatment inputs for care. Because EIMC was seen as requiring only 20 minutes of doctor time, the EIMC scenario results in a much lower need for doctors, even though the number of individuals to be circumcised is not much lower than in other scenarios. If Tanzania’s 2013 population of 36 trained doctors remains constant, it will not be possible to achieve the goals of any of the 3 scenarios without more training or task shifting. A more positive picture emerges when nurses and midwives are considered. With 853 trained nurses available, all 3 population scenarios are achievable; there is no human resource constraint when this level of staff is involved (although the EIMC scenario would require an emphasis on midwives).

When the focus is on EIMC, analysis by SOAR reveals that drug and supply costs are around US$6.9 million in year 1, rising to about US$7.6 million by year 6. When the strategic focus is on adolescents, the costs are a bit less, primarily due to the lower service numbers, beginning around US$4.6 million for year 1 and rising to US$5.8 million in year 6. The mixed-focus strategy is the most expensive for drugs and supplies. Its cost begins around US$8 million for year 1 and increases to almost US$10 million by year 6.

From this preliminary analysis, we reached the following conclusions with regard to human resources for health and commodity costs:

- Sustaining VMMC programs can challenge countries, but in the cases considered in this analysis, most resources suffice if a task-shifting policy is implemented.
- Scale-up and sustainability of VMMC could burden the health system if it demands specialists or a large number of providers.
- Additional analysis is needed, particularly around other health system issues such as the supply chain, but also across all 15 elements of the PEPFAR Sustainability Index.
Demand Considerations for VMMC Sustainability

As countries transition from the current catch-up model, with demand-creation efforts focusing on males ages 15 to 29, to one of the three population-focused scenarios described earlier, new communication strategies for demand creation will be necessary. Regardless of the sustainability path to meet targets efficiently, a country’s program must be supported by a communication strategy to ensure that demand matches supply. An overarching communication component would address common needs of early adolescent VMMC and EIMC to ensure coordination, prevent conflicts between the two, and address the potential addition of resources and channels that may not have been part of the catch-up approach.

For example, under the infant-focus strategy, EIMC education needs to be linked to a country’s maternal and child health and antenatal programs. Capacity strengthening of staff charged with client education and counseling will likely be required. Formative research will be needed to shape context-specific strategies and approaches that address the barriers to EIMC and the motivating factors inherent in the sociocultural environment. Although considerable knowledge and positive norms exist around VMMC, and although EIMC builds on VMMC platforms, EIMC is new to many populations in East and Southern Africa, and knowledge and experience around EIMC are not as extensive as for adult VMMC and even for early adolescent VMMC.

What Do We Know About Demand for EIMC?

Since we have more experience in generating demand for VMMC among the early adolescent population and limited experience with EIMC, we conducted a rapid literature scan on demand for EIMC. Using varied methodologies, we found 11 studies conducted between 2010 and 2015 in 6 countries (Botswana, South Africa, Swaziland, Tanzania, Zambia, and Zimbabwe). Three studies were pilots looking at factors influencing EIMC service uptake.14-16 Six studies, all theoretical, looked at EIMC acceptability in the absence of current EIMC services.17-22 One study, conducted in 2014, was a systematic review and thematic synthesis looking at factors associated with parental decisions not to use EIMC services.23 Although this literature review was not comprehensive, common themes emerged.

Key barriers: One recurrent theme was the lack of accurate information and poor knowledge about the EIMC procedure and its advantages. Men projected their own experience and pain with VMMC and traditional circumcision and failed to differentiate between VMMC and EIMC. Safety was a common concern, particularly the fear that EIMC would injure or irreparably damage the newborn’s penis, perceived as too fragile for the procedure. Fear of infant death and excessive bleeding emerged as more immediate concerns, along with concerns about future effects of EIMC, including decreased penile sensitivity, more sexual risk-taking by circumcised men, and ostracism or rejection by peers.

Studies also looked at parental preferences for circumcision timing, which often conflicted with the recommended window (before 2 months of age). In some cases, these parental preferences were linked to the timing of traditional rites of passage, while in other cases preferences were associated with beliefs around the fragility of the infant penis. Sociocultural beliefs and myths are also obstacles to demand for EIMC, including fears that the baby’s discarded foreskin would be used for satanic or other malicious purposes. Another critical hurdle identified in most studies was lack of support by fathers, who are key decision makers on circumcision. Although mothers and grandparents also play a role, fathers have the final say.

Motivating factors: Factors motivating EIMC uptake were: availability of EIMC services at no charge; recognized protection from HIV and sexually transmitted infections; improved hygiene; availability of highly trained personnel performing the procedure; word-of-mouth recommendation from satisfied parents; and the belief that infants heal faster and have less awareness of the procedure than older boys.

Key recommendations: To generate demand for EIMC, key recommendations emerging from the literature scan included:

• Strengthen knowledge of EIMC in the community as well as among parents.
• Include fathers directly among the key audiences for health communication.
• Target multiple generations, as grandparents are influencers.
• Time education early enough to allow for family discussion and planning.
• Use satisfied parents strategically in communication efforts.

One recurrent theme of our literature scan of demand for EIMC was the lack of accurate information and poor knowledge about the EIMC procedure and its advantages.
- Develop materials for service providers’ use (with clear information about the procedure).
- Address the sociocultural factors in each local context (e.g., parental age preferences for circumcision).

**SUSTAINABILITY APPROACHES IN KENYA AND TANZANIA**

Kenya and Tanzania have made great progress in meeting initial male circumcision targets and are in the process of transitioning to sustainability. As both countries have made gains economically, they are also under pressure to increase domestic resources for HIV overall.

**Tanzania**

The government of Tanzania introduced VMMC for HIV prevention in 11 priority regions in 2010 and set a target of 2.8 million circumcisions by 2016. Through the end of 2015, more than 1.3 million VMMCs were conducted. Two traditionally non-circumcising regions, Iringa and Njombe, made substantial progress toward their regional targets and reached complete VMMC saturation among adolescents (Table). In 2010, Njombe was part of the Iringa region and the regional target for Iringa/Njombe was 265,000 for 2010–2015. (In 2012, Njombe split off from Iringa region.) By the end of 2015, 173,362 VMMCs had been performed in Iringa and 130,118 in Njombe, totaling 303,480. Because they reached saturation in these 2 regions, Iringa and Njombe are now ready to pilot a sustainability approach that can help guide transition strategies for the other regions in Tanzania. The 3-pronged approach that Iringa and Njombe are piloting includes: (1) transitioning service delivery from donor-funded implementing partners to service providers funded by the government; (2) targeting clients entering adolescence; and (3) scaling up EIMC services.

Transitioning service delivery from donor-funded partners to government can be done in several ways. In one option, as donors transition programming, the government picks up funding and provides services directly through their facilities and staff. Alternatively, as the government picks up funding, it can guarantee long-term sustainability by funding NGOs and contracting out services to private providers. Or, in a combination of the 2 mechanisms, NGOs and private providers are integrated into the public-sector financing and delivery mechanism. For Iringa and Njombe, transitioning service delivery from donor-funded implementing partners to service providers funded by the government involves such activities as increasing the number of static service delivery sites, supporting district-led outreach and mobile services, shifting commodities from disposable to reusable, and integrating VMMC commodity requirements into the current national supply chain. These components and others require an assessment to evaluate status and plans to increase capacity or strengthen the system before full transition.

The second prong involves clients entering adolescence (i.e., beginning at age 10). This approach requires age-appropriate services and counseling, on-the-job training for all VMMC providers on making services adolescent friendly, and linking with schools and youth activities to create demand among adolescents.

The third prong of Iringa’s and Njombe’s sustainability approach focuses on scaling up EIMC services. Since 2013, more than 3,800 EIMCs have been conducted at 8 pilot sites in the Iringa region. The pilot uses an integrated model, in which EIMC services are offered as part of child health services.

**Kenya**

Kenya rolled out VMMC in late 2008 when it published its first VMMC strategy (2008–2013). The goal was to increase national VMMC coverage from 85% to 94% by circumcising 860,000 men. Circumcision rates vary by province, however, and in Nyanza, the region with the highest HIV prevalence, male circumcision coverage is lower than the national average. The baseline male circumcision prevalence in 2009 for males ages 15 to 49 in Nyanza region was 44.8%, compared with 90% or above in other provinces.

By the end of 2015, Nyanza achieved near-saturation among males ages 15 to 49, attaining coverage of about 84%. The first 5 years comprised the catch-up phase, in which the program circumcised nearly 800,000 men. Today the country is in the process of rolling out its second VMMC strategy, to run from 2014 to 2019, via an approach that focuses on:

- Maintaining momentum on the catch-up phase to reach all adult men who need VMMC
- Beginning phased roll-out of EIMC as a component of maternal, neonatal, and child health services
Increasing VMMC coverage to at least 80% in all regions and to 95% nationally

Lowering the adolescent target age to 10 years where demand is highest (from the current 14 years)

Although VMMC operated mainly as a parallel program during its first phase, the second-phase strategy is to integrate VMMC into the essential health package, ensuring local and sustainable financing.

CONCLUSIONS

Regardless of the VMMC sustainability option that a country selects—focusing on circumcision of adolescents, EIMC, or a combination of both—financing availability, service delivery modalities, and systems-level support will be important to ensure that high male circumcision prevalence can be maintained beyond the initial coverage targets. Countries need to look ahead to the availability of human resources, commodities, supplies, demand creation, data availability, and more. Transitions in other health programs have taught us that early planning is critical. Countries can no longer put off the sustainability discussion until tomorrow. The time for that discussion is now.

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Scaling Up and Sustaining VMMC


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Early Infant Male Circumcision in Cameroon and Senegal: Demand, Service Provision, and Cultural Context

Ernest Kenu, a Tin Tin Sint, b Claude Kamenga, c Rene Ekpin i

ABSTRACT

Background: Male circumcision is almost universal in North and West Africa, and practiced for various reasons. Yet there is little documentation on service delivery, clinical procedures, policies, and programmatic strategies. The United Nations Children’s Fund (UNICEF) commissioned country program reviews in 2014 to shed light on the delivery of male circumcision services for infants in Cameroon and Senegal.

Methods: We conducted a policy desk review, key informant interviews, and focus group discussions at health centers and in communities. Between December 2014 and January 2015, we conducted 21 key informant interviews (13 with regional and district officers, 5 with national officers, and 3 with UNICEF officials) and 36 focus group discussions (6 with men, 6 with women, 12 with adolescent boys, and 12 with service providers). Some of the men and women were parents of the adolescents who participated in the focus group discussions. In the French-speaking areas, the focus group discussions were conducted in French through an accredited translator, audio recorded, and transcribed into English.

Results: All of the facilities we visited in Cameroon and Senegal offer medical male circumcision, with 10 out of 12 performing early infant male circumcision (EIMC) routinely. Neither country has policies, guidelines, or strategies for EIMC. The procedure is done mainly by untrained service providers, with some providers using modern circumcision devices. There are no key messages on EIMC for families; the increasing demand for EIMC is led by the community.

Conclusion: Despite the absence of national policies and strategies, EIMC is routinely offered at all levels of the health care system in Cameroon and Senegal, mainly by untrained service providers. Improving circumcision services will require guidelines for EIMC and improvements in training, equipment, supply chains, recordkeeping, and demand creation.

INTRODUCTION

Male circumcision is typically referred to as the complete removal of the foreskin tissue that covers the tip or head of the penis. It is one of the oldest and most common surgical procedures worldwide, and is undertaken for many reasons: religious, cultural, social, and medical. It is widely practiced and almost universal in parts of West Africa, Central Africa, in most Muslim countries, Israel, and the United States.1

The hypothesis that male circumcision might protect against HIV infection was first suggested in 1986.2 Clinical trials conducted in sub-Saharan Africa revealed that medically performed circumcision is safe and can reduce men’s risk of acquiring HIV infection from heterosexual exposure by about 60%.3–5 In 2007, the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) convened a technical consultation to review these new data. The regional consultation in Montreux, Switzerland, recommended male circumcision in countries with high HIV levels, a generalized HIV epidemic, and
low prevalence of male circumcision. The recommendations called for first scaling up services for young and older men who are at high risk of HIV as a priority, and once saturation is reached in these age groups, expanding the services to male infants and young adolescents. Male circumcision within the first 60 days of life, called early infant male circumcision (EIMC), is less costly, less complicated, and less risky than circumcision performed later in life.

Although male circumcision is almost universal and culturally accepted in many countries in West and Central Africa, there is little information on national policies and guidance, service provision, adverse events, training, and demand for the procedure. The United Nations Children’s Fund (UNICEF) commissioned an EIMC program review in 2014 in Cameroon and Senegal to answer questions around 4 areas: service delivery, systems, policy, and monitoring.

Country Demographics
Cameroon is a bilingual country with defined francophone and anglophone areas. It is a young country with 63% of the urban population and 65% of the rural population under the age of 25 years. Only about two-thirds of women of reproductive age report receiving antenatal care from a skilled service provider. Cameroon has a national HIV prevalence of 4.3% among people ages 15 to 49 years. The average male circumcision rate is 90%, though it ranges from 75% to 100% in various regions. More than 90% of people in urban and rural areas report having no health insurance.

In Senegal, a francophone country, 94% of women of reproductive age report receiving antenatal care from a skilled service provider. The national HIV prevalence is 0.7% of people ages 15 to 49 years, and 97% of men and 95% of women report having heard of HIV. The country has almost universal male circumcision, ranging from 75% to 100% depending on the region. Ninety-eight percent of people do not have health insurance.

METHODS
The review comprised key informant interviews at national, regional, and district levels and with health facility in-charge; health facility assessments; focus group discussions with service providers and men, women, and adolescents, the beneficiaries of EIMC services; and policy framework desk reviews.

Selection of Review Sites
We selected areas for the reviews based on health indicators and demographic data from a 2011 Demographic and Health Survey (DHS) in Cameroon and a 2010–2011 DHS-Multiple Indicator Cluster Survey (MICS) in Senegal, with the aim of achieving a diverse sample of the population and health systems. We took ease of travel and time limitations into account. In Cameroon, we selected the Central, Littoral, and Southwest regions, and in Senegal, we selected the Dakar, Kaffrine, and Tambacounda regions. Within each region, we visited 2 health facilities (1 teaching or regional hospital and 1 health center or health post). We visited 6 facilities in each country.

In Cameroon, 3 facilities were teaching hospitals, 2 were health centers, and 1 was a district hospital. All of the facilities were government owned. In Senegal, 3 of the facilities were health centers, 2 were regional hospitals, and 1 was a teaching hospital. Of the 6 health facilities, the central government owned 4, the local government owned 1, and an NGO owned 1.

Information Collection
Data collection tools were developed in English, tested in Ghana, and revised based on the field test (see supplementary material). UNICEF had the data collection tools translated into French for the francophone sites. Information on national guidelines, policies, reports, and other related documents on EIMC was collected through (1) key informant interviews and consultative meetings with key stakeholders at national, regional, and district levels and with facility in-charges; (2) facility assessment and focus group discussions with service providers at the health facilities visited; and (3) focus group discussions with mothers of infants who have had circumcision, including pregnant, lactating, and older women; men and young adolescents who were circumcised when they were infants; and community leaders and traditional circumcisers.

For each visit, the team consisted of the lead investigator, the national HIV focal person(s) or representative(s), and the regional director of health services or a representative. An accredited translator accompanied the team in Senegal.
**TABLE 1.** Characteristics of Men and Women Ages 15–49 in Cameroon and Senegal

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Cameroon</th>
<th>Senegal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male circumcision rate</td>
<td>90%</td>
<td>80%</td>
</tr>
<tr>
<td>Religion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Catholic</td>
<td>40%</td>
<td>0%</td>
</tr>
<tr>
<td>Protestant</td>
<td>30%</td>
<td>0%</td>
</tr>
<tr>
<td>Muslim</td>
<td>20%</td>
<td>95%</td>
</tr>
<tr>
<td>Other</td>
<td>10%</td>
<td>5%</td>
</tr>
<tr>
<td>HIV prevalence</td>
<td>4.3%</td>
<td>0.7%</td>
</tr>
<tr>
<td>Age at sexual debut</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>17.1</td>
<td>19.0</td>
</tr>
<tr>
<td>Men</td>
<td>18.7</td>
<td>22.7</td>
</tr>
<tr>
<td>ANC with skilled attendant (among women)</td>
<td>64%</td>
<td>94%</td>
</tr>
<tr>
<td>PNC (among women)</td>
<td>58%</td>
<td>68%</td>
</tr>
<tr>
<td>Place of birth of last child</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public health facility</td>
<td>61%</td>
<td>69%</td>
</tr>
<tr>
<td>Home</td>
<td>37%</td>
<td>27%</td>
</tr>
<tr>
<td>Multiple sexual partners in the last 12 months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>4%</td>
<td>0.3%</td>
</tr>
<tr>
<td>Men</td>
<td>23%</td>
<td>8%</td>
</tr>
<tr>
<td>Polygamy (among men)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urban</td>
<td>11%</td>
<td>5%</td>
</tr>
<tr>
<td>Rural</td>
<td>16%</td>
<td>18%</td>
</tr>
<tr>
<td>Total</td>
<td>13%</td>
<td>17%</td>
</tr>
<tr>
<td>Knowledge of HIV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>96%</td>
<td>95%</td>
</tr>
<tr>
<td>Men</td>
<td>98%</td>
<td>97%</td>
</tr>
<tr>
<td>Have had HIV test and know results</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>51%</td>
<td>28%</td>
</tr>
<tr>
<td>Men</td>
<td>40%</td>
<td>17%</td>
</tr>
<tr>
<td>No health insurance coverage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>98%</td>
<td>94%</td>
</tr>
<tr>
<td>Men</td>
<td>96%</td>
<td>92%</td>
</tr>
</tbody>
</table>

Abbreviations: ANC, antenatal care; PNC, postnatal care.
Source of data: 2011 Demographic and Health Survey in Cameroon⁸ and a 2010–2011 Demographic and Health Survey – Multiple Indicator Cluster Survey in Senegal.⁹
whereas in Cameroon, the ministry officials who were part of the team acted as translators where necessary. The team had the questionnaires in both languages at all times.

We conducted 21 key informant interviews and 36 focus group discussions. Of the 21 key informant interviews, 13 were with regional and district officers, 5 with national officers, and 3 with UNICEF officials at the regional and country offices (Table 3). Thirteen of the key informants were men ages 35 to 57. For the 36 focus group discussions, 6 were with men, 6 with women, 12 with adolescent boys, and 12 with service providers (Table 4). Some of the men and women were parents of the adolescents interviewed. A minimum of 3 community focus group discussions were conducted in each of the regions, with each group comprising 8 to 12 participants. One focus group discussion was conducted for women only (including the pregnant, lactating, and older women and women who have had their children circumcised). Another was conducted for men who were community-based resource persons, such as traditional circumcisers, community leaders, and male partners; the last focus group discussion was with adolescent boys who had had EIMC. In the French-speaking areas, the focus group discussions were conducted in French through the accredited translator, audio recorded, and transcribed into English.

We conducted a comprehensive assessment of the selected sites using a health facility assessment tool. This tool collects information on the range of services offered, EIMC service provision, availability of policy documents for general service delivery, demand creation, human resource capacity, and quality control measures.

### Information Gathering and Review

Information gathered from the key informant interviews and the responses from the focus group discussions (with adolescent boys, men, women, and service providers) were translated into English, where necessary, and summarized along themes. Data collected from the health facilities and service providers using Data Collection Tool 2 (see supplementary material) were further coded and entered into Microsoft Excel and cleaned before the analysis was done.

Analysis of quantitative data involved summarizing and simple descriptive statistics, such as frequencies and proportions. We processed and summarized the qualitative data to derive the emerging themes, patterns, and key issues. Whenever feasible, we retained verbatim quotes from the respondents to put the findings into
context. These findings were checked against the quantitative data from the service delivery points.

**Validation of Findings**
We shared key findings at a national validation meeting attended by some participants of focus group discussions, service providers, and policy makers who were interviewed.

**Ethical Consideration**
We obtained approval from the ministries of health of Cameroon and Senegal to undertake the assessment. In addition, UNICEF shared the data collection tools in advance for comments and received approval for use before the visits. All participants gave their written consent before the discussion. Adolescent boys who were interviewed gave their assent and their parents gave their written consent.

**RESULTS**

**Policies and Guidelines**
Both Cameroon and Senegal have no written policy documents to guide the EIMC practice. Many policy documents on HIV services and care of children were available in the 2 countries, but none specifically addresses EIMC or circumcision in general.

In both countries, a number of newborn and child health guidelines and protocols were available in the 12 health facilities. These include: examining a newborn, resuscitation, managing a low-birth-weight baby, guidelines for integrated management of neonatal and childhood illness,
maternal health/reproductive health guidelines, guidelines for prevention of mother-to-child transmission of HIV, and child health guidelines. However, there was no guideline for the management of circumcision, though the facilities routinely offer the service. Infection prevention and control supplies such as running water, soap, disinfectant, and goggles were all available.

Beliefs and Acceptability
All 18 regional, district, and national officers from the 6 regions that we visited (excluding the 3 UNICEF officials in order to focus on the country perspective) indicated that circumcision is almost universally accepted and practiced as part of the culture and for religious beliefs. They accepted medical circumcision due to the evidence of HIV prevention by circumcision. However, 8 of the 18 key informants had concerns with circumcision in young infants. Among the key informants, 3 traditional circumcisers, 3 traditional leaders, 1 health worker circumciser, and 1 urologist opposed circumcision in young infants, and said it should be performed only if the health care delivery system is improved.

In Senegal, the chief of the Layenne community in Dakar, which is predominantly Muslim, said the procedure should be done by the seventh day after birth because it has both religious and medical benefits. He said:

A true Muslim must cut that thing off. It is Arabic, it is not halal; there is no better practice than ours.

A leader in Malem Hodar, a Muslim community in Kaffrine region in Senegal, believes traditional circumcision is a form of education, and if a child is too young, it defeats the purpose. The boy must be old enough to be in “Koranic school,” thus between 12 and 15 years old. He reiterated: “It cannot be done before.”

Meanwhile, a faith healer and circumciser in the same region said the right age at which he circumcises children is between 4 and 5 years. According to him, these children should be able to drink holy water, which he prepares, and have the grigri (native form of magic) put on them for 2 years. If the child is less than that age, the circumcision may result in complications.

A Muslim traditional leader in Dianke Makha community in Tambacounda region of Senegal pointed out that their community is not used to early child circumcision. Per their tradition, they wait until the children are 4 or 5 years old and bring a group of them for circumcision. However, the chief of the community said: “Our grandparents taught us to do it this way, but now we can change if we must.”

A leader in the Beninua community in Limbe in Cameroon believes the procedure should be done as early as possible.

We people who stay here do it in the hospitals and health centers on the third day of birth unless there is a problem with the baby, but some people wait for the children to grow small; but from this community, for our tradition we do it fast.

The practice in the francophone region (Littoral and Central) was the opposite of the anglophone region of Cameroon, where they believe the practice should be done between ages 2 and 10 years. It signifies transition from childhood to manhood and at the same time it is a sign of bravery, potency, and an ability to satisfy their future wives; hence it should not be done too early. According to the head teacher in the community and an opinion leader, if the procedure is done too early, it affects the size of the penis:

Eiii [sound of distress], the size of the penis will be small, the man will be weak and cannot make their wives happy, so we do not do it early.

This assertion was not supported by 4 professionals who were interviewed. A urologist who was also a professor at a university said:

Penile size has to do with genetic makeup and other environmental factors as well as use and disuse of the penis.

In general, mothers and their sons in Cameroon were satisfied with the outcome of the circumcision done by both traditional circumcisers and health providers; 1 person noted that her son’s circumcision was not done properly, and she is considering a second circumcision for him. Health facility records showed that acceptance of EIMC was high in the Southwest (anglophone) region of Cameroon (Buea, Tiko, and Limbe). Information from Buea Regional Hospital, for example, showed that 93% (241/259) of infants delivered at the hospital in 2014 were brought back for EIMC, and on average had the intervention done on day 14. Similarly, the Centre Médical d’Arrondissement (CMA) (district medical center) Limbe documented 99% (109/110) EIMC acceptance in 2014.
Demand for EIMC Service Provision, Advocacy, and Communication

In both Cameroon and Senegal, demand for circumcision services emanates from the community. There are no national communication strategies, mass media campaigns, and information, education, and communication materials (e.g., posters) in the facilities. Community leaders and fathers and mothers of male children regularly ensured that circumcisions were conducted as part of their cultural and religious practices.

With the exception of the Urologist Association of Cameroon, which organized a series of lectures and presentations on circumcision, neither country has developed messages or materials that integrate local issues into explanations of male circumcision and reduced risk of HIV transmission, the healing period, risk of adverse events, who should perform the procedure, where it should be done, at what age, and informed consent issues. Facilities providing circumcision services provide their own form of messages that are appropriate for their setting, such as the medical importance of infant circumcision, the timing of the intervention to be in line with their traditional beliefs, and wound care. The main sources of information about circumcision reported by respondents included traditional leaders, spiritual leaders, and service providers.

Availability and Accessibility of EIMC Services

The 6 facilities assessed in each country provided a comprehensive set of services (Table 5). In Cameroon, 5 of the 6 facilities provide EIMC and 3 have nutrition services. Of the 5 facilities that provide EIMC services, 3 include EIMC counseling as part of postnatal counseling for mothers who deliver boys. The facilities accepted complications referred from the communities, and most of these cases were seen at the Central Hospital of Yaounde, where there were a number of consultant urologists. In Cameroon, 79% (76/96) of parents indicated that they were able to access EIMC services anywhere they wanted, and that fathers made the decision to have their infant son circumcised. Ten percent (10/96) delayed circumcision due to the cost of the procedure.

In Senegal, EIMC services were available in all 3 regions visited. Of the 5 health facilities that provide EIMC, only 2 include counseling for mothers who deliver boys. The counseling covered the need to circumcise and who to see for the procedure when the parents are ready. The counseling did not include detailed information on EIMC, where and when it should be done, the clinical procedure, risk of adverse events, and potential benefits.

In both countries, parents bear the cost of the service, either full cost recovery or the subsidized cost. Costs range from 1,000 CFA to 25,000 CFA (US$1.70 to US$42.70) in health facilities, compared with 3,000 CFA to 5,000 CFA (US$5.10 to US$8.50) when performed by traditional circumcisers. In the Southwest region of Cameroon, some facilities operate performance-based funding supported by an NGO, Agence Européene pour le Développement et la Santé (AEDES) and Institut pour la Recherche, le développement Socio-économique et la Communication (IRESCO) (AEDES/IRESCO). The NGO pays the difference between the subsidized fees received from parents and the actual cost of the circumcision. However, in traditional settings, circumcision may be done for free.

