

A CALL TO ACTION ON VOLUNTARY MEDICAL MALE CIRCUMCISION

IMPLEMENTING A KEY COMPONENT
OF COMBINATION HIV PREVENTION

A JOINT REPORT FROM

AVAC, NATIONAL EMPOWERMENT NETWORK OF PEOPLE LIVING WITH HIV/AIDS IN KENYA,
SONKE GENDER JUSTICE NETWORK AND UGANDA NETWORK OF AIDS SERVICE ORGANIZATIONS



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A Call to Action on Voluntary Medical Male Circumcision

The global HIV epidemic, unprecedented in its scope and impact, has galvanized extraordinary action worldwide. It is now more than three decades since the first cases of AIDS were diagnosed. With a growing array of proven strategies and promising research on HIV prevention, it is now agreed that we have the means to begin to end HIV through strategic combinations of well-defined HIV prevention strategies—often referred to as combination prevention—and continued research for improved tools.

The precise components included in combination prevention vary by context, but core interventions recognized as high-impact and critical to an effective response include: antiretroviral therapy for people with HIV, which preserves health and reduces risk of transmission; expanded HIV testing and effective linkage to prevention and treatment services; prevention of pediatric HIV infection; and voluntary medical male circumcision (VMMC)*, a relatively inexpensive prevention strategy that offers lifelong partial protection from HIV. As a result of slow action on each of these strategies, the potential benefits of combination prevention have not been realized. The countries most heavily affected by the epidemic continue to suffer needless numbers of new infections.

To begin to end the epidemic, and as research for new and improved tools continues, all components of combination prevention need to be expanded based on the context of each country's epidemic. One of the greatest and most feasible short-term victories in the African context involves rapid scale-up of VMMC. This strategy alone will not end the epidemic, but it could dramatically slow the spread of the virus in countries most heavily affected by HIV. Delays in implementing VMMC will prolong the epidemic needlessly. Now is the time for action to bring this high-impact, high-value strategy to scale.

Nearly five years after UNAIDS and WHO issued recommendations for VMMC in countries with high HIV prevalence and low levels of VMMC, there has been limited progress in bringing this prevention intervention to scale. As of March 2012, the world was only about

* A note on terminology: throughout this document the term "voluntary medical male circumcision" or VMMC is used to denote the specific procedure, including counseling and supportive services, that has been evaluated and is being implemented as an HIV prevention tool. Various countries use slightly different terminology. VMMC is used here for the sake of consistency.

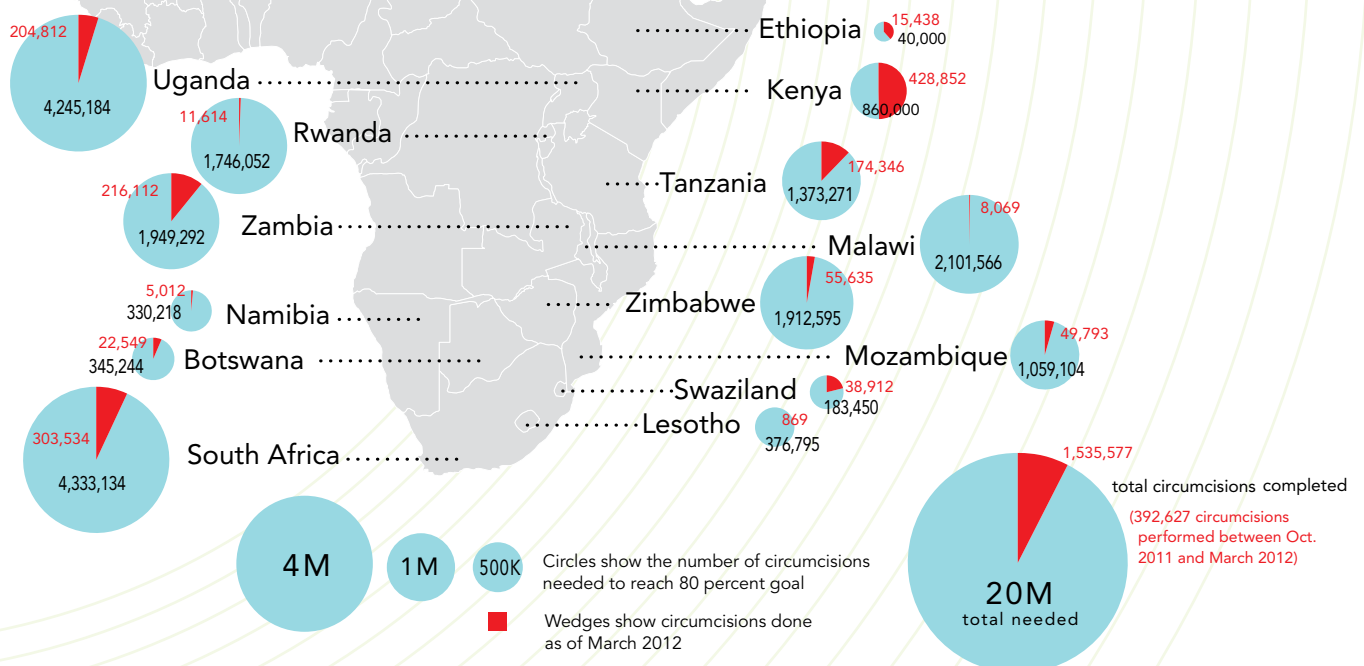
8 percent of the way to reaching the target of circumcising at least 80 percent of adult males between ages 15 and 49 in fourteen priority countries. The authors note that, given slow progress to date, meeting this by 2015 may not be possible, representing a major missed opportunity. As advocates, we call on governments in priority countries to set national timelines and targets that can be monitored going forward.

Countries, donors and communities must move with speed to realize the opportunity to alter the epidemic's trajectory in the most heavily affected countries. Modelling based on a timeline where 80 percent coverage is achieved by 2015 suggests that more than 20 percent of new HIV infections would be averted by 2025, with a savings of an estimated US\$16.6 billion in future medical costs. Even if this timeline shifts, there is still much to be gained. When used in combination with other proven prevention strategies, VMMC has the potential to dramatically cut rates of new HIV infections, AIDS deaths and the overall price tag for the AIDS response in sub-Saharan Africa.

Progress in VMMC Scale-Up in Priority Countries

As of March 2012

Experts hope to circumcise more than 80 percent of men in 14 African countries to reduce their risk of HIV infection



Source: PEPFAR Male Circumcision Technical Working Group

Priority Recommendations to Accelerate Scale-Up

Now is the time to redouble efforts and apply lessons learned to achieve the goal of **80 percent coverage of VMMC in men (ages 15-49) in fourteen priority countries (see p. 2)**. This goal should be linked to milestone-driven implementation plans in each country—and should receive full support from civil society, donors and implementers. There is no time to waste.

AVAC, The National Empowerment Network of People Living with HIV/AIDS in Kenya, Sonke Gender Justice Network and Uganda Network of AIDS Service Organizations make the following priority recommendations to achieve this ambitious target:

Leadership and Commitment

- **National political leaders should provide vocal, visible and consistent support for expedited VMMC scale-up**, actively exhorting their countrymen to get circumcised and positioning VMMC as a national social norm.
- **Regional bodies should actively embrace the goal of 80 percent coverage in priority countries as soon as possible and promote accountability and South-South collaboration on VMMC scale-up**. Key regional bodies that have potentially important roles to play in scale-up include the Southern Africa Development Community, the East African Community and the African Union.
- **VMMC scale-up should become a visible, high-priority item on the global political agenda**, with visibility comparable to the global push to eliminate mother-to-child HIV transmission. In particular, VMMC should be highlighted and promoted through such global forums as the 2012 International AIDS Conference, periodic reviews of progress by the United Nations (i.e., UNGASS process) and the annual World Health Assembly.
- **Civil society in priority countries should actively endorse and promote VMMC scale-up**. Donors and international agencies should provide support for civil society advocacy on VMMC, and global civil society networks should also embrace the goal of achieving 80 percent VMMC in priority countries.

Country Implementation

- **All countries should have in place by the end of 2012 a detailed, costed, timeline-driven operational plan for VMMC scale-up**. Country ownership and leadership is critical, and such plans can be used to align and mobilize resources and coordinate activities among national stakeholders, donors, international technical agencies and international NGOs.