Human Resource Capacity and Infrastructure

Although all cadres of health personnel perform circumcision, only urologists and general surgeons are formally trained. Qualified doctors have transferred skills through on-the-job training for operating room nurses and other cadres of workers. These highly motivated and dedicated staff use their own tools most of the time and carry out the service either before or after their normal work schedule. Nevertheless, we noted that the maximum number of staff directly involved in EIMC in each of the facilities was 2.

Most infan circumcisions (90%) were done in the surgical department or any available sterile area within the hospital, including the surgical preparation room. The service providers we interviewed thought that, though circumcision is surgical, it should be housed under reproductive, maternal, newborn, and child health care.

EIMC Commodities

Cameroon and Senegal do not have national clinical protocols and guidelines that list the medicines, supplies, and equipment needed to deliver all aspects of EIMC services. Most of the commodities, such as scalpel blades, syringes, anesthetic agent, gauze, and suture material, are
procured for other services like major surgery and not specifically for circumcision.

In Cameroon, none of the service providers had ever used the reusable Mogen clamp and disposable devices like Plastibell and AccuCirc; instead they use a scalpel and scissors for the circumcision. In contrast, in Senegal, 5 of the facilities visited used the Mogen clamp, and only 1 had a disposable device like Plastibell. From the assessment, 2 of 5 policy makers at the national level and 70% (67/96) of service providers think key circumcision commodities should be in the list of national essential medicines and equipment and in the procurement and distribution systems used by service delivery sites.

**Monitoring and Evaluation and Strategic Information**

Monitoring and evaluation officers did not have EIMC data collection and reporting tools in any of the facilities visited. The national monitoring and evaluation tool does not collect data on circumcision. Circumcision services were therefore recorded in different tools available to the service provider. Two of the facilities in Senegal that performed circumcisions were not collecting data on circumcision, and the other 4 that were collecting circumcision data did not record the ages of the infants. Hence, we could not determine the EIMC rate for the facilities visited.

The 6 facilities visited in Senegal recorded 6,608 deliveries in 2013.

**Findings From the Focus Group Discussions for Cameroon**

All of the 146 participants involved in the community and service provider focus groups in Cameroon were aware of and had knowledge of circumcision. Participants from the Southwest (anglophone) region said that they circumcise their infants between 0 and 60 days of life, which fits the definition of EIMC. Mothers in the anglophone region knew some of the medical benefits of circumcision. Adolescents in the anglophone region of Cameroon indicated that circumcised babies were protected from certain illnesses and diseases, such as urinary tract infection, and the infant may never remember the pain of the procedure. Their parents, however, were not sure of any medical benefit of circumcision.

The participants from the Littoral and Central (francophone) regions said they prefer to circumcise their sons between ages 2 and 10 years. Meanwhile, mothers from the francophone regions reported mainly cultural reasons for circumcision. Sixty-eight percent (24/35) of mothers in the francophone regions prefer circumcision done after age 5 to ensure penile size is not affected. They fear

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**TABLE 5. Number of Facilities Visited in Cameroon and Senegal Providing Selected Types of Services**

<table>
<thead>
<tr>
<th>Service</th>
<th>Cameroon (N = 6)</th>
<th>Senegal (N = 6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>General OPD services</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Antenatal care</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>HIV testing and counseling/PMTCT</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Male circumcision</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>EIMC</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>EIMC counseling in ANC and postnatal care</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Child health services</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>Laboratory services</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>Recommended immunization</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>Nutrition services</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

Abbreviations: ANC, antenatal care; EIMC, early infant male circumcision; OPD, outpatient department; PMTCT, prevention of mother-to-child transmission.
that infant circumcision will cause the penis to become small and interfere with their sons’ ability to satisfy future wives. Similar to the views of francophone women, francophone men prefer to have circumcision at a later age. One of the men said:

Circumcision is like childbirth in women, a warfare where real men are separated from boys.

Adolescent boys in the francophone region enjoy the celebratory feast associated with circumcision and therefore prefer to be circumcised late, which is directly opposite of the views of adolescent boys from the anglophone region. In addition, the francophone adolescent boys said the procedure should be done between ages 5 and 7 years:

You should feel the pain but not cry to show that you are brave, hmmm even remember who cut the thing for you; if you finish, big cock [rooster] be used for party for you to eat all, very, very nice.

All of the adolescent boys reported that after the procedure is carried out, they really enjoy the biggest rooster prepared for them on that special day. One of the boys said:

If the procedure is done too early, this culture will die.

All parents engaged in the focus groups did not know if service providers had been trained or not. Ninety percent of parents (57/63) had the service provided for their sons by health workers who sometimes provide the service in the homes of their clients.

The following were some of the suggestions from respondents for improvement of EIMC services:

Education in the various communities about EIMC will allow leaders to start sending the children for circumcision early.

Traditional circumcisers should be trained with the modern circumcision methods.

Educational materials need to address the cultural belief that circumcision is an act of manhood that proves bravery and potency.

Findings From the Focus Group Discussions for Senegal
A total of 96 people were involved in the 12 community focus groups in the 3 regions visited; 3 with men, 3 with women, and 6 with adolescent boys. In addition, 48 service providers were part of 3 focus groups. Most of them affirmed the availability of the EIMC services and their knowledge of the benefits of EIMC, and they were satisfied with the service provision. A participant from the predominantly Muslim Layenne community phrased the benefits as:

The first benefit is, science confirms that a child circumcised as a baby will be protected from certain illnesses and diseases, like phimosis and balanitis. And on a religious level, an adult should not show his private parts, so it is better to get him circumcised at a young age, so that he does not have to show his private parts when he is an adult. Some scientists and doctors also say that the child feels less pain when he is very young.

Other observations made in the focus group discussions were:

• If the procedure is done when the child is a baby, it will be less costly for the parents.

• Without circumcision, one cannot marry, have children, nor get into paradise.

Circumcision was common knowledge to all 144 participants in the community and service provider focus groups. However, 78% (112/144) were not familiar with the term EIMC, except for the communities in Dakar, where EIMC is the norm. Eighty-three percent (80/96) of parents used traditional circumcisers because they consider circumcision to be a religious practice and because it was more cost-effective. Overall, 83% (120/144) of respondents were satisfied with infant circumcision done for their sons or observed by both traditional circumcisers and service providers.

With one exception, none of the service providers and community focus group participants mentioned any serious complications of circumcision. One traditional circumciser mentioned a complication resulting in a “burst” penis during sexual intercourse in a 17-year-old 2 weeks after the circumcision (which he was able to fix).

Other observations from the focus groups:

• Fathers were the main decision makers when it comes to when and where a male child should be circumcised.

• In communities where the practice is carried out as part of religious activity, children are grouped for circumcision and the decision is made by the religious leader of the community.
These boys are kept together until wound healing has occurred.

- A minority of men and 1 traditional circumciser believed the age at circumcision has an effect on the size of the penis, which influenced their decision on the timing of the circumcision.

**DISCUSSION**

Despite the absence of national policies, strategies, and guidelines on EIMC, it is routinely offered at all levels of the health care system in Cameroon and Senegal, mainly driven by community demand. Across the continuum of care, 10 of the 12 facilities assessed in both countries provide EIMC services.

The decision about when and where to perform the circumcision, and by whom, is made predominantly by fathers and occasionally by community leaders. For religious and cultural reasons, some communities and service providers prefer circumcision to be done between ages 2 and 15 years.

There is no formal EIMC training for most service providers. The use of modern circumcision devices such as Plastibell and AccuCirc was rare. However, there were not many severe adverse events reported or observed during the assessment. The equally good innovative means of teaching through skills transfer during on-the-job training by qualified doctors for operating room nurses and other cadres of workers served as a stopgap measure for capacity building.

EIMC by service providers is either subsidized or fully paid for by parents. Payments cannot be made through national health insurance, but there is either full cost recovery from or cost sharing with the government or an NGO for some facilities in the Southwest region of Cameroon. Infant circumcisions done for purely traditional reasons by traditional circumcisers are usually done for free, though in some cases parents pay for the service.

**RECOMMENDATIONS**

A number of steps could be taken to improve and guide a more systematic provision of EIMC services in Cameroon and Senegal:

- Develop a clear policy and guidelines on provision of medical male circumcision for infants by health cadres.
- Create community engagement to establish a strong community coalition and raise awareness of medical services for infant circumcision.
- Develop communication strategies targeting men and influential members of the community to use trained service providers and/or trained traditional circumcisers for their infant circumcision.
- Develop and include medical male circumcision in preservice training for all health cadres.
- Investigate the potential to use both surgical and nonsurgical devices for EIMC.
- Set up EIMC commodities and supply chains and introduce data collection tools.

These recommendations may also be relevant for other countries where male circumcision is the norm, but where there is no formal system for circumcision in general and EIMC in particular.

**CONCLUSION**

EIMC is routinely offered at all levels of service delivery in Cameroon and Senegal mainly due to community demand, albeit in the absence of national policies and guidelines. Improvement of medical EIMC requires the development of guidelines, preservice training, the use of surgical and nonsurgical devices, supply chains, data collection tools, engaged communities to raise awareness, and communication strategies for men.

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**REFERENCES**


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During a pilot project in Tanzania’s Iringa region, more than 2,000 male infants were circumcised in less than 2 years in 8 facilities, representing 16.4% of all male births in those facilities. The age of the infant at circumcision and the time of return for follow-up visits varied significantly between urban and rural dwellers. Early infant male circumcision (EIMC) outreach activities and use of health outposts for follow-up visits should be explored to overcome these geographic barriers. EIMC programs will also require targeted investments in demand creation, especially among fathers, to expand and thrive in traditionally non-circumcising settings such as Iringa.

ABSTRACT

Iringa region of Tanzania has had great success reaching targets for voluntary medical male circumcision (VMMC). Looking to sustain high coverage of male circumcision, the government introduced a pilot project to offer early infant male circumcision (EIMC) in Iringa in 2013. From April 2013 to December 2014, a total of 2,084 male infants were circumcised in 8 health facilities in the region, representing 16.4% of all male infants born in those facilities. Most circumcisions took place 7 days or more after birth. The procedure proved safe, with only 3 mild and 3 moderate adverse events (0.4% overall adverse event rate). Overall, 93% of infants were brought back for a second-day visit and 71% for a seventh-day visit. These percentages varied significantly by urban and rural residence (97.4% urban versus 84.6% rural for day 2 visit; 82.2% urban versus 49.9% rural for day 7 visit). Mothers were more likely than fathers to have received information about EIMC. However, fathers tended to be key decision makers regarding circumcision of their sons. This suggests the importance of addressing fathers with behavioral change communication about EIMC. Successes in scaling up VMMC services in Iringa did not translate into immediate acceptability of EIMC. EIMC programs will require targeted investments in demand creation to expand and thrive in traditionally non-circumcising settings such as Iringa.

INTRODUCTION

Three randomized controlled trials showed unequivocally that voluntary medical male circumcision (VMMC) reduces female-to-male HIV transmission by approximately 60%. In March 2007, the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) issued guidance urging countries with high HIV prevalence, low male circumcision rates, and a generalized HIV epidemic to incorporate VMMC into their comprehensive HIV prevention programs.

Although Tanzania had an overall circumcision prevalence of 66.8% at the start of the VMMC program in 2009, Iringa region had a lower circumcision prevalence (29% of male adults) and at the time was Tanzania’s most HIV-affected region, with an adult HIV prevalence of 15.7%. Therefore, the Tanzanian Ministry
Rolling out EIMC from 2013 through 2050 in Tanzania could avert 2% of all HIV infections.

Beginning in April 2013, EIMC services were pilot-tested in 4 health facilities in Iringa region of Tanzania. Four more sites were added in April 2014 (Figure 1). From the pilot project’s inception through December 2014, more than 2,000 EIMCs were performed.

In the pilot program, EIMC services were offered in the outpatient reproductive and child health (RCH) services and conducted by health care providers who routinely provide services in the RCH or maternity ward. Counseling on EIMC, using standardized information from job aids, took place during antenatal care (ANC), maternity care, and/or postpartum care as well as during well-baby visits. Parents who heard of EIMC through counseling, community workers, or radio advertisements requested to have their child circumcised and were given appointments. Before the circumcision, parents/guardians were individually counseled on the risks and benefits of EIMC, offered HIV testing and counseling for themselves and their infants, informed about postoperative care, and asked to sign a written consent statement authorizing the procedure. The services were offered 3 to 5 days a week, depending on the facility. Parents were instructed to bring their infants back for follow-up on day 2 and day 7 after the circumcision procedure.

Iringa region was selected to host the EIMC pilot program as it was near to achieving the adult VMMC targets. It was unclear to what extent the gains in adult VMMC would translate into support for infant male circumcision; historically, the non-Muslim communities of Iringa region do not circumcise male infants. This paper presents findings from a quantitative and qualitative study conducted among users of the EIMC services and parents and guardians in the communities surrounding the EIMC pilot facilities. Demographic characteristics of clients in the EIMC pilot program are described, including the timing of circumcision and attendance at follow-up visits, as well as key qualitative findings associated with EIMC decision making. This paper aims to provide information to help guide rollout of EIMC services in Tanzania and similar settings in sub-Saharan Africa.

METHODS

We conducted a cross-sectional study, using qualitative and quantitative methods, from May through August 2014. We conducted qualitative interviews with parents and guardians of EIMC
clients in the 4 original pilot facilities as well as a review of EIMC patient files. The MOHSW and the regional authorities participated in selecting the EIMC pilot facilities, based on facility assessments that considered the number of deliveries in facilities (preference was given to higher volume), available human resources, availability of space, and capability for instrument processing/sterilization.

**Qualitative Component**

The qualitative component of the study took place between May and August 2014 in the original 4 pilot facilities: Ipogolo Health Centre, Iringa Regional Referral Hospital, Tosamaganga Hospital, and Ilula Lutheran Hospital.

Study participants were parents/guardians receiving antenatal care service, parents/guardians of infants circumcised in the EIMC facilities, and parents/guardians who brought their male infants to RCH services and received information about EIMC but chose not to have the infants circumcised within 60 days of birth. We invited study participants to attend focus group discussions (FGDs). We conducted separate FGDs with the parents/guardians who had the infants circumcised through EIMC services (EIMC acceptors) and with parents/guardians who decided not to circumcise the infants through EIMC services (EIMC non-acceptors).

Parents and guardians who were recruited for the study during ANC services were followed over time until 2 months after the birth of the infants; they were then grouped in the FGDs as acceptors or non-acceptors, depending on their decision to circumcise the infants. All study participants...
were 18 years old or older, lived within a study health facility catchment area, and consented to participate in the research. We held 24 FGDs, with a range of 4 to 10 participants per FGD and an average of 7 participants. In all, 165 people took part in FGDs (Table 1).

EIMC acceptors were recruited for FGDs on the day that the infants were circumcised and given an FGD appointment for a date within 2 weeks. They received reminders about the FGD 7 days after the circumcision, when parents or guardians brought the infants for the EIMC day 7 follow-up visit. FGD appointments for EIMC non-acceptors were scheduled within 2 weeks of recruitment.

Experienced and trained researchers conducted the FGDs in Kiswahili, using separate structured FGD guides for EIMC acceptors and for EIMC non-acceptors. These guides used open-ended questions to explore perspectives on decision making about EIMC.

The training for all study staff included research ethics and informed consent. All discussions were audio recorded, transcribed in Kiswahili, and then translated into English. Codes were grouped into categories, and emerging themes were then identified iteratively following the principles of grounded theory.12,13 A team of researchers (not the facilitators of the FGDs) reviewed and reached consensus on the themes. They based their analysis on theme saturation—once no new issues emerged, the description of the theme was considered exhaustive.

Quantitative Component
The quantitative component of the study involved reviewing the records of EIMC clients in all 8 pilot facilities (the original 4 facilities and 4 additional facilities: Frelimo Hospital, Mafinga District Hospital, Kidabaga Health Centre, and Igumbilo Dispensary). During the pilot project, providers filled in MOHSW-approved EIMC client record forms, which were kept at each facility. These records were stripped of identifiers and entered into a program monitoring database. The de-identified client records were pulled from the program database and imported for analysis into Stata statistical software (StataCorp. 2013. Stata Statistical Software: Release 13. College Station, TX: StataCorp LP). Variables of interest included location of birth, location of circumcision, number of days of age at circumcision, follow-up appointments at 2 days and 7 days, rural versus urban residence of the mother, HIV status of the mother, and adverse events occurring during or after circumcision.

Using Stata, we conducted both descriptive analysis and bivariate logistic regression. Descriptive analysis was used to determine mean age of the infants and standard deviation. We used frequencies to describe key characteristics of EIMC clients, with comparisons among facilities, by urban and rural residence, and by infant’s age at circumcision. For comparison of 2 proportions, we used chi-square ($\chi^2$) tests for statistical significance of the observed difference. We conducted bivariate logistic regression to determine the odds of returning to the clinic for the infant’s follow-up care among mothers residing in urban locations and those in rural locations. The outcome variable was whether the infant was brought back for the follow-up visit, and the independent/predictive variable was rural/urban residence.

In this paper, age at circumcision is presented in age strata, which we constructed based on Tanzania’s clinical management protocols for the

### TABLE 1. Overview of EIMC Study Participants

<table>
<thead>
<tr>
<th>EIMC Acceptors</th>
<th>EIMC Non-Acceptors</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No. of FGDs</strong></td>
<td><strong>Total No. of Participants</strong></td>
</tr>
<tr>
<td>Men</td>
<td>4</td>
</tr>
<tr>
<td>Women</td>
<td>8</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>12</strong></td>
</tr>
</tbody>
</table>

Abbreviations: EIMC, early infant male circumcision; FGD, focus group discussion.

<table>
<thead>
<tr>
<th></th>
<th>Iringa Regional Referral Hospital</th>
<th>Ipogolo Health Centre</th>
<th>Tosamaganga District Hospital</th>
<th>Ilula Lutheran Hospital</th>
<th>Frelimo Hospital</th>
<th>Igumbilo Dispensary</th>
<th>Mafinga District Hospital</th>
<th>Kidabaga Health Centre</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of male infants born during pilot project</td>
<td>5,175</td>
<td>851</td>
<td>2,203</td>
<td>1,674</td>
<td>174</td>
<td>54</td>
<td>2,442</td>
<td>105</td>
<td>12,678</td>
</tr>
<tr>
<td>EIMC uptake among male infants, No. (%)</td>
<td>483 (9.3)</td>
<td>268 (31.5)</td>
<td>303 (13.7)</td>
<td>263 (15.7)</td>
<td>66 (36.9)</td>
<td>36 (66.7)</td>
<td>86 (3.5)</td>
<td>24 (22.9)</td>
<td>2084 (16.4)</td>
</tr>
<tr>
<td>Age at circumcision, days, median (range)</td>
<td>32 (1–74)</td>
<td>27 (1–72)</td>
<td>4 (1–78)</td>
<td>14 (1–78)</td>
<td>28 (1–60)</td>
<td>30 (1–71)</td>
<td>14 (1–73)</td>
<td>3 (1–34)</td>
<td>22 (1–78)</td>
</tr>
<tr>
<td>No. of EIMC performed</td>
<td>528</td>
<td>503</td>
<td>326</td>
<td>297</td>
<td>179</td>
<td>125</td>
<td>99</td>
<td>27</td>
<td>2,084</td>
</tr>
<tr>
<td>EIMCs by mother’s place of delivery, No. (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>This facility</td>
<td>450 (85.2)</td>
<td>216 (42.9)</td>
<td>297 (91.1)</td>
<td>252 (84.9)</td>
<td>54 (30.2)</td>
<td>20 (16.0)</td>
<td>85 (85.9)</td>
<td>24 (88.9)</td>
<td>1,398 (67.1)</td>
</tr>
<tr>
<td>Another facility not offering EIMC services</td>
<td>45 (8.5)</td>
<td>235 (46.7)</td>
<td>23 (7.1)</td>
<td>34 (11.4)</td>
<td>113 (63.1)</td>
<td>89 (71.2)</td>
<td>13 (13.1)</td>
<td>3 (11.1)</td>
<td>555 (26.6)</td>
</tr>
<tr>
<td>Home</td>
<td>33 (6.3)</td>
<td>52 (10.3)</td>
<td>6 (1.8)</td>
<td>11 (3.7)</td>
<td>12 (6.7)</td>
<td>16 (12.8)</td>
<td>1 (1.0)</td>
<td>0 (0.0)</td>
<td>131 (6.3)</td>
</tr>
<tr>
<td>EIMCs by place of residence, No. (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urban</td>
<td>477 (90.3)</td>
<td>409 (81.3)</td>
<td>22 (6.7)</td>
<td>169 (56.9)</td>
<td>172 (96.1)</td>
<td>47 (37.6)</td>
<td>43 (43.3)</td>
<td>0 (0.0)</td>
<td>1,339 (64.2)</td>
</tr>
<tr>
<td>Rural</td>
<td>42 (8.0)</td>
<td>93 (18.5)</td>
<td>303 (92.9)</td>
<td>122 (41.1)</td>
<td>6 (3.3)</td>
<td>78 (62.4)</td>
<td>56 (56.6)</td>
<td>27 (100.0)</td>
<td>727 (34.9)</td>
</tr>
<tr>
<td>Infants brought for day 2 follow-up, No. (%)</td>
<td>510 (98.3)</td>
<td>495 (98.6)</td>
<td>210 (64.6)</td>
<td>289 (99.3)</td>
<td>172 (96.6)</td>
<td>125 (100)</td>
<td>91 (91.9)</td>
<td>27 (100.0)</td>
<td>1,919 (92.9)</td>
</tr>
<tr>
<td>Infants brought for day 7 follow-up, No. (%)</td>
<td>455 (87.7)</td>
<td>424 (84.5)</td>
<td>34 (10.5)</td>
<td>214 (73.5)</td>
<td>148 (83.2)</td>
<td>114 (91.2)</td>
<td>59 (59.6)</td>
<td>16 (59.3)</td>
<td>1,464 (70.9)</td>
</tr>
<tr>
<td>Circumcised infants with HIV+ mothers, No. (%) of all circumcised infants</td>
<td>34 (6.4)</td>
<td>27 (5.4)</td>
<td>28 (8.6)</td>
<td>34 (11.4)</td>
<td>14 (7.8)</td>
<td>8 (6.4)</td>
<td>13 (13.1)</td>
<td>1 (3.7)</td>
<td>159 (7.6)</td>
</tr>
</tbody>
</table>

Abbreviation: EIMC, early infant male circumcision.

* 18 mothers reported residence outside of the region and were excluded from this analysis.
postpartum period, the immunization schedule for young infants, and the WHO recommendation to provide EIMC within 60 days of birth. In Tanzania, the MOHSW recommends return visits for routine postpartum care and immunization at 7, 28, and 42 days. Age at circumcision is presented in reference to those milestones.

Ethical Considerations
Informed consent was required for all study participants, in addition to the nationally mandated consent required of parents or guardians before the infant underwent circumcision. The institutional review boards of the Johns Hopkins Bloomberg School of Public Health (IRB 00005145) and the Tanzania National Institute of Medical Research (NIMR/HQ/R.8a/Vol.IX/1684) conducted ethical oversight of the study with support from the Iringa regional medical authorities.

RESULTS
Demographic Characteristics of Infants in the EIMC Pilot Project
Table 2 presents characteristics of 2,084 infants circumcised during the pilot project, from April 2013 through December 2014. Of these infants, 1,398 had been delivered in one of the 8 participating facilities, 555 in other facilities that do not currently offer EIMC services, and 131 at home. During the pilot period, 12,678 male infants in total were born in the 8 pilot facilities; 16.4% of these were circumcised through the EIMC pilot program. Of the circumcised infants, 7.6% were born to HIV-infected mothers. The median age of the infants at circumcision was 22 days (range, 1–78 days), with variation by health facility, place of residence, and location of the baby’s delivery. Two-thirds (67.1%) of EIMCs were performed in the facility where the mother delivered her child, 26.6% in another facility, and a relatively small proportion (6.3%) at home. Almost two-thirds (64.2%) of EIMCs occurred among infants residing in urban areas, compared with 34.9% from rural areas. Overall, 93% of infants were brought back for the day 2 visit and 71% for the day 7 visit. This varied significantly by urban and rural residence—97.4% urban versus 84.6% rural for day 2 visit and 82.2% urban versus 49.9% rural for day 7 visit ($P<.001$) (Table 3).

As Table 4 shows, the majority of infants (73.1%) were circumcised between 8 and 60 days.
of age. Approximately one-quarter (26.2%) of the infants were circumcised within 7 days of birth, ranging from 13.1% in health centers to 22.4% in dispensaries. Half of the infants (52.5%) were circumcised in the 8- to 42-day range, which coincides with the second and third scheduled immunization visits (28 days and 42 days) in Tanzania.

As Figure 2 shows, nearly half of rural mothers who circumcised their infants did so

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### TABLE 4. Age at Circumcision by Level of Health Facility in the Iringa EIMC Pilot Project, April 2013–December 2014

<table>
<thead>
<tr>
<th>Facility Level (No. of EIMCs performed)</th>
<th>≤ 2 Days % (95% CI)</th>
<th>3–7 Days % (95% CI)</th>
<th>8–28 Days % (95% CI)</th>
<th>29–42 Days % (95% CI)</th>
<th>43–60 Days % (95% CI)</th>
<th>61–78 Days % (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitals (1,429)</td>
<td>12.0 (10.4, 13.8)</td>
<td>19.3 (17.3, 21.4)</td>
<td>29.2 (26.9, 31.7)</td>
<td>18.1 (16.1, 20.1)</td>
<td>20.6 (18.5, 22.7)</td>
<td>0.8 (0.4, 1.4)</td>
</tr>
<tr>
<td>Health centers (530)</td>
<td>3.8 (2.4, 5.8)</td>
<td>9.3 (7.1, 12.0)</td>
<td>41.9 (37.7, 46.1)</td>
<td>22.5 (19.1, 26.2)</td>
<td>21.7 (18.4, 25.4)</td>
<td>0.9 (0.4, 2.2)</td>
</tr>
<tr>
<td>Dispensaries (125)</td>
<td>12.8 (7.9, 20.0)</td>
<td>9.6 (5.5, 16.2)</td>
<td>22.4 (15.8, 30.6)</td>
<td>38.4 (30.2, 47.3)</td>
<td>16.0 (10.5, 23.6)</td>
<td>0.8 (0.1, 5.6)</td>
</tr>
<tr>
<td>Total (2,084)</td>
<td>9.9 (8.8, 11.3)</td>
<td>16.2 (14.6, 17.8)</td>
<td>32.1 (30.1, 34.1)</td>
<td>20.4 (18.7, 22.2)</td>
<td>20.6 (18.9, 22.4)</td>
<td>0.8 (0.5, 13.1)</td>
</tr>
</tbody>
</table>

Abbreviations: CI, confidence interval; EIMC, early infant male circumcision.