- Countries should establish and publicize annual scale-up targets for VMMC. Ambitious annual gains should build toward the ultimate goal of 80 percent coverage.
- Diverse, adaptable delivery strategies should be pursued toward the goal of 80 percent coverage in priority countries. Based on national circumstances, countries should consider a combination of delivery strategies, including stand-alone, dedicated sites; mobile services; time-limited campaigns; and integration of VMMC into mainstream health care delivery sites.
- Priority countries should adopt a comprehensive policy framework to accelerate progress toward 80 percent coverage. Formal policies should provide for task shifting and task sharing, infection control and waste management, and strategic configuration of clinical sites and surgical teams to promote efficiency. Policies should also mandate and guide needed education and counseling for VMMC clients.

Community Engagement

- Communities should embrace VMMC as an advocacy issue, and request donors, national governments and VMMC delivery sites to allocate substantial resources to these activities. Civil society partners have a key role to play in education about VMMC and related issues, such as gender equality, domestic violence, the need to continue risk reduction via partner reduction and condom use, and the importance of abstaining from sex until wound healing. In the context of resource-constrained service delivery, it is critical to work with community partners to create and share comprehensive messages that optimize the benefit of VMMC.
- National and local governments should work with community gatekeepers, including traditional and religious leaders, to implement inclusive community dialogues on VMMC for HIV prevention. It is critical to ensure that social, cultural and community leaders—including those engaged in traditional male circumcision rituals—are engaged as active partners in designing VMMC programs.

Demand Creation

- National governments, clinical sites, community leaders, international agencies and donors should collaborate in the formulation and implementation of operational research to inform demand-creation activities. Such research should investigate the reasons men do or do not access services, optimal messages and communications channels, and key message carriers to motivate VMMC uptake.
- Demand-creation activities should be adequately budgeted and regarded as an essential component of VMMC services.
- Demand-creation activities should focus particular efforts on reaching key stakeholder groups, including men in their 20s and 30s; women and girls; and traditional and religious leaders. These groups should be engaged as partners in communication and education.

Coordination

- National governments should take steps to strengthen the functioning, visibility and capacity of national VMMC task forces. These task forces should be ultimately responsible for overseeing the coordination, adaptation, implementation, monitoring and evaluation of national strategies for VMMC scale-up. Donors and international technical agencies should, where indicated and requested, provide support to build the capacity of national task forces.
- Donors, international agencies, international NGOs and sub-national units should coordinate and align their activities with national operational plans. Activities should be regularly reported to, and coordinated with, national VMMC task forces.

Resources

- All priority countries should make meaningful domestic budget allocations for VMMC services.
- National governments should use their costed VMMC plans to determine national budget allocations and to mobilize resources from in-country donors to ensure that funding gaps are met. National governments quantifying their resource gap should urge PEPFAR, the leading funder for VMMC scale-up, to ensure that needs are met. Where the resource needs have not been quantified, civil society should advocate for government to show leadership and donors to provide technical and financial assistance.
- Countries should prioritize VMMC scale-up in proposals to the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM). Countries should analyze needs and priorities to ensure that existing funds are aligned with the GFATM's new strategy for iterative support to maximize the public health impact of grant funding. The Global Fund Secretariat should provide technical support to countries to assist with rational reprogramming.

Monitoring and Evaluation

- Countries, donors, international agencies and other stakeholders should develop a set of core, standardized indicators to guide monitoring and evaluation efforts for VMMC scale-up. Countries should have the leeway to adapt indicators to national conditions and reporting structures, preserving in all instances the ability to provide regionally comparable reporting on core indicators.
- Donors, international agencies and international NGOs should take steps to synchronize and align their programs, reporting protocols and systems based on standardized indicators and streamlined national reporting structures.
- Individual countries, regional bodies and the global community (with leadership from WHO and UNAIDS) should issue annual reports on progress toward the goal of 80 percent coverage in priority countries. These reports should identify lessons learned, including best practices and implementation bottlenecks.

- All countries should implement routine, standardized, comprehensive reporting of adverse events relating to VMMC services. Donors, international agencies and international NGOs should provide countries with financial and technical support to build adverse-event surveillance systems.

Innovative Devices

- Data from completed and ongoing clinical studies on non-surgical devices for VMMC (the Shang Ring and PrePex are two such devices under evaluation) should be analyzed without delay and used to guide normative agency recommendations with broad applicability by mid-2013. Gaps left by current research, including operations research and additional confirmatory studies should be clearly defined and filled in a strategic, coordinated manner. Donors and international agencies should provide appropriate technical and financial support to ensure timely implementation, completion and analysis of these studies.
- Decision-making tools should be developed to help priority countries evaluate suitability and relevance of new devices. These tools should be in place by mid-2013. WHO should ensure that regional and national consultations are held to implement these tools and analyze results.
- All countries seeking program efficiencies should investigate the feasibility of implementing new devices and make ambitious implementation plans accordingly. WHO and UNAIDS should provide technical support for the development of national rollout plans.

Number of VMMC Procedures Needed to Avert a Single Case of HIV Infection, 2011-2025*	
Botswana	8
Lesotho	5
Malawi	13
Mozambique	7
Namibia	26
Kenya (Nyanza)	8
Rwanda	44
South Africa	5
Swaziland	5
Tanzania	10
Uganda	19
Zambia	8
Zimbabwe	4

Source: Njeuhmeli et al., 2011

*A 14th country, Ethiopia, has been added to this list by PEPFAR, which is the primary funding source of VMMC worldwide.

Introduction

In this report, AVAC, National Empowerment Network of People Living with HIV/AIDS in Kenya (NEPHAK), Sonke Gender Justice and Uganda Network of AIDS Service Organizations (UNASO) summarize the latest evidence on VMMC. After reviewing the evidence demonstrating the effectiveness of VMMC in preventing new infections, the report surveys the current state of progress in bringing VMMC services to scale. It also examines key factors that influence the success of efforts to promote scale-up of VMMC. This analysis supports the authors' *Call to Action*, (see p. 1). Recommendations from the *Call to Action* also appear alongside relevant topics throughout the text.

The goal of this *Call to Action* and the supporting report is to unite diverse stakeholders at country, regional and global levels in an unprecedented joint undertaking to capitalize on the unique promise of VMMC to reverse national epidemics in sub-Saharan Africa.

While redoubling efforts to implement this highly cost-effective HIV prevention strategy, it is equally important to recognize the challenges associated with scaling up VMMC. Unlike other prevention methods, such as delaying sex or using a condom, VMMC at present involves a surgical procedure, that many men may understandably be resistant to. Moreover, reaching saturation coverage of VMMC will require far-reaching changes in social norms in many settings. However, experience demonstrates that scaling up VMMC is, indeed, feasible. Drawing on learning to date, this report seeks to outline a way forward to overcome these challenges. This report also focuses almost exclusively on VMMC for adult men (ages 15-49) and does not address the programmatic, resource or advocacy considerations associated with neonatal male circumcision. Introducing neonatal male circumcision will help safeguard and sustain HIV prevention efforts over the long term. However for impact on the epidemic within the next decade, resources and attention must focus on VMMC.

"America's combination prevention strategy focuses on a set of interventions that have proven most effective—ending mother-to-child transmission, expanding voluntary medical male circumcision, and scaling-up treatment for people living with HIV/AIDS."

Hillary Clinton
U.S. Secretary of State
Washington, D.C., Nov. 8, 2011

In addition, while VMMC on its own offers dramatic potential to slow new infections, ending AIDS will require a combination of prevention strategies. VMMC is an important tool to accelerate results, but only strategic programs of combination prevention will enable us to begin to end the epidemic.

The Evidence for Voluntary Medical Male Circumcision

As early as 1989, observational studies in sub-Saharan Africa found that uncircumcised men were several times more likely to become infected through heterosexual intercourse than circumcised men (Cameron et al., 1989). Dozens of subsequent studies also found that HIV prevalence was considerably higher among uncircumcised African men than among their circumcised counterparts (Bailey et al. 2008; Weiss et al., 2000).

These observational data triggered a sharp debate in the HIV-prevention field. While some experts argued in favor of VMMC promotion based on the differential HIV prevalence noted in epidemiological studies, others raised methodological concerns, suggesting that other factors, such as background HIV prevalence or religious or cultural differences, might explain the higher HIV prevalence among uncircumcised men. Moreover, even if circumcisions of newborns or adolescents might protect against sexual transmission, it was argued, this did not necessarily demonstrate the effectiveness of adult VMMC in reducing HIV infection risk.