---

### FIGURE 2. Percentage Distributions of EIMCs by Infant’s Age at Circumcision and Mother’s Residence

Abbreviation: EIMC, early infant male circumcision.
within 7 days of birth (49.8% of infants, n = 362), whereas the rate of circumcision of infants among urban mothers was much higher after 7 days of birth (86.0% of infants, n = 1,151).

There were substantial differences between urban- and rural-dwelling mothers in terms of where their circumcised infant was delivered, who brought the infant for circumcision, and when and how often the infant was brought for follow-up (Table 3). Among mothers living in urban areas, attendance at the day 2 follow-up visit was close to universal (97.4%), whereas the rate among mothers living in rural areas was 84.6% (P < .001). The greatest difference, however, was seen in attendance at the day 7 follow-up visit; 49.9% among rural mothers compared with 82.2% among urban mothers (P < .001). On the day of circumcision, 77.5% of the infants were brought by mothers or female guardians alone (95% confidence interval [CI], 75.7% to 79.2%), and 22.5% were brought by both parents (95% CI, 20.7% to 24.3%). Rural-dwelling parents were more likely to bring the infant together (31.2% rural versus 17.7% urban parents, P < .001) (Table 3).

More than three-quarters (78%) of parents/guardians had heard of these services in a health facility setting, most often the labor and delivery ward (40%; range, 14%–44%) and the RCH clinic (36%; range, 35%–43%). Another 14% said they had heard about these services from the radio, 5% from a friend or relative, and 3% from a peer educator (Figure 3).

Six adverse events occurred among the 2,084 circumcisions conducted in the pilot project, for an overall AE rate of 0.4%. All AEs occurred during the circumcision procedure (intraoperatively). They included mild bleeding (n = 3), moderate bleeding (n = 1), and mild/excessive skin removal (n = 2). The AEs, which occurred in 2 of the 8 pilot facilities, occurred in procedures performed by assistant medical officers (2 AEs) and nurses (4 AEs). All AEs resolved completely. All providers performing EIMC in the pilot project had attended a competence-based 5-day training using a WHO Manual for EIMC.8 The EIMC providers in the pilot project included nurses (68%), physicians (18%), clinical officers (11%), and assistant medical officers (3%).

**Qualitative Study Findings**

The quotes from themes presented in this paper address decision making. Other themes that emerged, including gender and satisfaction, will be presented in upcoming papers.

**EIMC Information Received**

In keeping with the program model, participants in the FGDs said that when the mother had been counseled on EIMC as part of her RCH services, she was the one who provided information about EIMC to her partner as part of the family decision-making process. This was heard from both the female and male FGD participants: Most male “acceptors” indicated that they had heard about EIMC from their wives.

I got the [EIMC-related] information from my wife after she was advised by the doctors here. —EIMC male acceptor, Iringa Referral Hospital

**Decision Making**

Although women were characterized as bringing information about EIMC into the home, more
than 80% of women in both the acceptor and non-acceptor FGDs referred to the father as the decision maker about whether the child would be circumcised.

It’s true that dads are the problem. If the man says the child won’t be circumcised till he turns 2 years, it will be like that no matter what. And I have no power to force it other way round. —EIMC female non-acceptor, Iringa Referral Hospital

Among female non-acceptors, more than 60% in FGDs indicated that they had wanted their son to be circumcised, but the father refused.

I feel badly… I wanted to circumcise him soon after birth, but his father refused because he said he is still young, wait until he grows up. —EIMC female non-acceptor, Ipogolo Health Centre

Among some acceptors, decision makers involved the extended family, including the grandparents.

First of all I talked to my husband. Secondly I talked with parents of both sides who are in-laws…. When they all agreed, then I made a decision to circumcise him…. Because this child has a grandfather and a grandmother. Everything should be shared with these elders. —EIMC female acceptor, Iringa Referral Hospital

**Misconceptions and Relation to Traditional Circumcision**

FGD participants, particularly male non-acceptors, described 3 notable misconceptions. These were: (1) fear of suturing and resulting injury to the penis (a misconception since the EIMC procedure does not include suturing), (2) fear that the foreskin would be taken for witchcraft or another purpose, and (3) fear that the penis would not grow properly without the foreskin. Some male non-acceptors also equated the EIMC procedure with traditional circumcision, in which, typically, no pain medication is given.

Not knowing how an infant is circumcised, as far as I know it, circumcision is done by operation. Now, stitching is where my fears lie, taking into account the delicacy of the infant’s skin …. if the skin is to be stitched, I can’t imagine the type of stitches that are used! —EIMC male non-acceptor, Iringa Referral Hospital

They believe that the things that are cut might be taken to people who know how to use them … Maybe some people who have superstitious beliefs might have been asked to bring the child’s foreskin. —EIMC female acceptor, Ipogolo Health Centre

He does not want his son to be circumcised while he is still young, because if you do so his reproductive organs won’t grow at all. —EIMC female non-acceptor, Iringa Referral Hospital

For some fathers who volunteered the information that they had undergone traditional circumcision, the recollections of their experience made them decide against their sons’ circumcision. None of these fathers were aware that EIMC is performed using devices and with pain medication.

I was circumcised traditionally in the bush without anesthesia, without anything, you see? … Nowadays one is circumcised by using scissors, unlike in old days where a knife or something else was used … If you recall the way you were circumcised and think of your child going through the same process, you think, “Let him grow a bit.” —EIMC male non-acceptor, Ipogolo Health Centre

It is true that I opposed this circumcision … The reason for me to have such an argument is that I myself was circumcised [traditionally] when I was about 15 years old. … I can remember that there was a kid of about 5 years in the group. … In my observation he suffered, and I reached the conclusion that my parents had done the right thing when they decided that I should be circumcised [at an older age]. —EIMC male non-acceptor, Ipogolo Health Centre

**DISCUSSION**

In the pilot project in Iringa region, 16.4% (2,084) of all male infants delivered in the 8 health facilities were circumcised. In larger hospitals, coverage tended to be lower (4%–8% of male infants delivered in the facility), although greater numbers of infants were circumcised because of the larger patient population. In facilities with relatively low delivery volume, there was greater coverage—more than 25%. It is likely that human resource constraints limited the number of circumcisions performed per day at facilities with a high volume of deliveries.

The majority of the EIMCs were performed in the WHO-recommended window between 0 and 60 days after birth, and most occurred after 7 days of birth. Two-thirds of the EIMCs took place in the same facility where the infant was born. More than 80% of women said the father was the decision maker about their infant's circumcision.
On average, infants of urban mothers were circumcised later than infants of rural mothers. They also were more likely to be brought for the second follow-up visit.

delivered; relatively few (6.3%) were performed on infants born at home. The follow-up rate was very high for the 2-day follow-up visit (93%) and lower for the 7-day visit (71%), with substantial differences between urban and rural residence. A total of 7.6% of infants circumcised were born to mothers with HIV. Only 8% of mothers indicated that they had heard of EIMC services from a friend or relative (5%) or a peer educator (3%), implying that community awareness was quite low at the time of the pilot project.

Urban and rural residence played a role in the age of the infant at circumcision and the time of return for follow-up visits. EIMC generally occurred later for infants from urban areas than for those from rural areas (mean of 28 days for urban residents versus 17 days for rural residents, \( P < .001 \)). Because there is a limited window for EIMC (24 hours to 60 days after birth), there may be benefits for parents to seek services earlier; if the procedure needs to be delayed due to health facility constraints or ineligibility that may resolve over time (e.g., fever during health assessment), there may still be an opportunity to seek EIMC before the 60-day time frame. Although attendance at follow-up visits was very high among both groups for the 48-hour visit, infants with mothers who reported urban residence were 3.8 times more likely to return for a second follow-up visit. This may be attributable to barriers to health care access faced by rural residents. The service delivery model designed for EIMC following the pilot project must address urban and rural differences in access to services. These differences may affect potential EIMC outreach and logistics needed to ensure good follow-up rates; there may be a need to use rural health outposts for EIMC follow-up among rural residents.

The antenatal, perinatal, and postnatal periods are times when the mother and infant have multiple points of access to the health system.\(^{14,15}\) These times provide opportunities for the parents to make decisions for the immediate and longer-term health needs of their children. The 2010 Tanzania Demographic and Health Survey found that 65% of women whose last live birth occurred in the preceding 5 years did not receive a postnatal check-up.\(^{14}\) This indicates a large gap in infants being seen in the postnatal period, which, in addition to missing key health information and services, means that an opportunity for EIMC counseling may be missed. In the Southern Highlands zone, where Iringa region is located, 48% of babies are delivered at home.\(^{14}\)

EIMC services are highly integrated with RCH and maternity services, and EIMC procedures are performed by the same health care providers and in the same locations in the health facilities. Given this integration, our analysis included the timing of the EIMC procedure in order to inform program planners as to when, in the spectrum of maternal, newborn, and child health services, parents might be most open to having their infant circumcised. A South African study found that parents have distinct preferences regarding the age of circumcision for their infants—based on their perceptions of factors such as wound healing, pain, and caretaking—and that the majority of the mothers and fathers were willing to circumcise their infants during the first week after birth.\(^{16}\)

Our findings revealed that, although rural parents were more likely to seek EIMC before the infant was 2 days old, the majority of parents (73%) brought their child for circumcision between 8 and 60 days, meaning that the parents brought them back to the facility rather than having the infant circumcised before discharge from delivery. Despite WHO’s recommendation that the infant stay in the health facility for 24 hours after birth,\(^{17}\) anecdotal evidence suggests that, because of crowding in health facilities, mothers and infants are often discharged prior to 24 hours, making the male infants ineligible for circumcision. Similarly, because Tanzanian facilities generally do not allow birth companions in the delivery room, fathers are often not present at the delivery of their sons. Because fathers play an important role in deciding whether to circumcise male infants, their absence at delivery may mean a missed opportunity for EIMC before the mothers and infants are discharged. Given these realities, the programmatic implications of encouraging parents to circumcise the infant before discharge from the facility in the immediate postpartum period should be investigated. Potential behavior change communication models include encouraging women to discuss EIMC with their partners when they are attending ANC, or to integrate EIMC counseling specifically into services for the prevention of mother-to-child transmission of HIV, which men are more likely to attend. Further research may be warranted to look at the timing of the EIMC messages and counseling within the spectrum of RCH services, to explore whether earlier messages provide more time for mothers-to-be to discuss EIMC with the father.

This analysis focused on characteristics of families and infants and EIMC decision making. Gains in cultural acceptance of VMMC have been...
documented in Iringa region. Accounts suggest that circumcision has become socially desirable for a variety of reasons. However, the qualitative findings of this study suggest that acceptance of VMMC may not have as much of a positive effect on acceptance of EIMC as might be hoped. The specific reasons that non-acceptors gave for declining EIMC (fears about the delicacy of the skin of the infant and fears about growth of the penis) were quite different from those noted as barriers to VMMC, which had more to do with abstinence and relationship status. In addition, the positive social pressure for adult men in Iringa to be circumcised, based on the perception that male circumcision increases their sexual desirability, does not apply to EIMC.

Fathers were the least exposed to messages about EIMC from health care providers but held greater decision-making power and had the most misconceptions about EIMC. This finding parallels findings in Kenya, where fathers were reported to be the primary decision makers regarding EIMC in 66% of the couples interviewed. A study in Zimbabwe noted similar barriers. Fathers had strong decision-making powers, and men who had been traditionally circumcised often had negative perceptions of EIMC. The current study and the Zimbabwe study support our conclusion that, for effective EIMC scale-up, program planners must consider the household decision-making process and find ways to reach men with accurate information about EIMC.

A very low proportion (<10%) of EIMCs were performed on infants who were born at home. Reaching male infants who are born at home with EIMC will eventually become an important—and programmatically challenging—goal because approximately half of Tanzanian women deliver their babies at home. We found that the majority of infants were circumcised in the 8- to 60-day period, making the integration of EIMC with RCH—particularly immunization services—critical to reaching male infants born at home.

**Limitations**

The study had a few limitations. Qualitative findings are limited to the original 4 facilities, but the pilot project expanded to include 4 additional facilities during the course of the study, so the quantitative data for all 8 sites were included in this analysis. However, it should be noted that the communities served by the original 4 facilities have a sociodemographic profile that is similar to that of the 4 additional facilities, so we would expect similar responses. Our strata for analyzing age at circumcision were based on “best guess” estimates, which considered the immunization schedule and assumptions about convenience of travel with a newborn.

**CONCLUSION**

EIMC services were introduced with a high level of safety in Iringa region, but it was noted that successes in scaling up VMMC did not translate into immediate acceptability of EIMC. Babies born at home comprised less than 7% of the infants circumcised in the pilot project. Care-seeking behavior associated with EIMC, including age of the infant at circumcision and time of return for follow-up visits, varied significantly between urban and rural dwellers. Strategies such as EIMC outreach activities and the use of...
rural health outposts for follow-up visits to overcome geographic barriers should be explored when planning to expand EIMC services.

The majority of mothers heard about EIMC at a health facility rather than from radio messages or from community members. This highlights an important need and opportunity for expansion of community education and awareness-raising for EIMC via media outlets such as radio. It is particularly important that EIMC information and counseling reach men as well as women. Integrating EIMC counseling into services for prevention of mother-to-child transmission of HIV should be explored, because these services provide an opportunity for men and women to be counseled together. Women attending ANC should be encouraged to address the issue of EIMC with their partners and family early in their pregnancies. Based on our findings, targeted behavior change communication should be directed to fathers; using community forums to educate men about EIMC may be a good platform to explore.

Acknowledgments: The MOHSW of Tanzania rolled out the EIMC pilot project with technical support from Jhpiego. The authors would like to acknowledge the participants in this study and the regional medical authorities of Iringa and Njombe regions for their support of the study and for their outstanding dedication to reducing HIV infection in their regions. Thanks to Yusuph Kassim Kulindwa for the study and for their outstanding dedication to reducing HIV prevention of mother-to-child transmission of HIV should be explored, because these services provide an opportunity for men and women to be counseled together. Women attending ANC should be encouraged to address the issue of EIMC with their partners and family early in their pregnancies. Based on our findings, targeted behavior change communication should be directed to fathers; using community forums to educate men about EIMC may be a good platform to explore.

Competing Interests: None declared.

REFERENCES


Safety, Acceptability, and Feasibility of Early Infant Male Circumcision Conducted by Nurse-Midwives Using the AccuCirc Device: Results of a Field Study in Zimbabwe

Webster Mavhu, Natasha Larke, Karin Hatzold, Getrude Ncube, Helen A Weiss, Collin Mangenah, Prosper Chonzi, Owen Mugurungi, Juliet Mufuka, Christopher A Samkange, Gerald Gwinji, Frances M Cowan, Ismail Ticklay

Early infant male circumcision (EIMC) conducted by nurse-midwives using the AccuCirc device proved safe, feasible, and acceptable to parents in Zimbabwe. The AccuCirc device has the potential to facilitate widespread scale-up of safe EIMC in sub-Saharan Africa.

ABSTRACT
Background: For prevention of HIV, early infant male circumcision (EIMC) needs to be scaled up in countries with high HIV prevalence. Routine EIMC will maintain the HIV prevention gains anticipated from current adult male circumcision initiatives. We present here the results of a field study of EIMC conducted in Zimbabwe.

Methods: The study was observational and based on the World Health Organization (WHO) framework for clinical evaluation of male circumcision devices. We recruited parents of newborn male infants between August 2013 and July 2014 from 2 clinics. Nurse-midwives used the AccuCirc device to circumcise eligible infants. We followed participants for 14 days after EIMC. Outcome measures were EIMC safety, acceptability, and feasibility.

Results: We enrolled 500 male infants in the field study (uptake 11%). The infants were circumcised between 6 and 60 days postpartum. The procedure took a median of 17 minutes (interquartile range of 5 to 18 minutes). Mothers’ knowledge of male circumcision was extensive. Of the 498 mothers who completed the study questionnaire, 91% knew that male circumcision decreases the risk of HIV acquisition, and 83% correctly stated that this prevention is partial. Asked about their community’s perception of EIMC, 40% felt that EIMC will likely be viewed positively in their community; 13% said negatively; and 47% said the perception could be both ways. We observed 7 moderate or severe adverse events (1.4%; 95% confidence interval, 0.4% to 2.4%). All resolved without lasting effects. Nearly all mothers (99%) reported great satisfaction with the outcome, would recommend EIMC to other parents, and would circumcise their next sons.

Conclusion: This first field study in sub-Saharan Africa of the AccuCirc device for EIMC demonstrated that EIMC conducted by nurse-midwives with this device is safe, feasible, and acceptable to parents.

INTRODUCTION

Early infant male circumcision (EIMC) is simpler and less costly than voluntary medical male circumcision (VMMC). Also, EIMC is likely to prevent HIV acquisition more effectively than VMMC; EIMC is carried out long before an individual becomes sexually active and thus avoids the risk associated with sex during the healing period. In order for EIMC to maintain the HIV prevention gains anticipated through VMMC, it should be suitable for safe and efficient implementation in low-resource settings. Since large-scale EIMC has never been practiced in Southern Africa, demonstration of its safety, acceptability, and feasibility in this setting is crucial.

A number of circumcision devices are used with infants, including the Mogen clamp, Gomco clamp, and
Plastibell. Each of these devices is associated with rare but potentially serious complications. Circumcision using the Mogen clamp can result in partial or total amputation of the glans penis or removal of too little foreskin (in which case the remaining foreskin remains vulnerable to infection with HIV). A mismatch in sizes of the separate pieces of the Gomco clamp can result in laceration of the glans penis. Proximal migration of the Plastibell during circumcision can result in necrosis of the glans and other injuries; this risk is increased if the incorrect size of “bell” is used.

AccuCirc, a relatively new EIMC device (introduced in 2008), comes preassembled and thus may have the potential to address some of these shortcomings. In addition, it has a shielding ring that protects the glans penis, preventing laceration or amputation. The AccuCirc device is also disposable and does not require sterilization. These factors make it appealing for use in sub-Saharan Africa, particularly where health centers lack electricity and sterilization equipment. However, before AccuCirc is used to roll out EIMC in sub-Saharan Africa, further evidence is needed on its performance in comparison with other methods of EIMC.

Although the World Health Organization (WHO) has determined that it will not prequalify medical devices for EIMC, the WHO “Framework for Clinical Evaluation of Devices for Male Circumcision” provides a useful and valid guide for evaluating novel EIMC devices for safety, acceptability, and feasibility. The guide recommends that, for innovative male circumcision methods, at least 3 successive studies be conducted in countries of intended use: a case series, a comparative trial, and a field study. Two studies to determine the safety, acceptability, and cost of the AccuCirc device in sub-Saharan Africa have been conducted in Botswana and Zimbabwe. In line with the WHO framework, Zimbabwe also conducted a field study of the AccuCirc device in which nurse-midwives performed EIMC. Here, we present the findings of this field study on safety, acceptability, and feasibility of the AccuCirc device for EIMC. Study findings will inform EIMC scale-up in Zimbabwe and the wider region.

**METHODS**

**Study Design**

The field study was observational. As the WHO “Framework for Clinical Evaluation of Devices for Male Circumcision” recommends, we enrolled, circumcised, and followed 500 participants. Participants were circumcised using the AccuCirc device and followed for 2 weeks post-circumcision.

**Recruitment and Training of EIMC Providers**

In August and September 2013, doctors trained 4 study nurse-midwives over the course of 5 days to use the AccuCirc device. The trainers had previously performed circumcisions for the Zimbabwe EIMC comparative trial, described in detail elsewhere. The training curriculum consisted of didactic lectures, practical skill sessions, use of an EIMC anatomic model, written assessment, and practice evaluation. Trainees were required to score 100% on the written assessment and show competency using the anatomic model. Each provider then had to demonstrate competency performing 10 supervised circumcisions with the AccuCirc device.

**Participants**

Mothers and infants were enrolled between August 2013 and July 2014 at Edith Opperman and Mabvuku, 2 polyclinics in Harare, with 400 and 250 deliveries per month, respectively. Women attending the clinic were informed of EIMC and enrolled at the antenatal clinic and after delivery in the maternity ward. In the community, we used educational materials (posters and pamphlets) and demand-creation activities (sensitization shows, dramas, and group and person-to-person discussions) to educate people about the field study. Before discharge postdelivery, mothers who were interested in having their male infants circumcised were asked to (1) provide locator information and consent for an outreach worker to physically verify their address, (2) complete an interviewer-administered questionnaire (asking, among other questions, about sociodemographic information and knowledge about HIV and male circumcision), and (3) discuss the procedure with the infant’s father (if available) before attending for EIMC at their first postnatal visit.

We collected data on eligibility criteria from all mothers and infants. Maternal eligibility criteria were: (1) ability to attend follow-up appointments at the study clinic through 2 weeks postpartum, (2) readiness to provide a home address, and (3) written informed consent. Only infants ages 6 to 60 days were eligible. Although WHO guidelines state that infants can be...
circumcised as early as 12 to 24 hours old, we waited for 6 days to be sure that all body systems were stable and any immediate postpartum infant mortality would not be erroneously ascribed to EIMC. Additional infant eligibility criteria were: (1) male, (2) gestational age $\geq 37$ weeks, (3) birth weight $\geq 2,500$ grams, (4) no evidence of neonatal infection/sepsis or other illness requiring hospitalization, (5) no family history of bleeding disorder, and (6) no genital abnormality constituting a contraindication to EIMC. Between recruitment and enrollment, an outreach worker visited homes to verify the addresses of all potential field study participants.

**Intervention**

Before enrollment, study staff performed a physical examination to exclude infants with abnormalities precluding circumcision. We referred to a specialist all 10 infants who were ineligible due to genital abnormalities. The 4 trained nurse-midwives (2 at each study clinic) performed all the circumcisions, assisted by 2 registered general nurses. To minimize bleeding, all infants received vitamin K (1 mg) an hour before the procedure. Additionally, all infants had approximately 1 gram of EMLA Cream (eutectic mixture of local anesthetics containing 2.5% lidocaine and 2.5% prilocaine) applied to the outer foreskin and shaft of the penis about 45 minutes before the procedure. Administration of vitamin K and the anesthetic is part of standard operating procedures for conducting EIMCs and not specific to the AccuCirc device.

We assessed achievement of anesthetic effect by holding the foreskin using artery forceps. If there was no pain response from the infant, subsequent steps would commence. Otherwise, providers would wait until the EMLA Cream had achieved anesthetic effect (an additional 10 to 15 minutes). When the EMLA Cream had achieved anesthetic effect, the surgical area was cleaned with povidone-iodine. Physiologic adhesions between the foreskin and the glans were released by manual technique using the flexible foreskin probe that comes with the AccuCirc kit. The nurse-midwife then marked the circumcision site (around the corona) with a surgical pen that is also part of each AccuCirc kit. The pen mark helps to minimize excessive or insufficient skin removal.

In addition to the flexible foreskin probe, the AccuCirc device consists of a shielding ring plus a single-action clamp (i.e., can be used only once) that contains a circular blade. It is available in 2 sizes: 1.1 cm and 1.3 cm (penile diameter). The nurse-midwives performed EIMC using AccuCirc following manufacturer’s recommendations (www.accucirc.com) and as recommended by the study previously conducted in Botswana.9 During the procedure, glucose water was given to the infant using a gloved finger, as has been recommended for pain management for neonatal circumcision.15,17,18 After the procedure, the circumcision wound was dressed, and infants were checked for post-procedure bleeding or other immediate complications. Nurse-midwives gave mothers detailed post-procedure care instructions (how to deal with dressing, bleeding, and signs of infection) and emergency contact information. Nurse-midwives also encouraged mothers to phone the nurse-coordinator or to come to the clinic if they had any worries or if unanticipated events occurred between scheduled visits.

**Follow-up and Evaluation**

Follow-up appointments at the clinic took place at days 2, 7, and 14 after circumcision. At these visits, nurse-midwives asked parents about complications. The EIMC providers also conducted physical examinations of the infants, including inspection of the circumcision site. Seven days after the procedure we asked parents their views on the acceptability of circumcision.

**Outcome Measures**

Outcome measures for the field study were (1) EIMC safety, (2) acceptability, and (3) feasibility. Safety was indicated by the number of moderate and severe adverse events (AEs). EIMC-related AEs were categorized as bleeding, infection, inadequate or excessive skin removal, or penile injury (glans, urethra, or shaft) (Table 1). We recorded minor events such as bleeding that could be stopped with simple compression, but excluded them from analyses. We measured EIMC acceptability by the proportion of parents who (1) adopted EIMC for their sons, (2) reported being satisfied with the procedure, and (3) expressed willingness to adopt EIMC for a future son.

We asked parents to rate their satisfaction with and acceptability of the procedure on a numerical scale ranging from 0 (dissatisfaction) to 10 (very satisfied). Satisfaction was defined as a score between 6 and 10. We also asked parents to rate on a scale of 0 to 10 the likelihood that they would recommend EIMC to friends or relatives. A score of 0 was classified as “would
not recommend” and 10 as “would definitely recommend.” Feasibility was defined as spending the least amount of effort on a procedure and gauged by the time that the nurse-midwives needed to perform EIMC using AccuCirc (timed using a stopwatch plus video recording of each procedure), and the ability of nurse-midwives to safely perform the procedure. We considered 15 to 30 minutes a “feasible procedure time,” based on the typical time spent in previous studies of the AccuCirc device.

**Sample Size**

We chose a sample size of 500 subjects, as specified by the WHO “Framework for Clinical Evaluation of Devices for Male Circumcision.”

The rate of circumcision uptake was defined as the number of eligible male infants who were circumcised with AccuCirc, among those whose parents were asked to participate. With 500 infants undergoing EIMC, we could estimate a rate of 3% severe AEs with 95% confidence intervals (CIs) of 1.7% to 4.9%, and could therefore exclude a severe AE rate of greater than 5%.

**Statistical Analysis**

We used Stata 13 (StataCorp, TX, USA) to perform statistical analyses. We summarized characteristics of parents and infants, including socio-demographic characteristics, father’s reported circumcision status, and circumcision and HIV knowledge and attitudes. To evaluate the safety of the procedure, we calculated the proportion of procedures associated with AEs and the associated 95% CI. We calculated similar proportions and 95% CIs for the parental acceptability outcomes. To assess feasibility, we calculated the mean time for the procedure and an associated 95% CI.