In recent years, these questions have been definitively resolved by well-designed randomized controlled trials. Three trials—in South Africa, Kenya and Uganda—found that voluntary medical circumcision of adult males reduced the risk of female-to-male sexual transmission by roughly 60 percent (Auvert et al., 2005; Bailey et al., 2007; Gray et al., 2007). Based on these compelling research findings, WHO and UNAIDS in 2007 recommended implementation of VMMC in countries where HIV prevalence is high and the prevalence of VMMC is low (WHO, 2007).



Angelo Kaggwa undergoes VMMC in Kisumu, Kenya.
Credit: Simon Odiwuor

Why Does VMMC Protect Against HIV Transmission?

There appear to be several reasons that VMMC reduces the risk of female-to-male sexual transmission. First, uncircumcised men may be more likely than circumcised men to experience small tears and lesions that may function as portals for the virus. Second, the inner foreskin has a heavy concentration of HIV target cells. Finally, VMMC also reduces the risk that men will contract other sexually transmitted infections, which in turn increase the risk of HIV acquisition. (For a review of the biological evidence on VMMC and HIV transmission, see Weiss et al., 2008.)

VMMC And Men Who Have Sex With Men

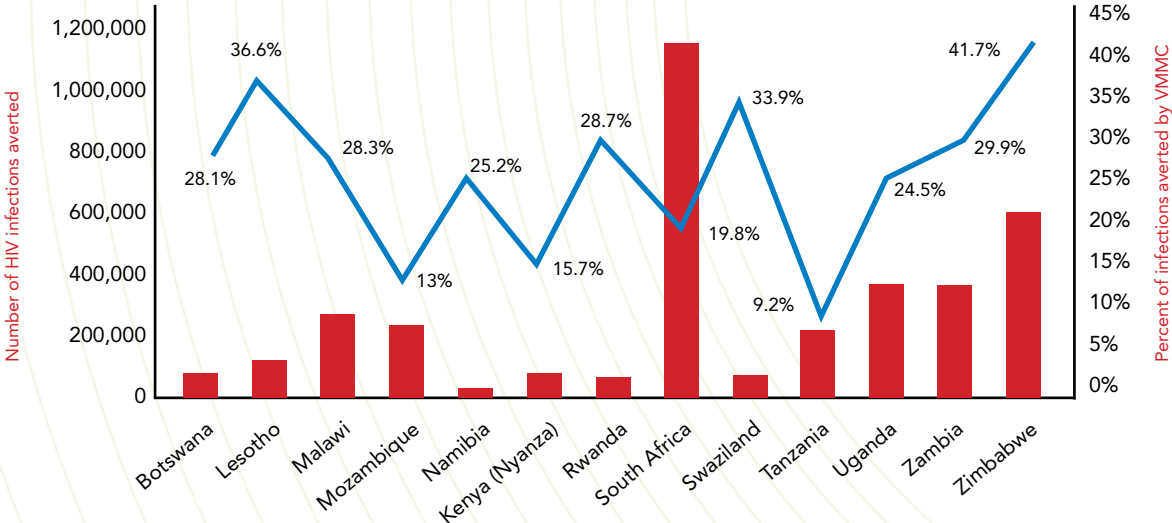
Although certain studies suggest that VMMC may offer a degree of protection from HIV infection to men who have sex with men (MSM) (Buchbinder et al., 2005; Kreiss et al., 1993), there has been no randomized controlled trial of the intervention in MSM. For now, the weight of available evidence has failed to identify a statistically significant difference in HIV risk among MSM who are circumcised and those who are uncircumcised (Sanchez et al., 2011; Millett et al., 2008).

Measuring and Modeling Impact

Early evidence confirms that high levels of VMMC coverage lead to durable, population-level benefits. In Orange Farm, South Africa, circumcised men were 76 percent less likely to become infected than uncircumcised men (Avert et al., 2011). Rollout of VMMC in Rakai, Uganda over roughly four years, was associated with a 37 percent reduction in HIV incidence compared to incidence in the same population over a three-year period before VMMC was introduced (Gray et al., 2012).