**Ethical Considerations**

The Medical Research Council of Zimbabwe and the ethics committees of University College London and the London School of Hygiene and Tropical Medicine approved the study. We obtained written informed consent from the infant’s mother and verbal consent from the infant’s father (if available) before enrollment. After the procedure, mothers received a 20-liter plastic bucket, 2 bars of washing soap, a 100-ml bottle

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**Table 1. Classification of Procedure-Related Moderate and Severe Adverse Events**

<table>
<thead>
<tr>
<th>Category</th>
<th>Moderate</th>
<th>Severe</th>
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<tbody>
<tr>
<td>Bleeding</td>
<td>Bleeding that is not controlled by new dressings or 5 to 10 minutes of manual pressure and requires a special return to the clinic for a pressure dressing, additional skin sutures, or additional vitamin K administration without surgical re-exploration of the wound.</td>
<td>Bleeding that requires surgical re-exploration, hospitalization, or transfer to another facility, or any case where blood transfusion or intravenous fluid is necessary.</td>
</tr>
<tr>
<td>Infection</td>
<td>Discharge from the wound, painful swelling with erythema or elevated temperature, or use of oral antibiotics.</td>
<td>Cellulitis or abscess of the wound, or infection severe enough to require surgical intervention, hospitalization, or intravenous or intramuscular antibiotic therapy.</td>
</tr>
<tr>
<td>Inadequate skin removal</td>
<td>Prepuce partially covers glans when flaccid but surgical correction is not necessary.</td>
<td>Prepuce partially covers glans when flaccid and immediate surgical correction is necessary.</td>
</tr>
<tr>
<td>Excessive skin removal</td>
<td>Tightness of the skin discernible, and additional sutures or skin mobilization needed for wound closure, but no other intervention needed.</td>
<td>Reoperation or referral/transfer to another facility required.</td>
</tr>
<tr>
<td>Penile injury</td>
<td>Significant laceration requiring either prolonged follow-up, care, and attention or repeated or additional dressings.</td>
<td>Significant injury including laceration or severed portion of glans, damage to the urethra, or laceration of the shaft with ongoing bleeding that requires hospitalization, transfer, or transfusion.</td>
</tr>
</tbody>
</table>
of Vaseline (for wound care), and 3 disposable diapers (total value US$8). At each scheduled clinic visit, mothers also received the equivalent of US$5 for bus fare.

RESULTS

Participant Flow
To enroll 500 infants in the field study, we approached 4,617 parents of newborn male infants. Thus, the uptake rate was 11% (95% CI, 10.1% to 11.9%). Some 4,107 parents (89%) declined to participate. Reasons for refusal included fear of harm and sociocultural considerations. A further 10 male infants were excluded as ineligible (Figure). Between August 2013 and July 2014, 500 male infants ages 6 to 60 days were circumcised. The mother was in attendance during the procedure in 99.6% of cases. In the 2 instances when the mother was not there, the male infant’s

![Diagram of Participant Flow](https://www.ghspjournal.org/EIMCinZimbabweWiththeAccuCircDevice)
father was present. Overall, fathers attended 34% of the male infant circumcisions (Table 2). All but 1 participant (described in detail later) attended all 3 scheduled follow-up visits on days 2, 7, and 14.

Characteristics of Enrolled Infants and Their Mothers

The median age of male infants at the time of circumcision was 22 days (interquartile range [IQR], 12 to 46) (Table 2). Eighty-five (17%) of the infants were exposed to HIV. The median age of mothers was 28 years (IQR, 24 to 32). The majority of mothers were married (n = 478, 96%), and more than half had completed secondary education (n = 295, 59%). Approximately 40% of fathers were reportedly circumcised. Among mothers whose partner was not circumcised, 80% stated they would like him to be circumcised. Knowledge of circumcision was high among mothers who completed the study’s quantitative questionnaire, with 431 (91%) mothers reporting that they had heard of the preventive benefits of circumcision for HIV, and 393 (83%) correctly stating that circumcision was partially protective against HIV. Some 185 mothers (40%) felt that EIMC will likely be viewed positively in their community; 63 (13%) said negatively; and 221 (47%) said both ways. Even though they were largely satisfied by the procedure performed by nurse-midwives, a majority of mothers (n = 433, 92%) thought trained doctors should perform EIMC.

Procedure Time and Intraoperative Events

Completing the procedure took a median of 17 minutes (IQR, 15 to 18). Mild post-circumcision bleeding occurred in 49 male infants (10%). For 46 of these infants (94%), simple pressure stopped this bleeding. Three cases of bleeding could not be stopped by simple pressure. We classified these as moderate or severe procedure-related AEs; we detail these cases below.

Adverse Events

We observed 7 AEs (1.4%; 95% CI, 0.4% to 2.4%) (Table 3). These included 2 cases of excessive removal of skin (moderate severity, requiring skin mobilization; wound completely healed 4 months post-EIMC in both cases) and 2 cases of inadequate skin removal (moderate severity; urologist concluded that neither required immediate corrective surgery), 1 case of moderate bleeding, and 2 cases of severe bleeding. There were no sequelae in any of the mild, moderate, or severe AE cases.

The 1 case of moderate bleeding required clamping of the bleeding vessel with forceps and an acetylated glucosamine dressing at the time of the procedure. The 2 cases of severe bleeding required hospitalization. In 1 case, the infant bled immediately post-circumcision. The bleeding was controlled with pressure but started again at home, and he was referred to a hospital. Three sutures were required to stem the bleeding. The other case of severe bleeding was in an infant who had a family history of hemophilia (unreported and undetected at the time of the procedure). The infant was given a blood transfusion (200 ml). He was hospitalized for 3 days.

Unrelated Newborn Death

One male infant left the study 2 days after the procedure without any formal follow-up visits. This infant developed an acute respiratory infection after the procedure was performed and died 36 hours post-EIMC. The respiratory infection was due to an outbreak of severe bronchiolitis and was deemed unrelated to the EIMC procedure.

Parental Satisfaction

All mothers who answered the question on satisfaction with EIMC (n = 498) reported being satisfied with the outcome (scores = 6 to 10), with 497 (99%) reporting that they were very satisfied (scores = 8 or greater). Nearly all mothers (n = 496, 99%) said they would recommend EIMC to other parents and would circumcise their next newborn son (n = 497, 99%). Among fathers who answered the question on satisfaction with EIMC, all 112 gave a score of 6 or greater. Nearly all the fathers would recommend the procedure to a friend (n = 109, 98%) and would have a future son circumcised (n = 110, 98%) (Table 3). The most common reason for dissatisfaction, cited by 5% of mothers and 8% of fathers, was the wound care requirements.

DISCUSSION

We have implemented the first field study in sub-Saharan Africa of EIMC conducted by nurse-midwives using the AccuCirc device. We found that the procedure is safe, feasible, and acceptable to parents who choose it for their infant sons. Overall, the rate of AEs was low and similar to those reported in the 2 previous AccuCirc studies.
### TABLE 2. Characteristics of Infants and Mothers (N = 500 Infants and 500 Mothers)

<table>
<thead>
<tr>
<th>Characteristics and Views</th>
<th>Infants</th>
<th>Mothers</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Infants</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, days, median (IQR)</td>
<td>22 (12, 46)</td>
<td></td>
</tr>
<tr>
<td>Birth weight, kg, median (IQR)</td>
<td>3.2 (2.9, 3.5)</td>
<td></td>
</tr>
<tr>
<td>Temperature, Celsius, median (IQR)</td>
<td>36.2 (36.0, 36.5)</td>
<td></td>
</tr>
<tr>
<td>Gestational age, weeks, median (IQR)</td>
<td>40 (38, 40)</td>
<td></td>
</tr>
<tr>
<td>Vitamin K given, No. (%)</td>
<td>500 (100)</td>
<td></td>
</tr>
<tr>
<td>HIV exposure status, No. (%)</td>
<td>85 (17)</td>
<td></td>
</tr>
<tr>
<td>Mother present, No. (%)</td>
<td>498 (99.6)</td>
<td></td>
</tr>
<tr>
<td>Father present, No. (%)</td>
<td>168 (34)</td>
<td></td>
</tr>
<tr>
<td><strong>Mothers</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mother’s age, years, No. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 20</td>
<td>39 (8)</td>
<td></td>
</tr>
<tr>
<td>21–25</td>
<td>123 (25)</td>
<td></td>
</tr>
<tr>
<td>26–30</td>
<td>159 (32)</td>
<td></td>
</tr>
<tr>
<td>31–35</td>
<td>123 (25)</td>
<td></td>
</tr>
<tr>
<td>&gt; 35</td>
<td>56 (11)</td>
<td></td>
</tr>
<tr>
<td>Current marital status, No. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>478 (96)</td>
<td></td>
</tr>
<tr>
<td>Not married</td>
<td>21 (4)</td>
<td></td>
</tr>
<tr>
<td>Widowed</td>
<td>1 (0.2)</td>
<td></td>
</tr>
<tr>
<td>With whom do you live?, No. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alone</td>
<td>9 (43)</td>
<td></td>
</tr>
<tr>
<td>Male partner</td>
<td>1 (5)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>11 (52)</td>
<td></td>
</tr>
<tr>
<td>Completed secondary level education?, No. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>205 (41)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>295 (59)</td>
<td></td>
</tr>
<tr>
<td>Ethnic group, No. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shona</td>
<td>406 (81)</td>
<td></td>
</tr>
<tr>
<td>Non-Shona</td>
<td>94 (19)</td>
<td></td>
</tr>
</tbody>
</table>
### Table 2. (continued).

**Characteristics and Views**

<table>
<thead>
<tr>
<th>Head of household, No. (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mother</td>
<td>28 (6)</td>
</tr>
<tr>
<td>Male partner</td>
<td>431 (91)</td>
</tr>
<tr>
<td>Someone else</td>
<td>14 (3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Infant’s father circumcised?, No. (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>187 (39)</td>
</tr>
<tr>
<td>No</td>
<td>273 (58)</td>
</tr>
<tr>
<td>Don’t know</td>
<td>13 (3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HIV knowledge score, median (IQR)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>6 (4, 6)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Circumcision knowledge score, median (IQR)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>6 (5, 8)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Heard of male circumcision as an HIV prevention method before today, No. (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>431 (91)</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Does male circumcision really protect men against HIV?, No. (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Completely</td>
<td>23 (5)</td>
</tr>
<tr>
<td>Partially</td>
<td>393 (83)</td>
</tr>
<tr>
<td>No, it does not protect</td>
<td>15 (3)</td>
</tr>
<tr>
<td>Don’t know</td>
<td>42 (9)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Would like male partner to be circumcised, No. (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>219 (80)</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Who should perform EIMC?, No. (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Trained doctors</td>
<td>433 (92)</td>
</tr>
<tr>
<td>Trained nurse-midwives</td>
<td>24 (5)</td>
</tr>
<tr>
<td>Traditional leader of the same tribe or religion</td>
<td>4 (1)</td>
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<tr>
<td>Other</td>
<td>9 (2)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How will EIMC likely be viewed in community?, No. (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Negatively</td>
<td>63 (13)</td>
</tr>
<tr>
<td>Positively</td>
<td>185 (40)</td>
</tr>
<tr>
<td>Both negatively and positively</td>
<td>221 (47)</td>
</tr>
</tbody>
</table>

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**Abbreviations:** EIMC, early infant male circumcision; IQR, interquartile range.

a HIV status unknown for 4 infants.

b In the 2 cases where the mother was not present, the infant’s father was present during the procedure.

c Among the 22 not married or widowed mothers, 1 mother did not give an answer.

d Data collected from only 473 mothers.

e HIV knowledge score composed of 8 questions, with 1 point for every correct answer (maximum score = 8).

f Circumcision knowledge score composed of 8 questions, with 1 point for every correct answer (maximum score = 8).

g Among 273 mothers who reported their partner was not currently circumcised.
TABLE 3. Adverse Events Associated With EIMC (N = 500), Time Taken for the Procedure, and Parental Satisfaction

<table>
<thead>
<tr>
<th>Outcome</th>
<th>All AEs, No. (%)</th>
<th>Moderate/severe bleeding</th>
<th>Infection</th>
<th>Inadequate skin removal</th>
<th>Excess skin removal</th>
<th>Injury to penis</th>
<th>Time taken to perform procedure, minutes, median (IQR)</th>
<th>Mothers’ satisfaction (N = 498)&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Satisfaction score (0–10), No. (%)</th>
<th>Reasons for dissatisfaction, No. (%)</th>
<th>Mother would definitely recommend MC,&lt;sup&gt;b&lt;/sup&gt; No. (%)</th>
<th>Mother would have a future son circumcised, No. (%)</th>
<th>Fathers’ satisfaction (N = 112)</th>
<th>Satisfaction score (0–10), No. (%)</th>
<th>Reason for dissatisfaction, No. (%)</th>
<th>Appearance</th>
<th>Wound care requirements</th>
<th>Complication</th>
<th>Other reason</th>
<th>Appearance</th>
<th>Wound care requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>All AEs, No. (%)</td>
<td>7 (1.4)</td>
<td>3 (0.6)</td>
<td>0 (0.0)</td>
<td>2 (0.4)</td>
<td>2 (0.4)</td>
<td>0 (0.0)</td>
<td>17 (15, 18)</td>
<td></td>
<td>0 (0)</td>
<td>7 (1)</td>
<td>23 (5)</td>
<td>26 (5)</td>
<td>442 (89)</td>
<td>109 (97)</td>
<td>3 (3)</td>
<td></td>
<td></td>
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<tr>
<td>Moderate/severe bleeding</td>
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<tr>
<td>Infection</td>
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<tr>
<td>Inadequate skin removal</td>
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<td>Excess skin removal</td>
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conducted in Botswana and Zimbabwe. In both of these studies, doctors performed the circumcisions. The Botswana study identified 1 moderate AE (0.7%; 95% CI, 0.1% to 4.6%), and the Zimbabwe study identified 2 moderate AEs (2%; 95% CI, 0.2% to 7.0%). Thus, our findings confirm previous findings that EIMC is a simple and safe procedure, characterized by a low rate of AEs. Moreover, AE rates were similar between the nurse-midwives in this study (1.4%; 95% CI, 0.4% to 2.4%) and the doctors in the Zimbabwe study (2%; 95% CI, 0.2% to 7.0%). This similarity suggests that it is both safe and feasible to roll out EIMC using non-doctor providers—a particularly important conclusion for sub-Saharan Africa, where nurses and midwives are in far greater supply than doctors. Despite accepting EIMC delivered by nurse-midwives, 92% of mothers thought that the procedure should be performed by trained doctors. Because this is a widespread preference, the need to educate parents on EIMC safety in the hands of nurse-midwives and other trained non-physician providers is a priority.

Nonetheless, the fact that we encountered 2 cases of severe bleeding (including a case of unreported hemophilia) that required hospitalization for monitoring and management has important implications for EIMC planning and subsequent roll-out:

1. Although EIMC can be offered at the lowest-level health facilities, there should be easily accessible backup services to deal with any life-threatening complications (e.g., excessive bleeding).

2. Intensive screening and history-taking before the procedure are required in order to exclude any infants with a family history of bleeding disorder.

3. Screening for other non-circumcision-related health issues is necessary to ensure that infants who are circumcised are clinically well.

The infant mortality rate is high in sub-Saharan Africa. Recent Zimbabwe Demographic and Health Survey findings suggest that infant and neonatal mortality rates are 57 and 31 deaths per 1,000 live births, respectively. Although the EIMC procedure itself is unlikely to result in major morbidity or mortality, it is important that babies who are unwell with other conditions are not circumcised. Such events may be mistakenly ascribed to EIMC. It will therefore be crucial to offer EIMC when all body systems are stable so that any immediate postpartum infant mortality is not erroneously ascribed to EIMC.

As in the Zimbabwe comparative trial, actual uptake of the procedure, at 11%, was far lower than the 60% hypothetical acceptability that other studies had predicted. Previous studies in Zimbabwe and Zambia reported similar discrepancies. However, in both Zambia and Zimbabwe, EIMC was still offered in a research setting. The rate of EIMC uptake may differ when it is offered as part of an ongoing program. Zimbabwe is traditionally a non-circumcising country. It is to be expected that it will take time, and the program will need to earn the trust of parents, before EIMC—now an unfamiliar and perhaps scary procedure—becomes accepted. Nonetheless, culturally appropriate demand-creation activities to promote EIMC need to be conducted if EIMC is to become the norm.

Sustained uptake and acceptability will depend greatly on perceptions of the safety and aesthetic aspects of EIMC. Encouragingly, in

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**Table 3. (continued).**

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<td>Father would definitely recommend MC</td>
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<td>Father would have a future son circumcised</td>
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Abbreviations: AE, adverse event; EIMC, early infant male circumcision; IQR, interquartile range; MC, male circumcision.

a Two mothers did not provide information on their satisfaction with the procedure.

b Parental recommendation score of 10 (out of 10).
It may be possible to use EIMC as a platform to strengthen other maternal and child health programs and to promote other health interventions to men.

This field study nearly all mothers (99%) reported high satisfaction with the outcome. These findings are consistent with others from the region (Botswana, Kenya, and Zambia), which report levels of satisfaction over 90%. With specific reference to satisfaction with EIMC performed via AccuCirc, the findings are consistent with those from our comparative trial and from Botswana, where over 91% of mothers reported high or complete satisfaction with the outcome. To maintain these high levels of satisfaction, EIMC provision will need to be carefully monitored and supervised to ensure that AEs are minimized and appropriately managed. As with most self-reported data, the high levels of satisfaction could be due to social desirability bias. However, after qualitatively exploring this issue and triangulating findings from different data collection approaches, we can safely conclude that the reported levels of satisfaction are a true reflection of what parents actually felt.

Most women who sought EIMC for their sons were knowledgeable about male circumcision and its HIV-preventive benefits. Our findings corroborate those from previous studies on the hypothetical acceptability of VMMC and EIMC; these studies found that this knowledge is likely to be associated with uptake. Widespread awareness campaigns to enhance men’s and women’s knowledge of male circumcision and its benefits will be essential for successful scale-up. Furthermore, about 40% of women who sought EIMC for their sons reported that the infant’s father was circumcised, whereas the prevalence of male circumcision in the general male population is estimated to be around 10%. This suggests that, as adult VMMC spreads, demand for EIMC is likely to grow.

A few women (n=63, 13%) felt that EIMC will likely be viewed negatively in their community. Hypothetical acceptability studies have suggested that fear of their son’s future social exclusion, including ostracism, derision, and rejection, may discourage parents from opting for EIMC. Current initiatives that portray VMMC as a lifestyle choice for a man who is clean, elegant, and confident are likely playing a critical role in changing community norms about the procedure. In addition, uptake of VMMC in Zimbabwe continues to rise (from 10,000 in 2009 to 600,000 as of December 2015); community norms are also likely to change as more men opt for circumcision.

EIMC may provide a rare opportunity to reach fathers via health care facilities. In this study, for example, about one-third of fathers accompanied their sons to the EIMC clinic. Otherwise, men are known to be hard to reach via health services. Additionally, men in general, and Zimbabwean men specifically, rarely accompany their wives to the clinic for antenatal or infant care. But it may be possible to use EIMC as a platform to strengthen other maternal, newborn, and child health programs and to promote other health interventions to men, such as VMMC and prevention of mother-to-child transmission of HIV.

Limitations

The sample size of this field study was guided by the WHO “Framework for Clinical Evaluation of Devices for Male Circumcision,” but the number was nonetheless small. Thus, it is possible that we did not detect all potential AEs that might occur during EIMC roll-out. Field studies of the AccuCirc device currently under way in Kenya will increase our knowledge of AEs associated with the procedure. We also studied EIMC only in an urban setting. Findings, particularly on acceptability, might be different in rural areas. Similar research needs to take place in a different setting in order to further inform EIMC programming and roll-out.

CONCLUSIONS

We circumcised 500 male infants in a field study of the AccuCirc device for EIMC in Zimbabwe. We found that EIMC can be safely and acceptably offered by nurse-midwives using the AccuCirc device. The AccuCirc device has the potential to facilitate widespread scale-up of safe EIMC in sub-Saharan Africa.

Acknowledgments: We thank study participants, their parents, and their extended families for making this study possible. We also thank Harare City Health for granting us the permission to conduct this study at the Edith Opperman and Mabvuku clinics, Harare. The Bill & Melinda Gates Foundation funded this study through Population Services International (PSI). The content of this article is solely the responsibility of the authors and does not necessarily represent the official views of the Gates Foundation or PSI.

Competing Interest: None declared.

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Perspectives of Parents and Health Care Workers on Early Infant Male Circumcision Conducted Using Devices: Qualitative Findings From Harare, Zimbabwe

Webster Mavhu, a,b Karin Hatzold, c Getrude Ncube, d Shamiso Fernando, a Collin Mangenah, a Kumbirai Chatora, c Owen Mugurungi, d Ismail Ticklay, e Frances M Cowan a,b

Parents who opted for early infant male circumcision (EIMC) and health care workers felt EIMC was a safe and acceptable procedure that would likely become more widely adopted over time. Barriers to EIMC uptake such as parental fears of harm and cultural beliefs are potentially surmountable with adequate education and support.

ABSTRACT

Background: The World Health Organization (WHO) and the United Nations Children’s Fund (UNICEF) recommend early infant male circumcision (EIMC) for prevention of HIV. Here, we present findings from a qualitative study in Zimbabwe that assessed parental and health care workers’ perspectives of EIMC conducted using devices.

Methods: This qualitative study was nested within a trial of EIMC devices. Between January and May 2013, we held 4 focus group discussions (FGDs) and 12 in-depth interviews with parents and 12 in-depth interviews with clinicians (7 trial clinicians and 5 non-trial clinicians). We also conducted 95 short telephone interviews with parents who had arranged to bring their sons for EIMC but then defaulted.

Results: Parents who had adopted EIMC spoke of their initial anxieties about the procedure. Additionally, they commented on both the procedure and outcome. Parents who decided against EIMC cited fear of harm, specifically the infant’s death, penile injury, and excessive pain. Misperceptions about male circumcision in general and EIMC specifically were a significant barrier to EIMC adoption and were prevalent among health care workers as well as parents. In particular, the findings suggest strong parental concerns about the fate of the discarded foreskin. Parents who chose EIMC for their newborn sons felt that the procedure was safe and expressed satisfaction with the outcome. For their part, health care workers largely thought that EIMC was safe and that the outcome was aesthetically pleasing. They also felt that it would be feasible to offer wide-scale EIMC for HIV prevention in the public sector; they recommended strategies to increase EIMC uptake, in addition to highlighting a few concerns.

Conclusions: The qualitative study enables us to better understand parental and health care workers’ perspectives of EIMC conducted using devices, especially their perspectives on EIMC safety, feasibility, acceptability, and barriers. These findings will be used to design demand-generation activities that support wider adoption of EIMC.

INTRODUCTION

In Africa, 14 countries are currently accelerating roll-out of voluntary medical male circumcision (VMMC).1–5 Modeling studies conducted between 2009 and 2011 suggested that circumcising males ages 15 to 49 years to reach 80% coverage within 5 years in these countries, and maintaining this coverage thereafter, could avert 3.4 million new HIV infections within 15 years and yield treatment and care savings of US$16.5 billion.2,3 In order to ensure that the protective effect of male circumcision is sustained in the longer term, the World Health Organization (WHO), the Joint United Nations Programme on HIV/AIDS (UNAIDS), and the United Nations
Children’s Fund (UNICEF) also recommend that early infant male circumcision (EIMC)—that is performed within the first 60 days of life—be implemented alongside VMMC. Presuming high rates of uptake of EIMC, it will then be possible to phase out the “catch-up” adult VMMC as circumcised infants come of age.

Although EIMC’s impact on the HIV epidemic will take some time to realize, infant circumcision is ultimately likely to be more effective at preventing HIV acquisition than adult male circumcision, as the procedure is carried out long before the individual becomes sexually active, avoiding the risk associated with sex during the healing period. EIMC can be viewed as background population-level protection for future generations.

Since 2009, Zimbabwe has provided circumcision to over 600,000 adult and adolescent men. The program aims to reach 1.3 million 15- to 29-year-olds by 2017. Zimbabwe intends to offer EIMC alongside VMMC. Since large-scale EIMC for HIV prevention, or indeed for any reason, has never been practiced in Zimbabwe or, more widely, in Southern Africa, there are concerns about its feasibility and acceptability. Clearly, the acceptability of infant male circumcision will have a bearing on uptake, roll-out, and resulting effectiveness in preventing HIV. In Zimbabwe, there are also concerns about the feasibility of rolling out EIMC for HIV prevention within the context of existing health services, many of which are already overburdened and understaffed. Here, we present findings from a qualitative study that was nested within a trial of EIMC devices to assess in depth parental and health care workers’ perspectives with a view to informing demand creation and roll-out.

**METHODS**

**Study Design**

This qualitative study sought to complement an earlier study that explored the hypothetical feasibility and acceptability of EIMC among health care workers, parents, and the wider family (described in detail elsewhere). Findings from the earlier study informed the design of an individually randomized non-inferiority trial that assessed the feasibility, safety, acceptability, and cost of rolling out EIMC using devices (AccuCirc and Mogen clamp) in Zimbabwe. During the trial, between January and June 2013, parents of newborn boys at a Harare clinic were invited to participate in this study. Some 150 eligible male infants were enrolled in the trial (13% uptake) and were circumcised at 6 to 54 days old by a doctor (n = 100 AccuCirc; n = 50 Mogen clamp).

In brief, the Mogen clamp is a reusable stainless steel device that requires a new, sterile scalpel blade for each infant male circumcision. Circumcision using the Mogen clamp can (occasionally) result in partial or total amputation of the glans penis or removal of too little foreskin (in which case the remaining foreskin remains vulnerable to infection with HIV). The Atraumatic Circumcision (AccuCirc) device is an instrument made largely of plastic. It has a shielding ring that protects the glans penis, preventing laceration or amputation.

The qualitative study reported here assessed in depth the actual (as contrasted with hypothetical) feasibility and acceptability of EIMC conducted using the 2 devices. EIMC was not available at the clinic outside the context of this trial.

Qualitative Study Sampling and Data Collection

Between January and May 2013, 2 teams of trained and experienced researchers (1 team of male interviewers; 1 team of female interviewers) held in-depth interviews and focus group discussions (FGDs) with parents. Budgetary and time constraints limited the numbers of interviews, discussions, and phone calls. In all, 24 participants took part in in-depth interviews and another 38 in FGDs. An additional 95 parents took part in short phone interviews. No one declined to take part in the qualitative study.

We conducted in-depth interviews and FGDs with parents who had adopted EIMC for HIV prevention—3 interviews and 1 FGD with a total of 10 mothers; 3 interviews and 1 FGD with a total of 9 fathers. We selected these participants randomly from a list of parents who had adopted EIMC. We also conducted interviews and FGDs with parents who had declined to circumcise their newborn sons—3 interviews and 1 FGD with a total of 10 mothers, and 3 interviews and 1 FGD
with a total of 9 fathers. We selected these participants randomly from a list of couples who had not adopted EIMC and had not been shortlisted for short phone interviews (see the Figure for qualitative study sampling).

With parents who accepted EIMC, discussions explored, among other topics, perceptions of the procedure’s safety and final appearance, as well as whether they would recommend EIMC to other parents. With parents who declined EIMC, discussions explored reasons for not taking up the procedure, their fears and/or concerns, as well as what would need to change for them to opt for EIMC.

We also interviewed in depth the 4 doctors who performed EIMC during the comparative trial and the 3 EIMC study nurse-midwives who assisted doctors during the trial. We also interviewed in depth 5 female nurses who worked at the study clinic but were not directly involved in performing procedures or recruiting infants for the EIMC trial. The 5 nurses were purposively sampled to include a sister-in-charge, 2 nurse-midwives based in the maternity unit, and 2 registered general nurses based in the family health services clinic (the unit where babies and children are seen for immunizations and growth monitoring). Discussions with clinicians assessed actual acceptability of the procedure and obtained their views on the feasibility of offering wide-scale EIMC using either the AccuCirc device or Mogen clamp. Discussions also elicited clinicians’ perceptions of the safety of the procedure when conducted with either device.

Further, we conducted 95 short phone interviews with parents who had arranged to bring their sons for EIMC but then defaulted. The phone interviews sought to ascertain only the parents’ reasons for not bringing the infant for
the procedure. In these phone interviews, we included 15 of the 17 parents (88%) who had gone through all study screening procedures (including providing locator information, comprehension of screening eligibility criteria, and responding to a one-time questionnaire) but did not eventually enroll. Of these 15, 10 were mothers and 5 were fathers. We selected the other 80 phone interview participants as follows: 65 women (10%) were randomly selected from a list of 650 mothers who had arranged to bring their sons for EIMC but then defaulted. An additional 15 men (10%) were randomly selected from a list of 150 fathers who had participated in weekend group meetings and had promised to bring their sons for EIMC but then defaulted (Figure). We contacted phone interview participants when their sons were no longer eligible for EIMC. We handwrote short statements of these phone conversations and later coded them.

FGDs lasted 2 to 2.5 hours; in-depth interviews lasted 45 minutes to 1 hour. All FGDs were conducted in Shona, the participants’ language. In-depth interviews were conducted in either English or Shona, depending on the participant’s preference. We audio-recorded all FGDs and in-depth interviews.

Data Analysis

We transcribed the recorded interviews and discussions and, where necessary, translated them verbatim into English. We identified initial themes during the interviews and discussions; these themes informed an initial coding framework. Then, 3 researchers used this framework to code 5 in-depth interviews and all FGDs line by line on paper. This led us to add additional codes to the coding framework. We entered the transcripts into NVivo 10 (QSR International, Melbourne, Australia), a qualitative data storage and retrieval computer program. Trained and experienced researchers (authors CM and SF) coded each transcription separately, using the modified coding framework, taking note of any emerging new codes. If the coders disagreed over the interpretation of some codes, the senior social scientist (WM) met with the 2 researchers. The 3 would examine the codes and collectively agree on the standard forms to use for coding. We then revised the coding framework accordingly. WM checked concordance of the 2 researchers’ coding in addition to independently coding all transcripts. We typed the handwritten statements from the phone interviews and entered the information into a Microsoft Excel document. Researchers read the statements and assigned each statement a code based on its key words.

We grouped codes into categories and then identified emerging themes following the principles of thematic analysis. As we wrote up the findings, we illustrated themes and subthemes with verbatim quotations.

Ethical Considerations

The study was approved by the Medical Research Council of Zimbabwe and the ethics committees of University College London and the London School of Hygiene and Tropical Medicine. We obtained written informed consent from participants on the day of the interview or discussion. At the start of each short phone interview, we sought verbal consent.

RESULTS

Parents who had adopted EIMC spoke about their initial anxieties concerning the procedure. Additionally, they commented on both the procedure and its outcome. Parents who had decided against EIMC mentioned fear of harm, specifically the infant’s death, penile injury, and excessive pain. There were no discernible differences between mothers’ and fathers’ responses.

On the whole, health care workers thought EIMC was a safe procedure, and the outcome was aesthetically pleasing. Nearly all EIMC study doctors and nurses expressed preference for the AccuCirc device over the Mogen clamp. We detail these findings below.

Parents Reported Initial Anxieties

Discussions suggested that most parents who had adopted EIMC initially had some anxieties; these came up mostly during the consent process. During the consent process, parents learned in greater depth the possible adverse consequences of EIMC. A father told how he had silently posed rhetorical questions during the consent process. I kept asking myself, “Isn’t it going to cause some deformities on the thing [penis]?” and “What happens if it [penis] starts decaying?” “What have been the results with regards to this exercise since they are saying it is research?” You know, research normally is research. (father, in-depth interview)

Despite assurances that the rate of EIMC-related adverse events is very low and also that, if
an adverse event occurs, it is usually minor and easily resolved, most parents remained agitated during the procedure.

I was so uncomfortable during the time I was sitting here [in the clinic boardroom] as I had been told that my child could possibly get injured during the process. (mother, FGD)

Parental Perceptions of Procedure and Outcome

Most parents who had adopted EIMC and who were interviewed after the infant had completely healed thought that the procedure was very safe. A mother remarked:

Ha-a, it’s safe, 100%; it’s 100% safe. My son healed well. I didn’t have a problem with it. In terms of bleeding, he didn’t bleed that much. It was just some minimal bleeding and that was it. Also, I simply applied Vaseline and he healed quickly. I can say it’s 100% safe. (mother, in-depth interview)

Another mother expressed similar sentiments:

It’s safe, the baby did not bleed, he was not sutured, and I did not have to immerse the wound in salt [salty water]. (mother, in-depth interview)

However, a father’s response suggested some uncertainty:

Ya-a, it’s safe, but you always wonder if everything is okay because you don’t know and there is no way to know you understand what I am saying? … You say to yourself, “Let’s hope I don’t end up regretting.” You always have that fear … and you say, “What if something didn’t go well?” … Like I am saying right now, there is no way one can tell whether or not everything was done successfully. (father, in-depth interview)

Despite assurances from study staff that the procedure had gone well, this participant still had fears that his son’s reproductive capability may have been damaged during EIMC, and he was anxious about his son’s later fertility or sexual functioning. He also felt that he would only be able to tell once his son had grown up and became sexually active. This shows the extent to which some parents view EIMC as a procedure that involves more than just foreskin removal.

Overall, parents who had adopted EIMC expressed satisfaction with the outcome. A mother remarked:

First of all, it’s smart. Secondly, it [penis] now has a better “shape” … I think that’s why they have the slogan “PINDA MUSMART” [local slogan that promotes VMMC as hygienic]. It’s just a good thing. (mother, in-depth interview)

On the whole, parents who had adopted EIMC said they would circumcise their next newborn son. Furthermore, they stated that they would recommend EIMC to other parents.

Parents’ Reasons for Not Adopting EIMC

Fear of Harm

Fear of immediate harm emerged as one of the major reasons that parents did not adopt EIMC. A few parents expressed concerns that the procedure and its associated complications (e.g., excessive bleeding) could possibly lead to an infant’s death. A father maintained:

Ya-a, something might be said to be safe, but at the same time, everything has loopholes. … Somehow it might not succeed, you understand? It’s just a simple operation you know. An operation on the appendix is supposed to be safe. A lot of people have undergone that kind of operation, and some have died. There are things that we presume to be safe but are not necessarily safe. (father, in-depth interview)

Such a concern as this one was based on the assumption that the infant’s penis was not only tiny but also “too fragile” for the procedure. A father asked:

How do you really know that the child’s foreskin starts here and ends there? What if they overdo it and end up cutting some veins …? (father, FGD)

Although some men mentioned that they had decided on EIMC for their sons because they themselves had undergone VMMC, it appeared that if fathers had found VMMC very painful, they were less likely to agree with male circumcision for their sons.

What you as an adult go through … you imagine the pain and your son undergoing such pain at that age … (father, FGD)

Another father noted:

… It [pain] was something that I still remembered very well … I thought of the pain that I had gone through and I refused … (father, FGD)
<table>
<thead>
<tr>
<th>Theme</th>
<th>Subtheme</th>
<th>No. of Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parent refused</td>
<td>Baby’s father refused</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>• The father refused. (8 responses)</td>
<td></td>
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<tr>
<td></td>
<td>• I really want but my husband does not want to hear anything about it. (1 response)</td>
<td></td>
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<tr>
<td></td>
<td>Baby’s mother refused</td>
<td>5</td>
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<tr>
<td></td>
<td>• His mother refused. (4 responses)</td>
<td></td>
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<tr>
<td></td>
<td>• My wife is refusing to bring him to the clinic. (1 response)</td>
<td></td>
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<tr>
<td>Someone else refused</td>
<td>Wider family refused</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>• My mother-in-law refused. (2 responses)</td>
<td></td>
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<tr>
<td></td>
<td>• My in-laws are against the idea. (2 responses)</td>
<td></td>
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<tr>
<td>SUBTOTAL</td>
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<td>18</td>
</tr>
<tr>
<td>Son still too young</td>
<td>Too young to undergo procedure</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>• He is still too young. (9 responses)</td>
<td></td>
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<tr>
<td></td>
<td>• It is still too early to circumcise him. (2 responses)</td>
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<tr>
<td></td>
<td>• It is too early; he is only 6 days old. (1 response)</td>
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<td></td>
<td>Too young to be taken out in public</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>• My baby is too young to be moved around. (2 responses)</td>
<td></td>
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<tr>
<td></td>
<td>• My baby is too young to mingle with the public. (2 responses)</td>
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<tr>
<td>SUBTOTAL</td>
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<td>16</td>
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<tr>
<td>Fear of harm</td>
<td>Fear of immediate harm</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>• It is too painful. (4 responses)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• The mother is afraid it may not go well. (1 response)</td>
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<td></td>
<td>• It’s my first child. What if it doesn’t go well? (1 response)</td>
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<td></td>
<td>• I do not want any sleepless nights. (1 response)</td>
<td></td>
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<tr>
<td></td>
<td>• My wife fears that the wound will take long to heal. (1 response)</td>
<td></td>
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<tr>
<td></td>
<td>• I am worried about what will happen to the removed foreskin. (1 response)</td>
<td></td>
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<tr>
<td></td>
<td>• The time for him to get circumcised has already passed. (1 response)</td>
<td></td>
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<tr>
<td></td>
<td>• It will ruin my marriage. (1 response)</td>
<td></td>
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<tr>
<td></td>
<td>Fear of future harm</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>• His peers will laugh at him when he is grown up. (2 responses)</td>
<td></td>
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<tr>
<td></td>
<td>• It might create problems for him in future. (1 response)</td>
<td></td>
</tr>
<tr>
<td>SUBTOTAL</td>
<td>Near future</td>
<td>14</td>
</tr>
<tr>
<td>Son to be circumcised later</td>
<td></td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>• I will come after his umbilical stump has fallen off. (3 responses)</td>
<td></td>
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<tr>
<td></td>
<td>• I will bring him after 6 weeks. (2 responses)</td>
<td></td>
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<tr>
<td></td>
<td>• I will come later; I first need to heal myself. (2 responses)</td>
<td></td>
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<tr>
<td></td>
<td>• I will come after the pain from injections subsides. (1 response)</td>
<td></td>
</tr>
<tr>
<td>Theme</td>
<td>Subtheme</td>
<td>No. of Responses</td>
</tr>
<tr>
<td>-------</td>
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</tr>
<tr>
<td><strong>Later</strong></td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>• Will come when the baby is older. (2 responses)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• We will consider it when he turns 5. (1 response)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SUBTOTAL</strong></td>
<td></td>
<td>11</td>
</tr>
<tr>
<td><strong>Held up by decision making</strong></td>
<td>Decision making in progress</td>
<td>6</td>
</tr>
<tr>
<td>• We need more time to think about it. (2 responses)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• I am still thinking about it. (1 response)</td>
<td></td>
<td></td>
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<tr>
<td>• As a mother, I cannot decide. (1 response)</td>
<td></td>
<td></td>
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<tr>
<td>• My wife and I have not thought about it. (1 response)</td>
<td></td>
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<tr>
<td>• I am still trying to convince my husband. (1 response)</td>
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<tr>
<td><strong>Still awaiting someone’s approval</strong></td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>• The father is not around so I cannot decide. (1 response)</td>
<td></td>
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<tr>
<td>• I am still waiting for the father to give the go-ahead. (1 response)</td>
<td></td>
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<tr>
<td>• I am still waiting for his grandmother’s approval. (1 response)</td>
<td></td>
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<tr>
<td>• I still need to hear from my in-laws. (1 response)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SUBTOTAL</strong></td>
<td></td>
<td>10</td>
</tr>
<tr>
<td><strong>Male circumcision not part of family tradition</strong></td>
<td>Male circumcision not practiced in clan</td>
<td>4</td>
</tr>
<tr>
<td>• No one has ever done that in our tribe. (2 responses)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• It is not part of my culture. (2 responses)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Father not circumcised</strong></td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>• I am not circumcised myself. (2 responses)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• He has to be like his father, who is not circumcised. (1 response)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Older brothers not circumcised</strong></td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>• His brothers are not circumcised. (3 responses)</td>
<td></td>
<td></td>
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<tr>
<td><strong>SUBTOTAL</strong></td>
<td></td>
<td>10</td>
</tr>
<tr>
<td><strong>Son to decide for himself</strong></td>
<td>Do not want to decide for him</td>
<td>6</td>
</tr>
<tr>
<td>• He will decide for himself when he grows up. (6 responses)</td>
<td></td>
<td></td>
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<tr>
<td><strong>SUBTOTAL</strong></td>
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<td>6</td>
</tr>
<tr>
<td><strong>External influence</strong></td>
<td>Wider family’s influence</td>
<td>2</td>
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<tr>
<td>• My older sister advised me not to. (1 response)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• My mother-in-law discouraged me from doing so. (1 response)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Health care workers’ influence</strong></td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>• My doctor said I should not do it. (1 response)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• My aunt who is a nurse said we should not just accept new things. (1 response)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SUBTOTAL</strong></td>
<td></td>
<td>4</td>
</tr>
<tr>
<td><strong>Son to be circumcised at home</strong></td>
<td>Grandmother to perform procedure</td>
<td>3</td>
</tr>
<tr>
<td>• His grandmother will circumcise him. (3 responses)</td>
<td></td>
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</tbody>
</table>
During phone interviews, a few parents also mentioned fear of pain as one reason for ultimately deciding against EIMC (Table).

Cultural Beliefs
Discussions suggested that cultural beliefs were a significant barrier to EIMC. For example, participants suspected that Satanists were conducting the EIMC research. A mother professed her initial fears:

I don’t want to lie; I suspected that you were Satanists and that you may take the foreskin … I really don’t know the process, but I was just scared because I don’t want to lie. Satanists are present but we don’t know the organizations they work for … (mother, in-depth interview)

Another female participant who had adopted EIMC described how someone had scared her after the procedure.

I met a certain woman who asked me if I had seen where the foreskin had gone. When I told her that I had not seen it but I had only been told that it would be incinerated, she said it was a real shame that I had chosen to sacrifice my child to Satanism. She insisted that I was supposed to have requested the foreskin and disposed of it myself. (mother, in-depth interview)

Men who did not choose EIMC for their sons stated in a group discussion that they would circumcise their sons only on condition that they would be allowed to take the removed foreskin with them.

Advice From Health Care Workers
An additional reason for non-adoption of EIMC was advice from someone considered an expert. In a phone interview, one respondent said, “My doctor said I should not do it” (Table). Another maintained, “My aunt, who is a nurse, said we should not just accept new things” (Table). Health care workers with inadequate knowledge of the procedure thus played a role in discouraging parents from adopting EIMC.

Non-Study Health Workers’ Misconceptions
Discussions suggested that despite several EIMC sensitization meetings with non-EIMC clinic staff, including an initial stakeholder meeting convened by the Ministry of Health, misconceptions remained prevalent among some of these health care workers.

We understand that the babies are circumcised “just like that,” under no anesthesia. Most nurses therefore think that this program is cruel. (non-EIMC health care worker, in-depth interview)

Perceptions such as these were a result of poor knowledge of the EIMC procedure; in fact, local anesthetic was applied prior to the procedure. Misconceptions were also prevalent among ancillary staff, including lay community health workers. The lay community health workers participating in the study were mostly hand-picked elderly women, many of whom had some basic education. A nurse said about them:

They [lay community health workers] think the infant has to be anesthetized first [general anesthesia], so they assume that if infants are anesthetized, they will “never wake up” [implying dying]. Some have heard of people who have died after being anesthetized. (non-EIMC health care worker, in-depth interview)

The same nurse went on to state that these community workers often passed on misinformation.

*Table (continued).*

<table>
<thead>
<tr>
<th>Theme</th>
<th>Subtheme</th>
<th>No. of Responses</th>
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</thead>
<tbody>
<tr>
<td><strong>SUBTOTAL</strong></td>
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<td>3</td>
</tr>
<tr>
<td>Other</td>
<td>Various other reasons</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>• Baby died. (1 response)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• We are no longer in Harare. (1 response)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• I will only do it if it is for medical reasons. (1 response)</td>
<td></td>
</tr>
<tr>
<td><strong>SUBTOTAL</strong></td>
<td></td>
<td>3</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td></td>
<td>95</td>
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</tbody>
</table>

Health care workers with inadequate knowledge of the procedure played a role in discouraging parents.
to the communities where they worked. Given their misconceptions about EIMC, perhaps it is not surprising that the 50 lay community health workers based at the study clinic (and who had been trained by Ministry of Health and study staff) did not refer a single infant for EIMC during the comparative trial, despite initial assurances that they would actively support the study.

Discussions with non-EIMC study nurses also suggested that some of their peers gave mothers ambivalent or contradictory advice regarding EIMC. You hear them saying, “Ya-a, it’s a good thing to have him [son] circumcised, but if it was my son, I would not have him circumcised.” (non-EIMC health care worker, in-depth interview)

This quotation suggests once again that some health care workers did not promote EIMC.

Study Clinicians’ Perceptions: EIMC Procedure, Devices, and Outcome

During discussions, study clinicians reported their initial anxieties with EIMC. A study doctor described her initial feelings:

Before I underwent training, I thought EIMC was such a difficult thing. I couldn’t imagine infants being circumcised; I had never seen such a thing. … And then during the lectures when I was taught the various techniques and their complications, it was a bit scary. (EIMC health care worker, in-depth interview)

Another doctor described the EIMC experience as “mind-opening.” He elaborated:

I had a preconception that the neonatal stage was the child’s most delicate period and that EIMC could predispose them to infections, would result in delayed wound healing, or anything like that. I never thought circumcision could be that safe and easy. (EIMC health care worker, in-depth interview)

Despite acknowledging initial anxieties, study doctors stated that, with more exposure and practice, they became confident conducting EIMC and subsequently began to feel that the procedure was both uncomplicated and safe.

Now I am very comfortable. I now feel that EIMC is a procedure that you can even do with your eyes closed. (EIMC health care worker, in-depth interview)

Another doctor maintained:

I think it’s a procedure that can safely be done not only by doctors but by any adequately trained health care provider. (EIMC health care worker, in-depth interview)

Study nurse-midwives also stated that, after assisting doctors with EIMC procedures, they now felt that they could safely perform the procedure.

From what I have observed, I am very confident that I can also perform the procedure. (EIMC health care worker, in-depth interview)

When asked if she thought that nurses other than those involved in the EIMC study could also perform the procedure, a study nurse-midwife responded:

They can. They are doing episiotomy; episiotomy is cutting a part that is even unmarked, a section you think the unborn baby might come through. (EIMC health care worker, in-depth interview)

Preference for AccuCirc

Discussions suggested that on the whole, study doctors preferred the AccuCirc device over the Mogen clamp due to the former’s safety features. A study doctor said:

AccuCirc is straightforward and it’s a device that can protect. … We have that thing that protects the glans, so you don’t have to worry about anything … (EIMC health care worker, in-depth interview)

Another study doctor explained why he preferred the AccuCirc device over the Mogen clamp:

I have realized that when using AccuCirc, there is less manipulation of the penis. With Mogen clamp, you manipulate the foreskin so much that the pen mark disappears just before you cut off the foreskin and so you won’t have a good approximation of the amount of foreskin that you should remove. As a result, you can either remove too little or too much foreskin. (EIMC health care worker, in-depth interview)

Clinicians Like Outcome

Just as with parents who adopted EIMC, study clinicians stated that the EIMC outcome was aesthetically pleasing. A study nurse-midwife commented:

It’s indeed a sweet outcome; you actually feel proud of it. (EIMC health care worker, in-depth interview)

A study doctor felt that, compared with adult male circumcision, EIMC produced a better cosmetic result.
EIMC has amazing results even when compared to adult MC [male circumcision]. I most liked the fact that the outcome was not only satisfactory to us as providers but to the parents and guardians of the infants as well. (EIMC health care worker, in-depth interview)

Clinicians’ Perceptions: Feasibility of Wide-Scale EIMC
Informed by their experience with EIMC in the context of a small research trial, health care workers felt that it was feasible to roll out wide-scale EIMC for HIV prevention in Zimbabwe. On the whole, these health care workers felt that AccuCirc was likely to have several advantages over the Mogen clamp when it came to wide-scale implementation, including, for example, through rural clinics.

Even nurses stationed at rural areas will be able to safely perform the procedure through AccuCirc, especially because the device is simple to use and the shielding ring makes it impossible to partially amputate the penile glans. (EIMC health care worker, in-depth interview)

Non-study nurses expressed optimism that, if adequately trained, they could safely perform EIMC using the AccuCirc device.

The other time one of the study guys had a meeting with us, he clearly demonstrated how that white plastic gadget [AccuCirc] works. If we are trained, we will be able to perform the procedure. Also, we already have knowledge of some of the aspects such as sterile procedures. We can do it. (non-EIMC health care worker, in-depth interview)

Despite overwhelmingly recommending that nurses and midwives be trained and delegated to perform EIMC, nurses (both EIMC and non-EIMC) felt that these clinicians should be covered by doctors in case of any major complications.

Clinicians’ Concerns
Dealing With Parental Anxieties
During the EIMC comparative trial, some parents called study staff whose mobile numbers were on the contact card (including at night) to report issues that the staff thought trivial (e.g., that the baby had soaked the bandage with urine). EIMC study clinicians wondered how these understandable parental anxieties would be addressed in the context of roll-out. Specifically, they questioned how the public health sector would be able to provide such intensive phone support.

Will the public clinics and hospitals be able to put in place the necessary supportive mechanisms such as taking night phone calls? (EIMC health care worker, in-depth interview)

Wound Care Management
EIMC study clinicians stated that, unlike disposable diapers, cloth diapers (the option used by most people) are less absorbent and perhaps changed less frequently, so that the baby was sitting in damp (cloth) diapers for long periods, resulting in delayed wound healing.

… Some delayed wound healing we experienced had to do with the fact that mothers were using nappies [cotton or cloth diapers], but once we gave them the Pampers [disposable diapers], the babies subsequently healed very well. (EIMC health care worker, in-depth interview)

The same doctor went on to question the feasibility of purchasing large volumes of disposable diapers during EIMC roll-out.

Will you be able to purchase Pampers [disposable diapers] for all those babies whose parents cannot afford Pampers during the roll-out? (EIMC health care worker, in-depth interview)

DISCUSSION
We nested a qualitative study within a trial that assessed the feasibility, safety, acceptability, and cost of rolling out EIMC using devices in Zimbabwe. The qualitative study enabled us to explore parental and health care workers’ perspectives on EIMC conducted using devices, especially as they relate to EIMC safety, acceptability, barriers, and feasibility.

Despite acknowledging initial anxieties with EIMC, parents expressed satisfaction with the procedure and its outcome. Despite initial misgivings, both parents and the clinicians who performed the circumcisions expressed satisfaction with the procedure and its outcome.

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sion of the procedure will need to be carefully supervised and monitored to ensure (1) a good cosmetic result and (2) that adverse events are prevented.14

Like parents, study clinicians, despite acknowledging initial anxieties with EIMC, reported satisfaction with EIMC. All felt that it is a simple procedure that can be performed by non-doctors. These opinions are especially important because they were expressed by health care workers experienced with the procedure. Moreover, based on their experience, clinicians felt that it was feasible to offer wide-scale EIMC for HIV prevention. Their recommendations need to be considered when planning EIMC scale-up, especially their recommendations that nurse-midwife providers should be covered by doctors in case of any major complications and that the AccuCirc device should be used during roll-out. Furthermore, issues concerning dealing with parental anxieties and EIMC wound management need to be carefully considered in the context of scale-up. The study also found a poor understanding of EIMC among health care workers not involved in conducting the procedure, highlighting the importance of adequate training of these stakeholders.

Parental reasons for non-adoption of EIMC included fear of harm, cultural beliefs, and misinformation from health care workers. These findings are similar to those of EIMC hypothetical acceptability studies.14,28–32 These recurring barriers highlight once again the need to enhance EIMC knowledge among both parents and health care workers. Information, education, and communication materials will need to provide understandable and accurate information explaining the procedure and state clearly that, when conducted by appropriately trained and experienced personnel, EIMC is safe.16,18,19

Additionally, communication materials need to highlight the several advantages of circumcising males during infancy rather than later in life. The materials also will need to include a “frequently asked questions” section that specifically addresses the parental concerns raised in this and other studies. Engaging satisfied parents to promote circumcision will be an important strategy to allay other parents’ fears. It may also be important to develop quality standards to assess provider–client communication, with a view to assuring the quality of the EIMC counseling process.