Drawing from the latest evidence regarding the effectiveness of VMMC, recent modeling indicates that achieving 80 percent VMMC coverage among men ages 15-49 in priority countries in sub-Saharan Africa will require roughly 20.3 million procedures from 2011 to 2015, as well as an additional 8.4 million procedures between 2016 to 2025 to maintain coverage (Njeuhmeli et al., 2011). Achieving this level of coverage by 2015 would avert 3.36 million new infections by 2025, or more than 20 percent of all new infections projected between now and 2025 (Njeuhmeli et al., 2011). Projected declines in HIV incidence through VMMC scale-up from 2011 to 2025 range from 9.2 percent in Tanzania to 41.7 percent in Zimbabwe (Njeuhmeli et al., 2011). Given slow progress in VMMC rollout to date, the 2015 target may not be feasible. It is imperative to act on the information in these models, setting and meeting targets with all due speed.

Cumulative Number and Percentage of HIV Infections Averted Between 2011 and 2025 by Scaling Up VMMC



Source: Njeuhmeli et al., 2011

In addition to preventing HIV transmission, VMMC also has other health benefits, such as reduced risk of other sexually transmitted infections (Avert et al., 2012; Wawer et al., 2011; Tarnaud et al., 2011; CDC, 2008; Weiss et al., 2006) as well as penile cancer (Larke et al., 2011; Daling et al., 2006). Overwhelming evidence suggests that VMMC is associated with no diminution of sexual satisfaction or function among either men or their female sex partners (Kogozi et al., 2009; Krieger et al., 2008; Kigozi et al., 2008; Senkul et al., 2004; Collins et al., 2002).¹ The rate of adverse events for VMMC is extremely low, with nearly all such problems resolved in time (Weiss et al., 2008).

1. An outlier in the body of evidence on the effects of VMMC on sexual performance is a 2006 study of 373 sexually active men that found that VMMC was associated with a reduction in masturbatory pleasure and sexual enjoyment (Kim & Pang, 2006).

A Unique Component of Combination HIV Prevention

The evidence is clear that VMMC constitutes an essential strategy of combination prevention, which in turn holds the key to minimizing the epidemic's future toll in sub-Saharan Africa. Offering substantial, albeit partial protection, VMMC needs to be used in combination with other prevention methods.² However, male circumcision has attributes that make it uniquely suitable as a cornerstone of prevention efforts in high-prevalence settings.

- **VMMC offers the opportunity to significantly reduce incidence of new infections among adults in high-prevalence sub-Saharan countries.** Multiple modeling exercises have demonstrated the potential to achieve significant reductions in HIV incidence through accelerated scale-up of VMMC. The results of theoretical modeling exercises have been confirmed by community-level data from Orange Farm, South Africa, where rollout of VMMC was associated with population-level reductions in HIV prevalence and incidence. Moreover, this impact will synergize with the prevention benefits of scaled-up combination prevention.
- **VMMC is a one-time intervention offering lifelong partial protection. Most prevention methods require consistent, ongoing adherence.** Using a clean needle during one instance of injection drug use will not protect against transmission from subsequent needle sharing, nor will using a condom at one point in time confer protection during a later episode of unprotected sex. And while antiretroviral therapy offers potent protection against ongoing transmission (Cohen et al., 2011), rigorous adherence is required to guard against the emergence of drug resistance, which may allow the virus to rebound (Sethi et al., 2003). By contrast, VMMC, a one-time intervention, obviates the adherence mandate, with available evidence suggesting lifelong partial protection for men who are circumcised. In Kisumu, Kenya, the site of a major clinical trial documenting the efficacy of VMMC for HIV prevention, follow-up on the study cohort has confirmed that the protective effect of VMMC is sustained over time (Bailey et al., 2010). Efforts to ensure that VMMC men adhere to safer sex and use other prevention tools are essential, but it is plain that the protective benefit from VMMC is durable.
- **VMMC is not only a highly cost-effective proven HIV prevention strategy, it actually saves money in the long run.** The direct cost of performing a procedure of VMMC ranges from US\$65.85 to US\$95.15 (Njeuhmeli et al., 2011), with an additional US\$60 per procedure required for system expenses such as supply chain and waste management (Edgil et al., 2011). For priority countries altogether, averting a single case of infection requires only nine male procedures, with ten or fewer procedures needed to prevent a case of HIV infection in ten countries (Njeuhmeli et al., 2011).