The finding that painful VMMC experiences among adult men leads them to reject EIMC for their sons has at least 3 implications for VMMC roll-out in general and EIMC promotion in particular. First, adult VMMC programs need to manage clients’ pain adequately. Second, VMMC clients circumcised via conventional surgery need to be empowered so that during the procedure they will alert providers whenever the anesthesia is not adequate. Last, EIMC awareness campaigns need to explain the differences between adult conventional surgery and EIMC—especially the fact that the latter does not require an anesthetic injection, sutures, or dipping the post-circumcision wound in salty water, often considered painful.33

Correcting misconceptions around VMMC in general and EIMC specifically will be another important strategy in awareness campaigns to allay parental concerns. Awareness campaigns need to specifically address the persistent concern about the discarded foreskin.14,31 The wider community needs to be informed that all removed foreskins will be incinerated according to national and international tissue disposal policies. It will be difficult for parents to obtain the discarded foreskin from EIMC clinics since it is likely that EIMC will be rolled out using the AccuCirc device, which is designed to retain the discarded foreskin; parents would need to obtain the entire used AccuCirc device in order to get the foreskin. This in turn would have implications for waste disposal, as AccuCirc is made largely of hardened plastic and will take years to biodegrade. A possible strategy would be to invite parents to see how the device is disposed of and to have community leaders witness the incineration process as a way of enhancing communities’ trust in the disposal process.

**Strengths and Limitations of the Study**

This qualitative study was nested within the first randomized comparison of AccuCirc and Mogen clamp devices for EIMC in sub-Saharan Africa. The advantages of conducting qualitative research with or within trials are now well recognized. For one thing, the qualitative components of trials gather information that helps to answer research questions in depth.34,35 In this case, the qualitative research brought out parents’ reasons for non-adoption of EIMC and thus helped to explain the low rate of EIMC uptake during the trial.

This study also triangulated various data collection methods (focus group discussions, in-depth interviews, and short phone interviews) to explore the actual as opposed to hypothetical acceptability and feasibility of EIMC among parents, study clinicians, and non-study clinicians. Triangulation has been widely adopted in qualitative research as a means to investigate the

**Awareness campaigns need to specifically address the persistent concern about the discarded foreskin.**
Parents who opted for EIMC and EIMC providers felt that EIMC was a safe and acceptable procedure that would likely be more widely adopted over time.

CONCLUSIONS

This qualitative study enabled us to explore parental and health care workers’ perspectives on EIMC conducted using devices. Parents who opted for EIMC and EIMC providers felt that EIMC was a safe and acceptable procedure that would likely be more widely adopted over time. However, some parents and health care workers without experience or knowledge of EIMC feared that the procedure might be harmful or painful. These findings will be used to inform the design of a demand-generation intervention to support wider adoption of EIMC.

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Comparative Cost of Early Infant Male Circumcision by Nurse-Midwives and Doctors in Zimbabwe

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ABSTRACT

Background: The 14 countries that are scaling up voluntary male medical circumcision (VMMC) for HIV prevention are also considering early infant male circumcision (EIMC) to ensure longer-term reductions in HIV incidence. The cost of implementing EIMC is an important factor in scale-up decisions. We conducted a comparative cost analysis of EIMC performed by nurse-midwives and doctors using the AccuCirc device in Zimbabwe.

Methods: Between August 2013 and July 2014, nurse-midwives performed EIMC on 500 male infants using AccuCirc in a field trial. We analyzed the overall unit cost and identified key cost drivers of EIMC performed by nurse-midwives and compared these with costing data previously collected during a randomized noninferiority comparison trial of 2 devices (AccuCirc and the Mogen clamp) in which doctors performed EIMC. We assessed direct costs (consumable and nonconsumable supplies, device, personnel, associated staff training, and waste management costs) and indirect costs (capital and support personnel costs). We performed one-way sensitivity analyses to assess cost changes when we varied key component costs.

Results: The unit costs of EIMC performed by nurse-midwives and doctors in vertical programs were US$38.87 and US$49.77, respectively. Key cost drivers of EIMC were consumable supplies, personnel costs, and the device price. In this cost analysis, major cost drivers that explained the differences between EIMC performed by nurse-midwives and doctors were personnel and training costs, both of which were lower for nurse-midwives.

Conclusions: EIMC unit costs were lower when performed by nurse-midwives compared with doctors. To minimize costs, countries planning to scale up EIMC should consider using nurse-midwives, who are in greater supply than doctors and are the main providers at the primary health care level, where most infants are born.

INTRODUCTION

Based on evidence that medical male circumcision reduces the risk of HIV acquisition among men by up to 60% and is a cost-effective intervention, a number of sub-Saharan African countries are considering offering early infant male circumcision (EIMC) services in parallel with existing voluntary medical male circumcision (VMMC) services that are typically for 15- to 49-year-old adolescents and adults. While the HIV prevention benefits from EIMC would not be realized immediately, increased uptake of EIMC could reduce the need for adult male circumcision in future years. The World Health Organization (WHO) and the United Nations Children’s Fund (UNICEF) recommend EIMC—performed within the first 60 days of life—for HIV prevention in countries with high HIV prevalence. EIMC has several advantages over VMMC, including being a more easily performed procedure with faster wound healing and lower rates of adverse events. In Zimbabwe and other sub-Saharan African countries that are most affected by HIV/AIDS, however, EIMC scale-up may be hindered by an acute
shortage of human resources for health, particularly doctors. The shortage of doctors has been reported elsewhere as being one of the most important supply-side barriers to scaling up VMMC.13

Nurse-midwives are nurses trained to manage women’s health care, particularly pregnancy, childbirth, the postpartum period, care of the newborn, and gynecology. For countries planning to roll out EIMC, using nurse-midwives to perform the procedure instead of doctors may be a solution. Nurse-midwives are able to provide comparably high-quality, affordable primary care.14 Studies have shown that with adequate training, nurse-for-doctor substitution is feasible for many health care interventions. Patient outcomes for trained nurse-midwives are similar to those for doctors.15 In a meta-analysis of VMMC performed by trained medical staff such as nurse-midwives, surgical aides, and clinical officers, the frequency of adverse events was similar to that of doctors or specialists.13 Substituting nurse-midwives for doctors not only provides solutions for the scarcity of doctors in resource-limited settings, but may also help to contain costs because personnel costs are lower.16,17

In relation to substituting nurse-midwives for doctors for medical male circumcision in general and EIMC in particular, there is a dearth of information on quality, outcomes, and costs. This situation is exacerbated by the fact that in some sub-Saharan African countries, including Zimbabwe, ministry of health guidelines preclude nurse-midwives from performing EIMC with devices that are currently in use, such as the Gomco clamp, Plastibell, and the Mogen clamp.11 A relatively new EIMC device, AccuCirc (introduced in 2008), has potential advantages for resource-limited settings18 since it requires less surgical skill than the other devices and can thus be more easily used by nurse-midwives.

In this study, we report results from a cost analysis of EIMC performed by nurse-midwives and compare them with costs estimated in a previous cost analysis of EIMC performed by doctors using the AccuCirc and the Mogen clamp in the same study setting in Zimbabwe.19 Because opportunities for cost savings may also exist in integrated primary care settings where staff, training, and other costs are shared across multiple activities, we did a secondary cost analysis of nurse-midwives performing EIMC integrated with other routine health services at the primary health care level versus a vertical approach.

METHODS

In this cost analysis, we sought to estimate the unit costs of EIMC performed by nurse-midwives in comparison with doctor-performed EIMC, and identify the key cost contributors. We collected cost data for nurse-midwives as part of a field trial (n = 500) which assessed the safety, acceptability, and feasibility of EIMC by nurse-midwives using the AccuCirc device.20 We then compared these data with cost data for doctor-performed EIMC that had been collected as part of a randomized noninferiority trial that took place before the field trial.21 Noninferiority trials test whether a new experimental treatment or strategy is not less efficacious than a treatment already in use.22 In this earlier trial, we compared the safety, acceptability, feasibility, and cost profiles of 2 EIMC devices, the AccuCirc and the Mogen clamp.21 For the current cost analysis, we used cost data for a doctor-led EIMC procedure using the AccuCirc device. The randomized noninferiority trial and the field study were performed at 2 City of Harare primary care clinics in Mbare and Mabvuku, 2 of Harare’s most populous suburbs. This analysis took the health care payer perspective of Zimbabwe’s Ministry of Health and Child Care (MoHCC) and therefore excludes client costs (transport, absenteeism from work, and caregiver costs).

Results from our companion paper suggest equivalence in safety profiles of EIMC performed by nurse-midwives in comparison with those for doctors.20 We therefore adopted cost minimization as the more suitable analysis for this purpose. A cost-minimization analysis defines a situation where, because the consequences of 2 or more treatments or programs are broadly equivalent, the difference between them reduces to a comparison of cost.23 We determined all costs in 2014 constant U.S. dollars, and because Zimbabwe officially adopted the U.S. dollar as its principal currency in 2009, our analysis assumes an exchange rate of US$1 = US$1.24 Between August 2013 and July 2014, we conducted a detailed cost-data collection exercise using instruments adapted from Costing Guidelines for HIV Prevention Strategies from the Joint United Nations Programme on HIV/AIDS (UNAIDS).25 We compared these data to those for doctors, collected as part of the earlier randomized noninferiority EIMC pilot trial (January to June 2013) to assess safety, acceptability, feasibility, and cost of AccuCirc compared with the Mogen clamp.19

In Zimbabwe and other sub-Saharan African countries, EIMC scale-up may be hindered by an acute shortage of human resources for health, particularly medical doctors.
We accessed costs of supplies from invoices and receipts sourced from the respective research partners’ procurement and accounts departments. Nurse-midwives routinely recorded actual resource-use data (drugs and consumable supplies, quantity of devices used, procedure duration, and quantity of waste) for each EIMC procedure on a supplies charge sheet in each infant’s binder. We captured and analyzed direct and indirect cost data using the Decision Makers’ Program Planning Tool (DMPPT), a Microsoft Excel-based model. The United States Agency for International Development (USAID) Health Policy Initiative and UNAIDS developed DMPPT to enable policy makers to analyze costs and impacts of different options for scaling up male circumcision services.26

Direct Costs

Supplies and Device Costs

We estimated the total cost of each consumable and nonconsumable drug and supply for 1 EIMC procedure using data on the number of units of each drug or supply needed per procedure and the corresponding unit cost of that drug or supply. The AccuCirc device was obtained for a unit price of US$10 from the international supplier, Clinical Innovations. Since AccuCirc is a single-use device, US$10 was the per-procedure device cost.

Personnel Training Costs

A local master trainer (doctor) provided theoretical and practical team training over the course of 5 days for 4 nurse-midwives. Personnel training costs included costs of the time spent by both the master trainer and the nurse-midwives, training material costs, and meal costs. We amortized training costs over a 3.6-year period in line with turnover rates of health care workers in Zimbabwe.19,27 Based on a clinic capacity of 6 EIMC procedures per day and 240 working days in a year (48 weeks and 5 days per week), we estimated that a team (both doctors and nurse-midwives) would perform 1,440 procedures annually. Although the Zimbabwe MoHCC intends to roll out EIMC through nurse-midwives, concerns have been raised about the potential for burnout as they assume additional clinical roles, which may result in time taken off work, additional training costs, and therefore more opportunity costs. To account for potential burnout and avoid underestimating the cost of EIMC delivered by nurse-midwives, we analyzed the cost impact of an annual 2-week leave (and thus 46 instead of 48 full working weeks per year).

Personnel Costs

To determine personnel unit costs, we conducted a time and motion study alongside the procedure to capture the time spent by nurse-midwives performing each task for all 500 infants involved in the study, as had been done in the earlier study involving doctors who performed EIMC.19 The study team used a stopwatch to time each EIMC procedure and then recorded procedure duration on an EIMC study procedure form. Video recordings were also taken for periodic procedure reviews and time recording. We estimated the total time of an EIMC procedure by averaging time data as captured in procedure forms or through video recordings of each infant’s EIMC procedure. We therefore based the total time needed by nurse-midwives to perform an EIMC procedure on direct and continuous observation of the procedure. We defined the beginning of the procedure as the point when the infant’s diaper was removed for cleaning the genital area. The procedure ended when the infant had been bandaged and wrapped up in a new diaper.

A nurse-midwife salary comprised basic pay plus housing and transport allowances and totaled US$13,596 per year. In the earlier comparative trial, a doctor’s salary comprising basic pay and benefits was US$31,800 per year. We derived the total unit cost contribution of personnel to each procedure by summing costs of time for each step of the EIMC procedure for each nurse-midwife. We calculated personnel costs by multiplying the total length of time spent by nurse-midwives performing EIMC by their salary per hour. To estimate the hourly salary rate of a nurse-midwife, we divided the annual salary (monthly salary * 12 months) by the total annual number of hours worked (assuming a 40-hour week * 48 weeks per year). Our primary analysis used research personnel salaries. However, as EIMC rollout is likely to be integrated into routine primary health care services, salary costs are expected to be lower and based on MoHCC salary scales. In sensitivity analysis, we analyzed personnel costs using MoHCC staff salaries, which are lower, in order to assess the cost impacts of different salary scales.

Waste Management Costs

To estimate waste management costs, we tracked the number of burn bins (sharps tin containers)
used throughout the field trial. We multiplied the total number of burn bins \((n = 90)\) sent to the clinic incinerators by the cost of incineration based on quotes from private service providers (US$10). To determine the contribution to unit cost, we divided the total waste management cost by the number of EIMCs performed in the field trial \((n = 500)\).

**Indirect Costs**

**Capital Costs (Buildings and Durable Equipment)**

Because EIMC is likely to be rolled out using existing public health facilities, we excluded costs of buildings. For durable equipment costs, we divided the purchase price of each capital good by an appropriate amortization period to derive an annualized depreciation value. We then summed the annualized depreciation values and divided the total by the estimated annual number of EIMC procedures \((n = 1,440)\) to estimate the unit cost contribution of durable equipment. We charged 100% of the capital cost to EIMC, as capital equipment was exclusively used by EIMC.

**Support Personnel Costs**

The services of support staff (clinic clerk and caretaker) were shared across other clinic services, such as maternity services, antenatal and postnatal services, HIV testing and counseling, pharmacy, outreach, outpatient, and family health services. We therefore apportioned a conservative estimate of 10% of the salaries of both types of personnel as support personnel costs for EIMC. We then divided the summed annual salary costs (including benefits) by the estimated annual number of EIMC procedures \((n = 1,440)\) to derive the unit cost contribution of support personnel.

**Sensitivity Analysis**

In one-way sensitivity analysis, we assessed the extent to which the main cost-differentiating components influenced our results by varying each of them, one at a time.\(^{28-30}\) We assessed the unit-cost impacts of using civil service salaries rather than research staff salaries (base case), and whether capacity utilization levels plus procedure duration varied. The capacity utilization analysis aimed to assess the unit cost of EIMCs in cases where staff were unable to reach the daily target of 6 EIMCs \((1,440 \text{ per year})\), a possibility in cases of lower demand for EIMC. We also assessed the cost impact of an annual 2-week leave for nurse-midwives to avoid burnout.

**Ethical Considerations**

The Medical Research Council of Zimbabwe, the University College London Research Ethics Committee, and the London School of Hygiene and Tropical Medicine Research Ethics Committee approved the EIMC comparative trial and the field study.

**RESULTS**

Table 1 summarizes the results for EIMC when performed by nurse-midwives and doctors. The unit cost per EIMC procedure performed by nurse-midwives in a vertical setting was US$38.87 compared with US$49.77 by doctors. Cost differences between nurse-midwives and doctors mainly emanated from personnel and training. Personnel costs were the main contributor to unit costs of EIMC for both nurse-midwives (US$10.57) and doctors (US$19.11). Training had a smaller contribution to unit costs for both nurse-midwives (US$1.51) and doctors (US$3.87). The proportional contribution of personnel declined from 38% for doctors to 27% for nurse-midwives. The unit cost contribution of training also declined from 8% for doctors to 4% for nurse-midwives, and remains constant even when a 2-week annual leave is factored in to account for potential burnout among nurse-midwives. Training costs for nurse-midwives to perform EIMC are therefore lower in comparison with doctors, as the latter cost more per hour.

Costs that were identical for nurse-midwives and doctors included consumable supplies (US$13.48) and nonconsumable supplies (US$0.27), both of which we assumed would remain inflexible even in an integrated setting because they would be dedicated to services offered exclusively in an EIMC department. Other identical costs were the AccuCirc device (US$10.00), waste management (US$1.80), capital equipment (US$0.08), and support personnel (US$1.16).

In secondary analyses, we also compared costs of an EIMC procedure when provided by nurse-midwives in a vertical setting with a procedure provided in a public health facility or clinic (integrated setting). As personnel in a public health facility are employed by the civil service, we also analyzed the impact of using public-sector salaries in the secondary cost analysis. We assumed zero capital equipment costs since setting up EIMC service provision within an existing public health facility would not require new capital equipment. In an integrated
In a public health setting, we found that the unit cost of EIMC was US$33.72 (Table 1). Device, consumable and nonconsumable supplies, waste management, and support personnel costs remained the same as those within the research setting.

In one-way sensitivity analysis (Table 2), we assessed the unit cost impacts of MoHCC salary levels that were below the base case. The unit cost of EIMC procedures performed by nurse-midwives was highly sensitive to personnel costs. Closely related to personnel costs was the time to complete an EIMC procedure. In comparison with a doctor-performed EIMC procedure that took an average of about 16 minutes (rounded up from the exact average of 15.6 minutes) in the comparative trial, results from our companion paper show that nurse-midwives took an average of about 18 minutes (rounded up from the exact average of 17.5 minutes). In a few cases, however, procedures were either shorter (a minimum of 12 minutes) or longer. In one case, it took much longer to bring the bleeding under control (total duration of the procedure was 48 minutes). In sensitivity analysis (Table 2), we therefore assessed the impact on unit cost of using these outlier durations. For the 12-minute procedure, the cost was US$37.69 (compared with US$38.87 for the 18-minute average time), and for the 48-minute procedure, the cost was US$46.19. We also assessed the impact on unit cost of time observations using the 25%–75% interquartile range (middle 50%) as it was felt

TABLE 1. Component Cost of EIMC Performed by Nurse-Midwives and Doctors, 2014

<table>
<thead>
<tr>
<th>Cost Category</th>
<th>Nurse-Midwives</th>
<th>Doctors</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Vertical Program</td>
<td>Integrated Program</td>
</tr>
<tr>
<td>Direct Costs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device</td>
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<td>10.00</td>
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<tr>
<td>% Contribution to Unit Cost</td>
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<tr>
<td>Consumable supplies</td>
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<td>13.48</td>
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<tr>
<td>% Contribution to Unit Cost</td>
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<td>40.0</td>
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<tr>
<td>Nonconsumable supplies</td>
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<td>0.27</td>
</tr>
<tr>
<td>% Contribution to Unit Cost</td>
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<td>0.8</td>
</tr>
<tr>
<td>Waste management</td>
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<td>1.80</td>
</tr>
<tr>
<td>% Contribution to Unit Cost</td>
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<td>5.0</td>
</tr>
<tr>
<td>Personnel</td>
<td>10.57</td>
<td>6.53a</td>
</tr>
<tr>
<td>% Contribution to Unit Cost</td>
<td>27.0</td>
<td>19.0</td>
</tr>
<tr>
<td>Training</td>
<td>1.51</td>
<td>1.32</td>
</tr>
<tr>
<td>% Contribution to Unit Cost</td>
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<td>4.0</td>
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<tr>
<td>Subtotal (Direct)</td>
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</tr>
<tr>
<td>% Contribution to Unit Cost</td>
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<td>99.0</td>
</tr>
<tr>
<td>Indirect Costs</td>
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<td></td>
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<tr>
<td>Capital equipment</td>
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</tr>
<tr>
<td>% Contribution to Unit Cost</td>
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<td>0.0</td>
</tr>
<tr>
<td>Support personnelb</td>
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<td>0.32c</td>
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<tr>
<td>% Contribution to Unit Cost</td>
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<tr>
<td>Subtotal (Indirect)</td>
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<tr>
<td>% Contribution to Unit Cost</td>
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<td>1.0</td>
</tr>
<tr>
<td>Grand Total</td>
<td>38.87</td>
<td>33.72</td>
</tr>
</tbody>
</table>

Abbreviation: EIMC, early infant male circumcision.
a Assumes civil servants salary for nurse-midwives.
b Clinic clerk and caretaker.
c Assumes 10% of civil servants salary for caretaker and receptionist.
that 48 minutes was such a far outlier. For the 13-minute procedure (25th percentile), the cost was US$37.92 (compared with US$38.87 for the 18-minute average time), and for the 30-minute procedure (75th percentile), the cost was US$41.94.

We found the largest cost difference between vertical and integrated EIMC in personnel costs (US$10.57 vs. US$6.53, respectively) (Table 1). Training costs were also lower in the integrated model of EIMC delivery (US$1.51 vs. US$1.32), as were support personnel costs (US$1.16 vs. US$0.32), because we assumed that they were shared across other clinic services. We also assessed the effect of capacity utilization and staff time but found that the EIMC unit cost was not sensitive to either one.

**DISCUSSION**

Substituting nurse-midwives for doctors presents considerable opportunities for minimizing costs in a future EIMC rollout, without impacting safety. Our results show that in a vertical EIMC program it would cost substantially less to perform an EIMC procedure in Zimbabwe using nurse-midwives compared with doctors. Further opportunities for cost savings exist if EIMC were performed using 48 or 18 minutes for nurse-midwives; 16 for doctors (base case). The largest cost difference between vertical and integrated EIMC by nurse-midwives was found in personnel costs (US$10.57 vs. US$6.53).

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**TABLE 2. One-Way Sensitivity Analysis of Costs of EIMC Performed by Nurse-Midwives and Doctors, 2014**

<table>
<thead>
<tr>
<th>Cost Category</th>
<th>Nurse-Midwives</th>
<th>Doctors</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Personnel salaries</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Base case (study salaries)</td>
<td>38.87</td>
<td>49.77</td>
</tr>
<tr>
<td>Public sector&lt;sup&gt;a&lt;/sup&gt; (integrated)</td>
<td>34.00</td>
<td>N/C</td>
</tr>
<tr>
<td><strong>Capacity utilization (EIMC/day)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>44.36</td>
<td>N/C</td>
</tr>
<tr>
<td>4</td>
<td>40.23</td>
<td>N/C</td>
</tr>
<tr>
<td>6 (base case)</td>
<td>38.87</td>
<td>49.77</td>
</tr>
<tr>
<td>8</td>
<td>38.18</td>
<td>N/C</td>
</tr>
<tr>
<td><strong>Staff time for EIMC procedure (using outlier times observed), minutes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>37.69</td>
<td>N/C</td>
</tr>
<tr>
<td>18 for nurse-midwives; 16 for doctors (base case)</td>
<td>38.87</td>
<td>49.77</td>
</tr>
<tr>
<td>48</td>
<td>46.19</td>
<td>N/C</td>
</tr>
<tr>
<td><strong>Staff time for EIMC procedure (using 25%–75% interquartile range), minutes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13 (25th percentile)</td>
<td>37.92</td>
<td>N/C</td>
</tr>
<tr>
<td>18 for nurse-midwives; 16 for doctors (base case)</td>
<td>38.87</td>
<td>49.77</td>
</tr>
<tr>
<td>30 (75th percentile)</td>
<td>41.94</td>
<td>N/C</td>
</tr>
<tr>
<td><strong>Effect of nursing staff leave (due to burnout), weeks</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>46</td>
<td>38.93</td>
<td>N/C</td>
</tr>
<tr>
<td>48 (base case)</td>
<td>38.87</td>
<td>49.77</td>
</tr>
</tbody>
</table>

Abbreviations: EIMC, early infant male circumcision; N/C, no change.

<sup>a</sup> Public sector salaries inclusive of benefits are US$26,400 for a doctor, US$8,400 for a nurse-midwife, US$3,000 for a receptionist, and US$1,800 for a caretaker.
rolled out using an integrated model because civil service medical personnel costs are lower. In our analysis, personnel costs for EIMC performed by nurse-midwives fall below US$10.57 in a vertical program and US$6.53 in an integrated program (assuming use of civil service salaries). A combination of these factors, therefore, makes it more feasible for MoHCC policy makers to meet the goal of rolling out the EIMC procedure more widely and at a lower cost.

This cost analysis of EIMC performed by nurse-midwives and doctors is, to the best of our knowledge, the first analysis based on actual costs of providing EIMC using nurse-midwives in sub-Saharan Africa. For other contexts, actual EIMC costs may differ from those described in this analysis. In a hypothetical modeling study conducted in Rwanda, EIMC was estimated to cost US$19 (direct costs only) using the Mogen clamp. Using similar assumptions (including integration of EIMC in routine primary health services), our analysis of actual costs using AccuCirc yielded a unit cost of US$33.72, which is much higher than that for Rwanda. In our study, however, we used a greater number of inputs, including staff, essential consumables, and consumables used during 3 follow-up visits, whereas the Rwanda study limited the costing to the actual circumcision procedure.

This study has at least 3 limitations that influence whether the costs reported here would be the same as those in a scaled-up program. First, EIMC procedures were performed in an urban setting, and thus the results may be different for rural settings. Second, we based this cost analysis on a pilot implementation among a sample of 500 infants. To facilitate our analysis, we assumed that each team of nurse-midwives would perform 1,440 EIMC procedures each year. While this number was based on conservative assumptions, lower demand for EIMC may lead to lower capacity utilization resulting in higher unit costs of EIMC. Finally, our analyses did not include costs of demand creation due to the short duration (6 months) of the field study and the small sample size. Including realistic estimates of demand creation will be essential for fully costing a scaled-up EIMC program.

The potential impact of VMMC in reducing the number of new HIV infections has led some countries in sub-Saharan Africa to consider rolling out EIMC in order to achieve higher prevalence of male circumcision in the medium to long term. However, the shortage of medical personnel, particularly doctors, threatens the feasibility of these strategies and has led policy makers to consider substituting nurse-midwives for doctors to scale up EIMC. An understanding of the unit cost of EIMC performed by nurse-midwives can aid policy makers in decision making regarding the optimal delivery models to use. Despite its limitations, therefore, this study along with data from a companion study provides valuable data for planning EIMC scale-up and illustrates the advantages of using a nurse-midwife model. It also highlights that an integrated EIMC program is cost-minimizing compared with a vertical program, and helps determine the overall resources needed to implement a scaled-up EIMC program. Nurse-midwives could facilitate widespread low-cost scale-up of EIMC in sub-Saharan Africa. However, as nurse-midwives are currently overburdened, this strategy can only succeed if additional nurse-midwives are trained.

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Comparative Cost of EIMC by Nurse-Midwives and Doctors in Zimbabwe


Scaling Up Early Infant Male Circumcision: Lessons From the Kingdom of Swaziland

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Swaziland is the first country to introduce national early infant male circumcision (EIMC) into voluntary medical male circumcision (VMMC) programming for HIV prevention. With more than 5,000 EIMCs performed between 2010 and 2014, Swaziland learned that EIMC requires inclusion of stakeholders within and outside of HIV prevention bodies; robust support at the facility, regional, and national levels; and informed demand. Expansion of EIMC and VMMC has the potential to avert more than 56,000 HIV infections in Swaziland over the next 20 years.

ABSTRACT

Background: The government of the Kingdom of Swaziland recognizes that it must urgently scale up HIV prevention interventions, such as voluntary medical male circumcision (VMMC). Swaziland has adopted a 2-phase approach to male circumcision scale-up. The catch-up phase prioritizes VMMC services for adolescents and adults, while the sustainability phase involves the establishment of early infant male circumcision (EIMC). Swaziland does not have a modern-day tradition of circumcision, and the VMMC program has met with client demand challenges. However, since the launch of the EIMC program in 2010, Swaziland now leads the Eastern and Southern Africa region in the scale-up of EIMC. Here we review Swaziland’s program and its successes and challenges.

Methods: From February to May 2014, we collected data while preparing Swaziland’s “Male Circumcision Strategic and Operational Plan for HIV Prevention 2014–2018.” We conducted structured stakeholder focus group discussions and in-depth interviews, and we collected EIMC service delivery data from an implementing partner responsible for VMMC and EIMC service delivery. Data were summarized in consolidated narratives.

Results: Between 2010 and 2014, trained providers performed more than 5,000 EIMCs in 11 health care facilities in Swaziland, and they reported no moderate or severe adverse events. According to a broad group of EIMC program stakeholders, an EIMC program needs robust support from facility, regional, and national leadership, both within and outside of HIV prevention coordination bodies; robust support at the facility, regional, and national levels; and informed demand. Expansion of EIMC and VMMC has the potential to avert more than 56,000 HIV infections in Swaziland over the next 20 years.
Conclusion: The vast majority of public-sector facilities in Swaziland are led by nurses, and nurses and midwives have borne the brunt of caring for patients with HIV/AIDS in Swaziland. Like prevention of mother-to-child transmission, EIMC provides an opportunity for nurses and midwives to stand at the forefront of HIV prevention efforts. Rapid scale-up of VMMC and EIMC in Swaziland has the potential to avert more than 56,000 HIV infections and save US$370 million in the next 20 years.

BACKGROUND

With an HIV prevalence of 26% among adults and 41.1% among pregnant women, the Kingdom of Swaziland faces a substantial HIV and AIDS burden. The government recognizes that in order to alleviate this burden, it must urgently scale up effective, evidence-based HIV prevention interventions. To contribute to this goal, the government prioritized voluntary medical male circumcision (VMMC) in its initial “National Strategic Framework for HIV and AIDS 2009–2014” because VMMC is a safe procedure that has reduced the risk of female-to-male HIV transmission by approximately 60% in randomized controlled trials. Swaziland’s Ministry of Health (MOH) adopted VMMC for HIV prevention in 2009 with the endorsement of a national male circumcision policy and strategy. Swaziland does not have a modern-day tradition of circumcision, and the VMMC program has met with client demand challenges. Still, as of April 2014, Swaziland’s national adolescent and adult male circumcision prevalence was an estimated 24% (based on personal correspondence with Population Services International [PSI] Swaziland, which provided monitoring and evaluation support to the MOH for VMMC and early infant male circumcision [EIMC] data collection), triple the 8% circumcision prevalence reported in the 2006–2007 Demographic and Health Survey.

The subsequent “Extended National Multi-sectoral Strategic HIV and AIDS Framework (eNSF) 2014–2018” details a rapid scale-up of VMMC to 70% coverage for adolescents and adults ages 10 to 49 by 2018. It also outlines an ambitious goal for Swaziland’s national EIMC program: 50% EIMC coverage by 2018. This strategy is aligned with a recommendation by the World Health Organization (WHO) that VMMC scale-up should consist of 2 phases: the catch-up phase and the sustainability phase. The catch-up phase prioritizes VMMC services for adolescents and adults, or those who are most at risk of acquiring HIV. The sustainability phase involves the progressive establishment of EIMC within the first 60 days of birth. According to modeling data from the United States Agency for International Development (USAID) Health Policy Project using the Decision-Makers’ Program Planning Tool 2.0, provision of 200,700 adolescent and adult circumcisions and 26,970 EIMCs in Swaziland would avert over 56,000 HIV infections and save US$370 million by 2035. This figure is 78% of Swaziland’s total budget for health, education, sanitation, safe water, and social protection in 2013–2014.

In April 2009, with support from the United Nations Children’s Fund (UNICEF), Raleigh Fitkin Memorial (RFM) Hospital, a faith-based hospital in the commercial capital of Manzini, piloted the first EIMC model in Swaziland. The hospital introduced the pilot to strengthen delivery of maternal and newborn health services. Data from the RFM Hospital pilot demonstrated the feasibility of implementing EIMC as an integral part of maternal and newborn care services in Swaziland. Factors contributing to the successful adoption of EIMC at RFM Hospital included hospital ownership of the intervention, effective communication with stakeholders, no severe adverse events, and collaboration with development partners to meet the start-up costs of training medical staff, facility improvements, and supplies.

In October 2009, while the pilot was underway at RFM Hospital, the Swaziland MOH initiated planning for an EIMC program by hosting an international expert consultation on EIMC. Hosting the first consultation of its kind gave Swaziland a voice in the global discussion around EIMC. Swaziland’s MOH immediately moved forward on clinical and programmatic recommendations that emerged from the consultation. The resulting EIMC surgical guidelines endorsed the Mogen clamp as the preferred EIMC method for Swaziland. Less than a year after the consultative meetings, the MOH incorporated these guidelines into the existing national male circumcision surgical protocol.

The timeline in Figure 1 illustrates the progression of Swaziland’s EIMC program.
Between 2011 and 2013, Swaziland expanded integrated EIMC services to 17 facilities. We collected data through structured stakeholder focus group discussions and in-depth interviews with key informants.

Implementation and expansion. Between 2011 and 2013, through MOH leadership, funding from UNICEF and the US President’s Emergency Plan for AIDS Relief (PEPFAR), and technical assistance from implementing partners, including PSI, Jhpiego, and others, integrated EIMC services expanded to 17 facilities: 11 public facilities (referral hospitals and health centers), 3 NGO sites, and 3 private clinics. Before initiating EIMC expansion, selected facilities underwent comprehensive readiness assessment and site-strengthening processes. The site-strengthening process involved assigning space for procedures, procuring EIMC equipment and supplies, ensuring the quality of waste management and reporting systems, and training and mentoring service providers according to MOH quality assurance tools.

The MOH and stakeholders established EIMC within its national VMMC and HIV prevention program and integrated it into existing health service delivery outlets, namely the maternal, newborn, and child health (MNCH) service delivery platforms. The Swaziland EIMC experience offers a useful template for other countries with generalized HIV epidemics and low circumcision prevalence that are embarking on EIMC programming.

METHODS

We collected data during a consultation process with both VMMC and EIMC stakeholders between March and May 2014 in preparation for the document, “Male Circumcision Strategic and Operational Plan for HIV Prevention 2014–2018.” The drafting of this important guiding document offered a timely opportunity to reflect on the first years of EIMC program implementation and consolidate lessons learned.

We collected data through structured stakeholder focus group discussions and in-depth interviews with key informants. We conducted 30 in-depth interviews with:

- Individuals from key MOH departments, including Central Medical Stores, the Public Health Unit, the Strategic Information Department, the Legal Advisor, the Swaziland National AIDS Program, the Rural Health Motivator Program, the Sexual and Reproductive Health Unit (SRHU), and the Expanded Program on Immunization (13 interviews)
- NGOs involved in EIMC service delivery and programming, including PSI, the Family Life Association of Swaziland, the Elizabeth Glaser Pediatric AIDS Foundation, and mothers2mothers (5 interviews)
- Professional associations, including the Swaziland Democratic Nurses Union, the Swaziland Nursing Council, and the Private Providers Association (3 interviews)
- Donors supporting EIMC programming (2 interviews)
Lessons From Swaziland’s Scale-Up of Early Infant Male Circumcision www.ghspjournal.org

RESULTS

With a total of 5,149 EIMCs performed between 2010 and the end of 2014, Swaziland now leads the Eastern and Southern Africa region in the scale-up of EIMC. By mid-2014, 123 health care workers (45 doctors and 78 nurses) had been trained through 11 clinical trainings. Five providers, trained as trainers, facilitated clinical trainings and conducted mentorship visits to newly trained providers. Approximately 80% of the infants were circumcised in the immediate postpartum period before discharge. The remaining approximately 20% of infants were circumcised later, and included referrals from other facilities or in tandem with immunization or routine postpartum visits. Notably, Swaziland’s EIMC program has not reported any moderate or severe adverse events to date at the time of publication of this article. Severe adverse events require extensive intervention with referral or specialist input, mild adverse events require minimal or no intervention, and moderate adverse events can be classified as neither severe nor mild, but do require intervention and are usually managed on-site. Because moderate adverse events are managed on-site, providers may have under-reported these adverse events, but this did not emerge as an issue in any focus group discussions or in-depth interviews. In 2015, Swaziland became the first PEPFAR male circumcision priority country to draft a costed operational plan that includes EIMC.

Technical Approach and Service Delivery

In Swaziland, EIMC integration starts during the pre-pregnancy period and continues through the postnatal period (Figure 2). Antenatal care, labor and delivery, postnatal care—all with integrated prevention of mother-to-child transmission (PMTCT) of HIV services—as well as child welfare clinics serve as entry points for EIMC services. EIMC messages accompany those of birth preparedness, antenatal care/PMTCT, and comprehensive “day of birth” care for the mother and newborn. At the facility level, health care providers and NGO-supported EIMC motivators and “mentor mothers” offer comprehensive information and education for parents and guardians so they can make informed choices about EIMC.

Swaziland registers approximately 34,249 births per year.14 In the public sector, 11 hospitals and health centers across Swaziland’s 4 regions routinely provide labor and delivery services. The MOH

- A traditional organization, Khulisa Umntfwana (“Grow a Child”)
- Providers and clinical managers working at 2 regional hospitals, 3 health centers, and 1 private clinic that offer EIMC (6 interviews with 5 doctors and 5 nurses). These were among the most informative interviews.

We selected stakeholders for in-depth interviews based on their involvement with MNCH or HIV/AIDS health issues from a policy or practice perspective, those with expertise in the Swazi health care workforce, and those with direct clinical or program experience with EIMC. While it was not feasible to visit all 17 facilities conducting EIMC services, we involved facilities from all 4 geographic regions of Swaziland as well as the varying types of facilities. Each interview lasted between 30 and 60 minutes, and we tailored them to informants’ areas of expertise: EIMC technical approach and service delivery, coordination, human resources, or communication and education.

We convened 2 focus group discussions. Traditional leaders from Manzini Region attended the first discussion, which addressed cultural values related to EIMC, and optimal approaches to building informed community demand for EIMC. The second discussion, an MNCH stakeholders’ forum with 27 participants, included 10 EIMC-trained nurses and facility matrons representing facilities across all 4 regions, as well as other NGO and national MOH representatives. Forum participants broke into small groups to discuss questions of (1) provider support and staffing for MNCH services, including EIMC, (2) EIMC entry points and service coordination and linkages between VMMC and EIMC, (3) facility-based client education and counseling, (4) EIMC demand creation and community awareness, and (5) EIMC expansion and scale-up. Note-takers documented the focus group discussions, and we analyzed the notes for consistent themes. An implementing partner responsible for VMMC and EIMC service delivery contributed all service delivery data presented here: numbers of EIMC procedures performed by month, year, and location, as well as the incidence of documented moderate and severe adverse events. All data collection and analysis were conducted according to international principles of maintaining privacy and confidentiality of personal information.
chose these facilities for the introduction of EIMC services so that EIMC could be performed by midwives and nurses before mothers and babies are discharged. EIMC is integrated within delivery and postpartum services and offered as a routine part of the MNCH package of services for healthy baby boys regardless of HIV exposure.

In 2011, the MOH developed the “Swaziland Task-Shifting Implementation Framework in Support of Quality Health Service Provision.” According to the framework, some minor procedures were to be shifted from doctors to nurses. However, nurses’ scopes of practice and job descriptions have been reviewed to incorporate shifted tasks, including EIMC. Currently, nurse-midwives perform EIMC in hospitals and health centers with physician backup.

According to a representative sample of both doctors and nurses at RFM Hospital, the facility with Swaziland’s most established EIMC program, when doctors and nurses are trained together, doctors feel more comfortable providing nurses the autonomy to lead the program. RFM Hospital started task shifting for EIMC in 2010 because doctors could not meet client demand for the service. Although hesitant in the beginning, hospital management embraced task shifting for EIMC because of the excellent clinical outcomes. The strong safety record to date at the time of publication of this article, as evidenced by the absence of documented severe or moderate adverse events, has further strengthened national confidence in EIMC-trained nurses. Global evidence in support of task shifting for male circumcision, particularly from Kenya, reinforces the argument in its favor.

FIGURE 2. Swaziland’s Model of EIMC Integration Into Reproductive, Maternal, Newborn, and Child Health Platforms

Abbreviations: EIMC, early infant male circumcision; PMTCT, prevention of mother-to-child transmission (of HIV).
Development partners have primarily supported the procurement and distribution of EIMC instruments, including Mogen clamps, prepackaged EIMC kits, and consumables. Within the next 5 years, the MOH plans to assume responsibility for EIMC supply and equipment procurement within its supply chain systems for the MNCH platform.

In 2011, the MOH established the position of National Male Circumcision (MC) Coordinator under the Swaziland National AIDS Program. This position supports both the VMMC and EIMC programs. According to the National MC Coordinator, Swaziland’s MOH viewed the EIMC program as both a way to further its HIV prevention goals and as an opportunity to strengthen MNCH services. EIMC stands to improve health outcomes for mothers and their babies by increasing attention to improving services, including strengthening infection prevention measures, reinforcing close monitoring of newborn health, encouraging routine neonatal physical examinations, discouraging early discharge, and promoting postpartum follow-up for both mothers and babies.

Swaziland has not yet completed a formal evaluation of EIMC, but EIMC integration into the MNCH platform appears to have been an effective approach to the delivery of services based on the number of EIMCs conducted as well as the following markers:

- EIMC indicators were integrated into national monitoring tools including the antenatal care (ANC) register, ANC card, child welfare card, child welfare register, and postnatal register.
- EIMC has been integrated into the comprehensive package of essential services for healthy baby boys.
- EIMC is part of the health education content discussed during routine antenatal care visits.
- EIMC consent forms for parents (Figure 3) are distributed through the MNCH platform.
- Health facility management has identified EIMC focal people.
- All public health facilities that offer labor and delivery services have allocated space to perform EIMC within their maternity units.
- Facility doctors oversee the EIMC service delivery as well as facility-level EIMC training activities.

**Coordination**

In the early stages of VMMC programming in Swaziland, a technical working group led by the MOH with participation from development and implementing partners provided oversight. Under the broad technical working group for VMMC, a subgroup focused on technical aspects of EIMC. This subgroup coordinated various aspects of the EIMC program, including macro-level program planning, clinical skills training, facility identification and assessment, and quality assurance. In February 2011, this technical team developed and piloted EIMC quality assurance supportive supervision tools, as well as a quality assurance implementation plan. As EIMC expanded to additional facilities, program planners recognized that it was critical to fully engage the MNCH platform for an integrated, robust, and sustained EIMC program. Efforts are currently under way to bring the SRHU, which is responsible for the MNCH platform, fully into the coordination framework.

It is envisaged that the VMMC technical working group, under the leadership of the National MC Coordinator, will include the manager of the SRHU. EIMC issues will be addressed through ad hoc working groups under the VMMC technical working group.

**Human Resources to Support EIMC**

The majority of key informants stressed that the human resource needs of an EIMC program are different from those of the intensive, time-bound, VMMC catch-up program. While EIMC is the long-term sustainability plan for VMMC, it is linked to, but also distinct from, the VMMC program. For adolescent and adult VMMC services, dedicated nurses and doctors were hired to meet the ambitious VMMC catch-up targets. MOH interviewees stated that this approach would be neither practical nor desirable for an integrated, sustainable EIMC program.

To face the human resource challenges for EIMC scale-up, the MOH, in collaboration with its partners, first trained EIMC providers, doctors, midwives, and nurses, through competency-based clinical training beginning in February 2011. Swaziland was the first country to pilot the competency-based clinical skills training in EIMC using the WHO/Jhpiego “Manual for Early Infant Male Circumcision Under Local Anaesthesia” and the associated UNICEF/Jhpiego facilitators guide and learners workbook.17-19 Implementing partners stated that during the planning stage, trainers realized that it might be difficult to gain informed consent for sufficient numbers of infants
FIGURE 3. Early Infant Male Circumcision Consent Form Used in Swaziland

VMMC CONSENT FORM FOR EARLY INFANTS

The name of my son is _______________________.

My name is _______________________. I am the boy’s parent or his legal guardian.

I consent that you do the male circumcision (removal of the foreskin) operation on my child.

Sign _______________________

Parent or legal guardian _______________________

Date _______________________

ID Number _______________________

Phone Number _______________________

My name is _______________________. I am the counsellor/EIMC Educator/nurse/doctor who has given information to the client and the parent/guardian. I have given information about:

- What circumcision is
- The benefits of circumcision
- What to do before and after the circumcision
- What to do if there are any complications or problems after circumcision
- The risks of circumcision
- How circumcision is done
- An emergency contact number and information about where to go in an emergency

I have given the above client and parent/guardian an opportunity to ask me questions about all the above. I have asked the client and the parent/guardian some questions to make sure that they understand the above information. I believe the client and parent/guardian are capable of giving consent and they have enough information to make a proper decision about whether to proceed with the operation of circumcision.

Sign _______________________

Counsellor/EIMC Educator/nurse/doctor _______________________

Date _______________________

Phone number _______________________

Date of Circumcision

File Number

Name Surgeon/Assistant

Signature

For further information or in case of emergencies please contact _______________________.

at _______________________. Or alternatively contact the toll free number 2005 (free of charge).
in order to ensure provider competency before completion of the 2-week training. In response, the MOH adapted the training program to include on-site clinical mentorship for newly trained providers until they achieved competency. EIMC-specific performance standards also reinforced best practices and post-training follow-up.

With the introduction of EIMC services, MOH stakeholders anticipated concerns about the introduction of an “additional” task without providing additional compensation. This was a particular challenge because doctors and nurses involved in the VMMC program had been compensated for the extra hours worked in support of the program. The MOH also needed to ensure that routine and emergent demands of the MNCH platform were not compromised by the introduction of EIMC in MNCH units. For these reasons, according to representatives from the Swaziland National AIDS Program, the MOH scaled up EIMC slowly. A considered, unhurried scale-up allowed time for facility teams to develop creative and practical solutions to any problems that arose. While the issue of compensation is still a sensitive one, ongoing inclusive dialogue is helpful in clarifying decision-making rationale.

To address human resource constraints, some higher-volume sites, such as the Mbabane Government Hospital and the RFM Hospital, allocated dedicated, trained midwives to EIMC. Facility management redistributed staff despite human resource shortages and without financial incentives, which demonstrates ownership of the EIMC program at the facility level. Assistance from partner-supported EIMC motivators—to educate clients, link clients to services, and help complete paperwork—also relieved providers of some supportive functions.

Client Education and the Informed Consent Process
Formative research has emphasized that EIMC sensitization efforts must provide parents with the information to make informed decisions. At present, health care providers, EIMC motivators, and mentor mothers at the facility level provide the bulk of EIMC counseling and education. Organizations, including the Elizabeth Glaser Pediatric AIDS Foundation and mothers2mothers, have been instrumental in training facility-level providers and support staff to educate clients about EIMC. At the community level, interpersonal communication agents and structured community dialogues sensitize and mobilize communities for both EIMC and VMMC. This approach provides adequate time for parents to make informed decisions or consult with extended family members. Written consent forms are available in both English and siSwati, the local language, and are thoroughly reviewed with clients (Figure 3). One parent, the mother or father, or the legal guardian, as well as the counselor or provider, must sign the consent form. Because these forms are distributed during the antenatal period, mothers have the option to take the forms home for discussion with family and partners and obtain fathers’ signatures if couples decide that they want their sons circumcised. To protect human rights, the MOH designed this rigorous consent process, supported by a national strategy that states that circumcision should be voluntary in all cases. In the case of EIMC, much like immunization, parents determine the best interests of their children.

DISCUSSION
In reviewing EIMC program data and feedback from key stakeholders, several critical program components emerge. Distilled findings across all results areas highlight the presence of the following factors and themes that contributed to the development of Swaziland’s fledgling EIMC program:

- Program backing from committed MOH leaders who have been termed early adopters in implementing an evidence-based EIMC intervention. Despite the fact that no other country in the Eastern and Southern Africa region was implementing EIMC at the time of Swaziland’s EIMC program initiation, there was strong, early political will and commitment (via the national strategic plan) from Swaziland’s MOH.

- Consistent and coordinated funding for EIMC across multiple funding sources during the early stages. UNICEF funded the first EIMC pilot at RFM Hospital in 2009. Since then, PEPFAR has provided consistent funding through USAID-supported EIMC expansion, which has helped the program establish a sound foundation.
The role played by RFM Hospital, whose model EIMC pilot encouraged Swaziland to move quickly from EIMC adoption to program implementation. RFM Hospital’s initiative and leadership informed the later roll-out of the EIMC program, highlighting the need for dedicated EIMC staff and space as well as linkages and coordination across the MNCH platform.

Targeted technical support from implementing partners. An example of technical assistance that supported program scale-up included formative research, supported by PSI and completed in 2013, that informed EIMC program decision making. This research found that there was a near-universal perception that consent for EIMC cannot be granted by one parent alone, and emphasized that EIMC sensitization efforts must provide parents with the information needed to make informed decisions. Another example of targeted technical support included the efforts of Jhpiego’s Maternal and Child Health Integrated Program to help providers achieve competency through a mix of classroom and clinical mentorship. Other organizations, such as the Elizabeth Glaser Pediatric AIDS Foundation and mothers2mothers, also played pivotal roles in informing potential clients through community and facility education sessions.

Formative research that informed decision making. A study of knowledge, attitudes, and practices (KAP) conducted by RFM Hospital helped direct the EIMC pilot and, eventually, national implementation. Later, an MOH-led, PSI-supported KAP study informed community- and facility-based EIMC demand-creation efforts.

A policy environment open to task shifting. To overcome the human resource challenge, in 2011 Swaziland’s MOH developed the “Swaziland Task Shifting Implementation Framework in Support of Quality Health Service Provision.” This framework allows nurses to perform minor procedures that were previously conducted only by doctors.

While these components contributed to a growing national program, EIMC stakeholders also stated that scale-up and implementation of EIMC in Swaziland were not without the following challenges, listed by results area:

### Technical Approach and Service Delivery

- Legislation is required to enact task shifting. Although the MOH approved the task shifting framework, fully operationalizing it remains a challenge, as does securing task shifting support from all relevant stakeholders.
- Early postpartum discharge of the mother/baby pair results in missed opportunities for EIMC. WHO recommends that EIMC should be performed at least 12 hours after birth to ensure that babies are healthy and stable before the procedure. However, due to high birth volumes and limited space, clients are often discharged before 12 hours postpartum, despite global guidance that mothers and babies should remain at facilities for 24 hours after birth, the period of greatest risk.23 Addressing challenges of early discharge could both improve EIMC uptake as well as ensure better monitoring of mothers and babies after birth.

### Coordination

- EIMC requires broad coordination across multiple stakeholders at the national level. In Swaziland, because EIMC was conceived within the larger VMMC strategy and coordinated by the Swaziland National AIDS Program, involvement of key stakeholders from the SRHU was not as extensive as desired.
- Program ownership should be fostered at all levels to avoid the perception of a donor-driven process. Although the EIMC program has been implemented within public health facilities, it still depends on donor support for material and financial resources. Moving forward, Swaziland will need to assume greater financial ownership as donors limit funding for EIMC.

### Human Resources to Support EIMC

- Human resource constraints can pose challenges for service continuity. The EIMC program is constrained by regular staff rotations of EIMC-trained providers. EIMC services are further challenged by limited numbers of EIMC-trained providers in high-volume facilities and already-limited human resources for health care services.
Client Education and the Informed Consent Process

- **The consent process for EIMC is complex.** Parents should be ready to make a decision about EIMC by the time they are admitted to facilities for deliveries. Parents and key decision makers should be sensitized before pregnancy or in early pregnancy. Early education allows couples and families the time to make considered decisions about EIMC.

- **Client counseling needs dedicated educators.** Especially in the early stages of program implementation and scale-up, dedicated educators can help establish and sustain EIMC services amid the multiple demands of busy and often understaffed MNCH units.

- **EIMC has vocal global and regional opponents.** Misinformation can jeopardize fledgling EIMC programs unless these programs continue to involve and educate communities and health care workers.

**CONCLUSION**

Like PMTCT, EIMC provides an opportunity for nurses to help lead the way toward an HIV-free generation. Because there are approximately 12 times as many registered nurses as doctors in Swaziland, and because an overwhelming number of public sector facilities are led by nurses, nurses and midwives have borne the brunt of the HIV/AIDS burden in Swaziland. Empowerment of nurses and midwives to take and embrace this critical role will help engender greater support for the EIMC program.

As with all VMMC programming, program staff must establish a careful balance between service delivery and community awareness. Informed demand from parents and communities for the service may also support the establishment of EIMC as a service delivery priority. However, for countries with developed VMMC programs that are now introducing EIMC for sustainability, it is also important to recognize that EIMC requires a different approach—standards and guidelines for VMMC must be expanded and adapted to address service provision on a different platform.

Swaziland has become the first country to implement EIMC programming quickly in response to the growing evidence supporting the health benefits of the procedure. In a country without a tradition of circumcision, where the sociocultural norms are not favorably predisposed to EIMC, and where VMMC scale-up faced challenges related to client demand, the EIMC program has expanded, which is particularly impressive because of the absence of a targeted national EIMC communication campaign. Continued expansion holds the promise of averting thousands of HIV infections and is a large step toward creating an HIV-free generation in Swaziland.

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Scale-Up of Early Infant Male Circumcision Services for HIV Prevention in Lesotho: A Review of Facilitating Factors and Challenges

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Key elements of Lesotho’s phased introduction of early infant male circumcision were strong commitment from the Ministry of Health and donors; adequate training and supervision; integration with maternal, newborn, and child health; and appropriate communication. Challenges around cultural acceptance, the availability of health care providers, and task sharing will need to be addressed.