2. UNAIDS has identified voluntary medical male circumcision as one of six basic programmatic activities that warrant focused funding under its new HIV Investment Framework, which aims to optimize the efficiency and strategic impact of HIV responses (Schwartlander et al., 2011).



A provider greets clients waiting for VMMC services at Mafinga District Hospital in Iringa region, Tanzania. Credit: Jhpiego/MCHIP/Tanzania

- **This inexpensive, high-impact intervention will, if taken to scale, yield significant cost savings** (see Uthman et al., 2010; Galárraga et al., 2009; Gray et al., 2007; Kahn et al., 2006). Rapid scale-up of VMMC would result in substantial cost savings as a result of averted treatment and care costs; achieving 80 percent coverage by 2015 in high-prevalence countries would save an estimated US\$16.6 billion in health costs between 2011 and 2025 (Njeuhmeli et al., 2011). In Zimbabwe alone, it is projected that rapid scale-up would save US\$2.9 billion over the next four years (Njeuhmeli et al., 2011). Such estimates actually understate ultimate savings from VMMC, as they do not take into account those additional economic savings to societies, associated with labor and household productivity, such as those accrued by averting other STIs, or the non-monetary benefits of preserving families and communities.
- **VMMC is a powerful prevention tool for women as well as men.** Although the direct prevention benefit from VMMC is for men, women also have an enormous stake in VMMC scale-up. By reducing the number of newly-infected HIV positive men who are living with HIV, VMMC scale-up will result in concrete health benefits for their female sex partners (and, by extension, for their future offspring). In addition, VMMC reduces the risk that men will transmit other sexually transmitted infections, which further lowers women's risk of becoming infected with HIV (Wawer et al., 2011). According to mathematical modeling, by 2025 VMMC scale-up would avert as many infections in women as in men (Njeuhmeli et al., 2011). In some countries, such as Zimbabwe, the number of averted infections among women is projected to exceed the corresponding number among men by 2025 if 80 percent VMMC coverage is rapidly achieved and maintained (Njeuhmeli et al., 2011). VMMC programming also provides an opportunity for education and dialogue on gender roles, shared sexual decision-making and male involvement in HIV prevention—key issues to address as part of mitigating women's risk of HIV.

Progress to Date in Bringing Voluntary Medical Male Circumcision to Scale

Notwithstanding the enormous promise of VMMC for HIV prevention, only incremental progress has been achieved to date in bringing VMMC programs to scale. With an estimated 20.3 million procedures needed to reach 80 percent coverage among men ages 15 to 49, only about 1.5 million had been performed as of March 2012, according to information supplied by PEPFAR. This represents progress of about 8 percent toward the 80 percent target.

Coverage varies considerably among priority countries. While implementation of VMMC has barely begun in some countries—with coverage of 0.7 percent or lower in Lesotho, Malawi and Rwanda—other settings have achieved more promising results. In Nyanza Province, the sole region in Kenya where the majority of men were uncircumcised when scale-up began, coverage now exceeds 70 percent. Less marked, yet still important, gains have been reported in Swaziland, where coverage reached 21 percent as of March 2012.