ABSTRACT

Background: The World Health Organization and the Joint United Nations Programme on HIV/AIDS recommend early infant male circumcision (EIMC) as a component of male circumcision programs in countries with high HIV prevalence and low circumcision rates. Lesotho began incorporating EIMC into routine maternal, newborn, and child health (MNCH) services in 2013 with funding from the United States Agency for International Development and United Nations Children’s Fund. This presented unique challenges: Lesotho had no previous experience with EIMC and cultural traditions link removal of the foreskin to rites of passage. This process evaluation provides an overview of EIMC implementation.

Methodology: The Lesotho Ministry of Health and Jhpiego conducted a baseline assessment before service implementation. Baseline information from an initial assessment was used to develop and implement an EIMC program that had a pilot and a scale-up phase. Key program activities such as staff training, quality assurance, and demand creation were included at the program design phase. Facilitating factors and challenges were identified from a review of information collected during the baseline assessment as well as the pilot.

Results: Between September 2013 and March 2015, 592 infants were circumcised at 9 sites: 165 (28%) between 1 day and 6 days after birth; 196 (33%) between 7 and 30 days, and 231 (39%) between 31 and 60 days. Facilitating factors included strong support from the Ministry of Health, collaboration with stakeholders, and donor funding. Providers were enthusiastic about the opportunity to offer new services and receive training. Challenges included gaining consent from family members other than mothers, and parents’ concern about pain and complications. The EIMC program also had to manage providers’ expectations of compensation because overtime was paid to providers who took part in adult circumcision programming but not for EIMC. Limited human resources, including authorization only for doctors to perform EIMC, impeded provision of services.

Conclusion: Despite communication, compensation, and task-shifting challenges, integrating EIMC services with MNCH services could be a sustainable model for EIMC service delivery in Lesotho.

INTRODUCTION

Observational and ecological studies indicated that male circumcision provides partial protection for men against HIV infection. Three randomized clinical trials confirmed that male circumcision reduces female-to-male HIV transmission by approximately 60%, and modeling studies showed that male circumcision indirectly reduces infections in women. Based on these findings, in 2007 the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) issued guidance urging countries...
with high HIV prevalence and low male circumcision rates to incorporate voluntary medical male circumcision (VMMC) into their HIV prevention programs. The guidance also recommended that “countries should consider how to promote neonatal circumcision in a safe, culturally acceptable and sustainable manner.”

In response, the Lesotho Ministry of Health (MOH) created a male circumcision task force in 2007 and began implementation of adult VMMC services in February 2012 in partnership with the Maternal and Child Health Integrated Program (MCHIP), led by Jhpiego with financial support from the United States Agency for International Development (USAID)/U.S. President’s Emergency Plan for AIDS Relief (PEPFAR), and the United Nations Children’s Fund (UNICEF). Based on the success of the VMMC program, especially among younger boys, in 2013 the MOH piloted early infant male circumcision (EIMC) services as a component of its broader HIV prevention strategy to institutionalize male circumcision and reduce the need for future adult male circumcisions. These services were to be implemented not as a stand-alone program, like the VMMC program, but integrated with maternal, newborn, and child health (MNCH) activities. (See Box 1 for an implementation timeline.) This review describes the pilot and initial scale-up phase of the EIMC program in Lesotho.

**BACKGROUND**

**Early Infant Male Circumcision**

As per WHO guidance, VMMC programs need adult circumcision to reach 80% coverage and EIMC to be institutionalized to maintain the benefit of the fast scale-up of the adult circumcision program. Compared with VMMC, the EIMC procedure is less complicated because it uses clamp devices that do not require stitches, healing is faster, and the complication rate is lower. EIMC also avoids barriers faced by adolescents and adults, including fear of pain, fear of HIV testing and learning one’s serostatus, and indirect costs—such as lost days of work or school for healing or return visits. In addition, EIMC is performed before initiation of sexual activity so there are no concerns about pain from erections or resumption of sexual activity before the wound heals. EIMC can be offered at a lower cost than VMMC and implemented economically in developing countries hard hit by HIV/AIDS. One study in 2010 estimated the cost of neonatal male circumcision at US$15 and adolescent and adult male circumcision at US$59. Thus, some international health experts have recommended that countries consider the provision of EIMC services. Nonetheless, EIMC cannot be considered as the sole VMMC service for HIV prevention because the reduction of HIV incidence through EIMC will take decades.

According to WHO guidelines, EIMC is safe for full-term infants who weigh more than 2.5 kg and who have the procedure from 12 to 24 hours through 60 days after birth under local anesthesia and with the use of WHO-recommended devices. While VMMC programs are usually stand-alone programs, EIMC can be integrated into existing, routine MNCH programs, including immunization clinics.

EIMC projects have faced challenges around uptake of services in East and Southern Africa, where, unlike in West Africa, infant male circumcision is not commonly practiced. For example, in some communities of Botswana and Zimbabwe, infants are considered too young for circumcision because male circumcision is linked with rites of passage to adulthood and newborns are thought to be too vulnerable for surgery. Another challenge is obtaining consent: in most settings, only 1 parent is required to provide written consent for EIMC, but many new mothers prefer to involve other family members in the decision, including fathers and grandparents. Yet, these family members are often not present to provide consent when the mother has delivered or goes for postnatal care.

On the service side, in most countries in East and Southern Africa, only physicians are licensed to provide male circumcision, while nurse-midwives and nonphysician clinicians are the primary care providers during and after delivery.

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**BOX 1. Timeline for Implementation of the Early Infant Male Circumcision Program (EIMC) in Lesotho**

- 2007: Male circumcision task force formed
- February 2012: Ministry of Health (MOH) launches voluntary medical male circumcision (VMMC) services
- February 2013: MOH commits to introduction of EIMC services
- April and May 2013: Rapid assessment of initial facilities
- September 2013: 4-month pilot launched
- February 2014: Start of phased scale-up
In some countries, including Lesotho and Zimbabwe, concerns have been raised about the feasibility of introducing EIMC services into health services that are already overburdened and short-staffed. Despite these challenges, countries in the region have an opportunity to tackle HIV prevention and address broader neonatal and maternal health issues by scaling up EIMC.

Lesotho Context
Lesotho has one of the highest HIV prevalence rates in the world, with an estimated 23.7% of adults infected. The national HIV prevention strategy identifies VMMC as a priority component of the national response. The Lesotho VMMC implementation plan, developed in 2012, outlines the 5-year strategy for reaching 80% of eligible males ages 15 to 49 years and institutionalizing EIMC services. Modeling studies have estimated that for every 5 circumcisions in Lesotho, 1 HIV infection would be prevented. VMMC services were introduced in Lesotho in 2012 at 4 fixed sites. The MOH organized scale-up at the national level and integrated VMMC services at all hospitals before initiating services at health centers through regular outreach. The MOH decided to introduce EIMC services as soon as the adult VMMC program was launched. In Lesotho, services are offered free of charge, but only doctors can perform the procedure, which is a challenge because of the limited number of health care providers in Lesotho.

In 2013, the MOH established an EIMC task force within the Family Health Division, which oversees MNCH activities. The MOH held meetings to present the strategy and to determine the best approach to introduce EIMC in Lesotho. Meetings brought together a number of experts from United Nations (UN) agencies and other organizations supporting the MOH in the implementation of core HIV prevention and treatment programs. Stakeholders included MNCH, sexual and reproductive health, and family planning technical leads in the MOH and members of district management teams, UN agencies, the Christian Health Association of Lesotho, international and local NGOs, and managers at the selected hospitals. These meetings were organized to discuss guidelines for EIMC services in Lesotho and to determine how provision of EIMC services could be used as an opportunity to strengthen other MNCH services.

The proposed program model sought to integrate EIMC services into existing MNCH services, with EIMC provided to infant boys between 1 and 60 days after birth. The stakeholders developed a road map for implementation of EIMC services that included the comprehensive package of services recommended by UNAIDS (Box 2). Based on programs in other countries, and after discussion and consultation with the EIMC task force, the Lesotho MOH chose the Mogen clamp for program scale-up, because it is a 1-piece device, it does not need to be assembled, and it can be reused after sterilization. Other devices under consideration are placed on the infants and require a return visit to the facility for removal, which is a challenge due to Lesotho’s mountainous terrain.

Both doctors and nurses were trained on the EIMC procedure with specific roles. The procedure is performed only at the hospital level and only by doctors; however, trained nurses assist with the surgical procedure and perform follow-up care of circumcised infants. In Lesotho, either parent of the male infant can provide written consent for the procedure even though culturally fathers are expected to be the ones who authorize mothers to circumcise the infant.

METHODS
A pilot of EIMC services in Lesotho was conducted over 2 years from September 2013 to
March 2015. A phased approach was used to ensure that all steps of program implementation were in place. Three phases were designed: a rapid assessment to gather baseline information regarding readiness of facilities as well as potential demand (see Supplementary Material 1: Facility readiness assessment form); a pilot phase at 2 facilities; and a moderate program scale-up phase with services being rolled out at 6 other hospitals and 1 health center. Members of the EIMC task force assessed each phase and drew up recommendations to inform the following phase.

Data collected included numbers of EIMCs provided and results from the rapid assessment, which included information collected from interviews of key informants and stakeholders. The EIMC task force held discussions to identify potential facilitating factors and challenges to the scale-up of the national EIMC program. At the 2 facilities, the MOH and Jhpiego conducted an initial training for providers (doctors and nurses) after their selection by hospital management. The program procured equipment and supplied it at each site (e.g., Mogen clamps and restraining boards). Nurses conducted education on EIMC at antenatal care (ANC) clinics at hospitals and health centers. Circumcised babies were routinely assessed at 48 hours and 7 days after the procedure, either in the hospital or at their health center, to evaluate wound healing and to detect and document adverse events.

**Ethical Considerations**

Ethical oversight was provided by the Lesotho MOH. Data presented in this manuscript are anonymous and analysis was done without identifiers. Informed consent to circumcise the child was obtained from the parent after information highlighting benefits and risks of the procedure was given. The local institutional review board (IRB) and the Johns Hopkins University IRB provided approval for secondary data analysis.

**RESULTS**

**EIMC Provision**

During the pilot, 45 providers, including 4 doctors, 25 hospital nurses, and 16 health center nurses were trained during 3 workshops to perform various aspects of EIMC services. During the scale-up phase, 149 health workers, comprising 131 nurses, 16 doctors, and 2 lay counselors, received training in 9 workshops at the 7 sites where services were scaled up (Table 1).

Between the start of the pilot in September 2013 and March 2015, 592 male infants were circumcised (Table 2), including 40 infants circumcised during the pilot at Mafeteng District Hospital and Scott Hospital. A total of 28% of infants were circumcised at 1 to 6 days after birth, 33% at 7 to 30 days after birth, and 39% at 31 to 60 days after birth. Most infants were circumcised after the neonatal period; no infants were circumcised from 12 to 24 hours after birth.

Only 1 mild adverse event was recorded during the reporting period, representing 0.2% of total circumcisions. No severe adverse events were recorded. The adverse event occurred on a procedure performed during a training activity by a trainee doctor on a 6-week-old infant at Mafeteng District Hospital. Upon completion of the procedure, it was noted that excessive skin had been removed from the shaft on the ventral aspect of the penis. The trainer on-site consulted with the master trainer off-site and a decision was made to allow for healing to proceed and to determine any remedial action at the infant’s follow-up visit after 48 hours. At the 48-hour visit, the wound was exposed and assessed. The infant was examined again at the seventh day post-circumcision and again at 4 weeks post-circumcision. By the third checkup and review visit, the wound was satisfactorily healed and the defect had been covered by new skin.

**BOX 2. Early Infant Male Circumcision (EIMC) Proposed Package of Services**

- Information about EIMC for parents
- Processes to document HIV status of the mother; if not known, HIV testing and counseling
- Adherence counseling for mothers in the prevention of mother-to-child transmission of HIV program to continue with their medication
- Counseling and consent from mother or parents
- Infant feeding education
- Messaging to reinforce postnatal visit on day 7
- Information to reinforce immunization
- Aftercare instructions—post-EIMC care
- Analgesics
- General HIV prevention pamphlets
- Condom provision to mothers
From October 2014 through March 2015, 11% (246/2,171) of male babies delivered at the 9 implementation sites (2 hospitals of the pilot, 6 hospitals and 1 health center of the scale-up) were circumcised; rates ranged from 27% (81/299) in Berea Hospital to 2% (8/403) in Leribe Hospital.

Initial Rapid Assessment of Pilot Facilities
The rapid assessment in May 2013 provided information for upgrading sites to offer EIMC services. Specifically, it assessed MNCH programs in selected facilities, identifying opportunities and mechanisms for integrating EIMC services with MNCH services, sensitizing site managers and health care providers on the introduction of EIMC services in their facilities, and assessing the willingness of parents expecting a baby, should they have a son, to allow him to be circumcised.

The methodology for data collection included interviews with site managers, health care providers, and expectant parents (and accompanying relatives) attending ANC services, data collection of key information (including statistics regarding deliveries of male babies, opportunities for demand creation, range of MNCH services provided, human resource capacity, infection prevention and control practices, and proposed space for EIMC services), and direct observation of newborn care services (see Supplementary Material 2: Interview questionnaire for potential parents).

The rapid assessment was conducted at 2 sites that were considered for the pilot phase. These sites were selected as they were already offering VMMC (the doctors at those sites were trained for adult VMMC provision), and they were close to the MOH headquarters in the capital—for ease of monitoring. The 2 sites were Mafeteng District Hospital and Scott Hospital (see Supplementary Material 3: Feasibility facility assessment).

The findings from the assessment showed that both hospitals’ proposed locations for EIMC required improvements for safe provision of services and that 2 locations for EIMC would be needed in both hospitals: one at the maternity ward and the other at the postnatal care clinic. All staff interviewed at the hospitals expressed an interest in the introduction of EIMC services in their respective facilities and a willingness to be trained. Most of the interviewees (expectant parents) at the hospital also showed an interest in EIMC services. The parents raised concerns about pain for the neonate, timing of the surgery, and potential negative consequences, such as mutilation of the newborn by the EIMC procedure. However, a majority of those interviewed thought that EIMC was good for health and reduced chances of infections. The interviews indicated that a communication plan would need to address community concerns around EIMC (Box 3).

| TABLE 1. Number and Cadre of Providers Trained in Lesotho From September 2013 to March 2015 |
|-----------------------------------------------|-----------------------------------------------|------------------|
| Number of training workshops                   | 3                             | 9                             | 12    |
| Total number of providers trained              | 45                            | 149                           | 194   |
| Doctors                                        | 4                             | 16                            | 20    |
| Nurses at hospitals                            | 25                            | 60                            | 85    |
| Nurses at health centers                       | 16                            | 71                            | 87    |
| Lay counselors                                 | –                             | 2                             | 2     |

| TABLE 2. Number and Timing of EIMCs and Adverse Events in Lesotho From September 2013 to March 2015 |
|-----------------------------------------------|-----------------------------------------------|------------------|
| Total number of infants circumcised            | 40                            | 552                           | 592 (100%)     |
| Age at circumcision, days                      | 1–6                           | 5                             | 165 (28%)      |
|                                              | 7–30                          | 14                            | 196 (33%)      |
|                                              | 31–60                         | 21                            | 231 (39%)      |
| Adverse events                                | 0                             | 1                             | 1 (0.2%)       |

Abbreviation: EIMC, early infant male circumcision.
Pilot at 2 Facilities
EIMC services were introduced at the 2 pilot facilities in September 2013. The objectives of the pilot were to introduce EIMC services at the 2 hospitals and to consider integration of EIMC services into MNCH services. Specific objectives included developing appropriate trainings for the Lesotho context; finalizing and implementing EIMC program guidelines; and ensuring targeted communication on EIMC services through the development and distribution of information, education, and communication (IEC) materials; as well as education of pregnant women.

Key documents developed during this phase included guideline documents, “Minimum Standards for Performing Early Infant Male Circumcision” (see Supplementary Material 4), a group education and counseling flipchart, a step-wise procedure chart to guide health workers in performing circumcision with the Mogen clamp, a complications pamphlet, and IEC brochures (see Supplementary Material 5a, b, c: IEC materials). Monitoring and evaluation tools, including registers, adverse event forms, and quality standards assessment tools, were also developed and piloted at the 2 hospitals. When finalizing EIMC guidelines, it became clear that there was a need also to finalize and update guidelines on essential newborn care.

Results from the pilot showed that, for the most part, providers felt comfortable with their level of training and capable of mobilizing and educating families and assisting with or performing the procedure. Provider concerns primarily revolved around limited staffing and time allotted to EIMC services in the context of insufficient human resources at hospitals (Box 4).

Scale-Up at 7 Sites
A roll-out plan detailing steps to be taken to expand services nationally was developed with consideration of recommendations from the pilot (Box 5). EIMC services were started at an additional 7 sites between February 2014 and March 2015. These included Carewell Clinic and St. Joseph’s Hospital in Maseru district; Berea Hospital and Maluti Adventist in Berea district; Motebang Hospital in Leribe district; Butha-Buthe District Hospital; and Ntsekhe Hospital in Mohale’s Hoek district.

KEY PROGRAM ACTIVITIES
Training of EIMC Service Providers
Training for both the pilot and scale-up phases took place immediately before service initiation at each of the implementing sites. Eligible trainees were qualified and licensed health care workers, preferably working in the maternity unit or in the maternal and child health clinic at the hospitals where service initiation was being planned. Each training ran for 5 days, and doctors and nurses trained together. Trainers conducted regular visits and worked with EIMC trainees until they reached competency in the circumcision procedure and could identify and manage complications. Other components of the training included education and counseling for parents of male infants. Specific training was developed for nurses at health centers on providing education and counseling of prospective parents, pre-procedure screening to ensure infants were fit for circumcision, and post-procedure checkup and care.

Teaching methods included 1 day in the classroom for theory presentations and discussion, 1 day of practice with models at different skills stations, and 3 days of hands-on clinical practice with babies in the clinic. To ensure competence, trainers closely monitored and supervised the physicians and nurses during the first 5 procedures. Trainers assessed knowledge at the end of the training through an examination, and they assessed skills by observing each step of the procedure.

Demand Creation and Social Mobilization for EIMC
The EIMC technical working group developed a communication plan to address myths and
misconceptions about EIMC. IEC materials regarding EIMC services are continuing to be provided to the primary audience (parents and potential parents of male infants) at ANC clinics, maternity wards, postnatal clinics, clinics seeing children under the age of 5, and VMMC clinics. These IEC materials were also provided through routine community mobilization activities.

**Quality Assurance**

Early in program implementation, the technical working group developed tools for quality assurance. The MOH, WHO, and Jhpiego conducted external quality assurance visits to all sites. Lesotho uses guidelines based on WHO’s quality assurance guidelines for male circumcision.

In addition, each site has a quality assurance assessment team (MOH technical staff, site staff, and EIMC providers from a different site) that undertakes a quality assurance review, to identify performance gaps and to develop action plans to bridge those gaps. EIMC service providers and managers also conduct periodic self-assessments of their services to improve quality. The process helps providers develop a sense of ownership of the assessment findings so that they become involved in making recommendations and implementing solutions.

**DISCUSSION**

While the EIMC program in Lesotho is still in the early stages, demand for services has increased slowly as the program has expanded from 2 to 9 sites.

Introduction of the EIMC program was supported by a strong commitment from the MOH, close cooperation with stakeholders (UNICEF, USAID, the Christian Health Association of Lesotho, etc.), and stable funding from USAID and UNICEF. In addition, when providers were offered the chance to train, they were enthusiastic about the opportunity to acquire a new skill and offer new services. The phased introduction of services helped to ensure a smooth start-up and, where possible, recommendations from the assessment were applied to the pilot, and recommendations from the pilot were applied to the scale-up at 7 facilities (see Supplementary Material 6: EIMC pilot implementation program assessment).

With the launch of EIMC and its integration with the MNCH program, it became apparent that the national neonatal care manual had not been finalized. As a result, the MOH updated and finalized the manual, which now includes an EIMC component. Providers being trained in EIMC now receive refresher training on neonatal care, which is important because of Lesotho’s high infant mortality rate (74 deaths per 1,000 live births). The program will continue to review the EIMC service provision package for potential improvements. The program is also exploring the possibility of using the provision of EIMC services as an opportunity to increase male involvement in infant care, increase facility-based births, and improve infant health care generally.

**Challenges**

The primary challenge to EIMC uptake in Lesotho is that even though either parent can provide consent individually, the mother still consults

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**BOX 4. Recommendations From the Pilot for the Scale-Up**

- Continue task-sharing discussions
- Explore ways to increase male involvement to improve rates of facility births, infant care, and overall child health
- Scale up demand creation for services, including during antenatal care, by increasing awareness of early infant male circumcision (EIMC) availability
- Train additional providers from existing and new service sites to ensure the expansion of services
- Ensure the quality of services at all sites by providing training for all managers and health care workers involved in service provision
- Ensure that the few trained staff are scheduled to provide services daily to avoid missed opportunities due to staff unavailability

**BOX 5. Key Steps to Introduce Early Infant Male Circumcision Services During National Scale-Up**

- Engage facility management team
- Conduct rapid site assessment—look at infrastructure and personnel
- Conduct initial demand creation in hospital and community
- Set up site
- Select and train providers
- Initiate services
- Provide supportive supervision and mentoring

Providers being trained in EIMC now receive refresher training on neonatal care, which is important because of Lesotho’s high infant mortality rate.
The primary challenge to EIMC uptake in Lesotho is the mother’s need to consult with the father and other family members before consenting to the procedure.

with the father and other family members before consenting to the procedure, as has been reported in other programs in Southern Africa. In Lesotho, a mother can provide legal consent for EIMC, but most prefer to consult with the father as well as other family members about the decision to have a male child circumcised, which can delay the procedure. In Lesotho, most fathers do not accompany mothers to ANC visits, to the hospital for the birth, or to postnatal care visits, the main sources of EIMC information. Therefore, most fathers are reluctant to give consent since they do not have firsthand information about the safety and benefits of the procedure. Possible solutions to this challenge include ensuring that fathers are invited to the facility to give their informed consent and providing informed consent forms to the mother during ANC visits in order to get the father’s consent prior the baby’s birth.

In Lesotho, low rates of institutional childbirth (58.7%) and limited use of neonatal and early infant care services also limit access to EIMC information and services as many infants’ first contact with the health system is at their 6-week immunization visit. Early discharge from the hospital also limits access to EIMC. As per the Lesotho guidelines, mothers who deliver normally at hospitals are discharged as early as 4 to 6 hours postpartum, which limits opportunities to provide EIMC after the recommended 12 hours.

Cultural practices also have an impact on uptake of EIMC services. Traditionally, boys in Lesotho are circumcised during ritual initiation into adolescence and adulthood. Some mothers feel that infancy is not the proper time to have their sons circumcised because they fear their sons will not be accepted for initiation. Research is needed to determine how best to scale up and tailor demand creation activities to address the Lesotho context.

Another challenge in Lesotho and supported by other studies is parents’ reluctance to have their baby boys circumcised due to concerns about pain, the infant being too young to undergo a surgical procedure, and potential harm. The Lesotho VMMC/EIMC program addressed these concerns through its IEC materials and expects that as more babies are circumcised, the very low rate of adverse events will help allay these concerns.

The program also had some difficulties integrating EIMC services into the MNCH program. The VMMC program in Lesotho is a stand-alone program that operates year-round from clinics and through seasonal campaigns. While MNCH providers have been enthusiastic about getting trained in EIMC service provision, this enthusiasm has been hard to sustain, one reason being compensation. Unlike VMMC providers, EIMC providers do not receive incentives for providing male circumcision services. The MOH sees the provision of EIMC services as part of the standard package of MNCH services and has not provided for extra compensation. As a result of the discrepancy, some MNCH providers have lost enthusiasm for including additional tasks in their already busy schedules. In addition, some hospitals that provided EIMC services for a fee before the launch of the official EIMC program are now expected to provide these services for free, which has undermined management buy-in.

A notable challenge is the lack of available providers, which is partly the result of a shortage of doctors, the only cadre authorized by their regulatory body to perform EIMC. However, under the new, recently revised preservice education curriculum, nurses are being trained to perform the EIMC procedure. In practice, most nurse clinicians are not sure they have the authority from their regulatory body and are hesitant to perform the procedure. Furthermore, nurse clinicians are a recently revived cadre and very few in number, and therefore they cannot meet the demand for EIMC services. There are fewer than 50 nurse clinicians for the entire country. All cadres of nurses should be authorized to perform EIMC to meet the growing demand. The need for task sharing of the male circumcision surgical procedures between medical doctors and nurses was identified before program inception and is seen in other programs as well. This need is especially important in Lesotho where, due to the deficit of medical doctors, maternity units are usually not staffed with full-time doctors. Doctors assigned to maternity units are often available only for emergencies as they usually do not have time for providing routine services. We have seen that there are times in hospitals when nurses, who are the primary providers of information on EIMC, have women who would like to have their babies circumcised, but a doctor is not available. In addition, EIMC is supposed to be routinely performed in maternity units and postnatal clinics, which are frequently staffed with nurses who are currently not allowed by their regulatory organization to perform the procedure. Furthermore, most mothers who deliver
at hospitals are encouraged to go to health centers for their postnatal clinic checkups, where EIMC is presently not offered. Studies in East and Southern Africa have shown that nurses and clinical officers can be trained to provide EIMC safely.4,11

**CONCLUSION**

The introduction of EIMC services for HIV prevention into MNCH services in Lesotho demonstrates the feasibility of such a program in a low-resource setting with leadership and commitment from the MOH and key stakeholders. EIMC can be institutionalized to complement gains from the adult VMMC program.

Allowing nurses to perform EIMC procedures would increase the availability of services in hospitals and would also allow the procedures to be performed in health centers, where a large number of potentially eligible infants are seen. Stakeholders should encourage the MOH and professional regulatory organizations to license nurses to provide EIMC services.

Circumcision services should also be offered on a daily basis at implementation sites. Currently, EIMC services are offered once or twice a week at each site, based on the providers’ workload or on set service days. We also believe that the MOH should explore offering EIMC services on a daily basis at district hospitals. EIMC services would then be available during the 3 visits (delivery, postnatal care Day 7, and postnatal care Week 6) that are most likely to present an opportunity for babies to be circumcised, and the mothers would not have to make a return visit, which is difficult for them.

With only 1 adverse event reported during the assessment, we believe that this review will assist program implementers in Lesotho to tailor the national scale-up of services to their local context.

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