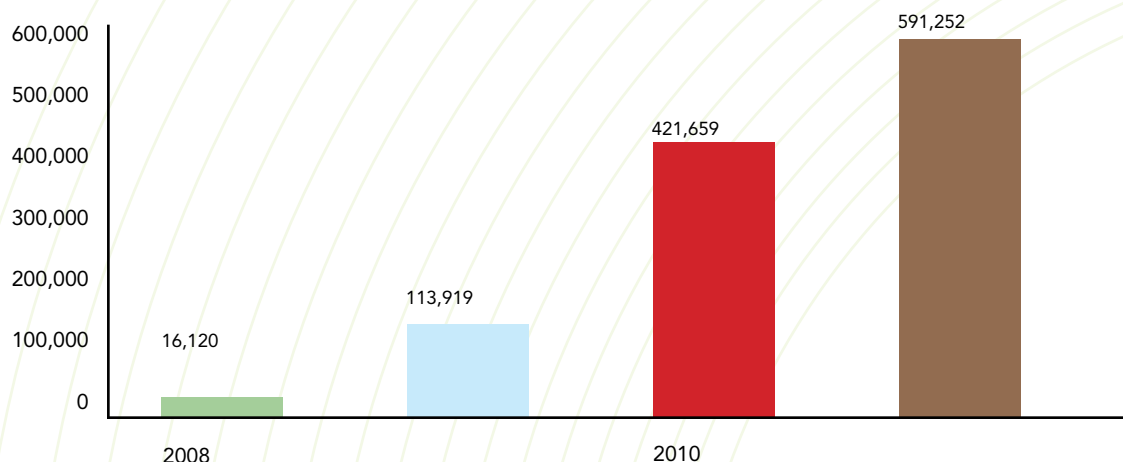
Status of VMMC Scale-up in Priority Countries		
Country	Target number of circumcisions to achieve 80% coverage	Progress toward 80% target as of March 2012
Botswana	345,244	6%
Ethiopia	40,000	38%
Lesotho	376,795	0.2%
Malawi	2,101,566	0.4%
Mozambique	1,059,104	4.7%
Namibia	330,218	1.5%
Kenya (Nyanza)	860,000	50%
Rwanda	1,746,052	0.7%
South Africa	4,333,134	7%
Swaziland	183,450	21%
Tanzania	1,373,271	12.7%
Uganda	4,245,184	4.8%
Zambia	1,949,292	11%
Zimbabwe	1,912,595	3%

Source: Njeuhmeli et al., 2011

Although overall progress has been disappointing, there are a number of encouraging signs. During the first ten months of 2011, more procedures were performed in priority countries than in 2008, 2009 and 2010 combined.

The scale-up trajectory has been especially steep in a number of countries, with a considerable quickening of the pace reported over the last two years. In Kenya, for example, while only 11,663 men underwent VMMC in 2008, roughly 220,000 procedures were performed in the first ten months of 2011. In Tanzania and Uganda, no VMMC procedures were reported for 2008, but 95,903 and 57,132 men underwent VMMC in these two countries, respectively, in 2011.

Medic Male Circumcisions Performed in Priority Countries by Year, 2008–2011



Source: Njeuhmeli et al., 2011

A Note on Country Statistics

PEPFAR has led efforts to collect up-to-date data from countries on VMMC scale-up, providing an essential service for the field. WHO and UNAIDS have also announced plans to collect data on an annual basis. However, challenges remain. National health service utilization data systems are weak in many countries, and the routine collection of data on VMMC is in its infancy, suggesting that figures on scale-up should be regarded as rough approximations. In particular, some countries reportedly include traditional male circumcisions in service utilization figures. However, in addition to safety concerns (see p. 24), traditional circumcision often involves somewhat minor cuts or removal of only a portion of the foreskin, whereas the clinical trials involved removal of the entire foreskin (see WHO, 2009). As discussed in this report, it is key to improve monitoring and evaluation of adverse events, risk behaviors, women's experiences, and overall numbers of procedures performed as part of VMMC scale-up.

Factors That Influence the Success of National Scale-Up Efforts

While recent progress in scaling up VMMC is encouraging, the pace of service expansion is clearly insufficient to achieve the goal of 80 percent coverage in 14 priority countries in the timeframe needed to optimize impact.. As with earlier efforts to expand access to antiretroviral therapy and prevention of mother-to-child transmission, which were extremely slow at the outset but ultimately gathered momentum in many countries, scale-up of VMMC needs to take into account available information on the factors that affect and impede success. Experience to date highlights several essential factors that will help determine whether countries achieve and maintain optimal coverage.

Political Leadership and Commitment

Efforts to scale up antiretroviral treatment and prevention of mother-to-child transmission have benefited from political support at global, regional and country levels. VMMC, by contrast, has until recently attracted limited attention and commitment, with front-page headlines from early trials giving way to minimal attention to this most cost-effective prevention strategy.

In the absence of strong political leadership, VMMC initiatives inevitably lag. In an era of stagnating funding for HIV, tough decisions do not always prioritize VMMC scale-up. Without the energetic encouragement of political and community leaders, it is impossible to make VMMC a social norm. And when national health systems are already overburdened with multiple health problems, health workers are unlikely to tackle the challenges associated with implementing VMMC unless there are political or economic incentives to do so.

Of late, encouraging signs of growing political commitment on VMMC have emerged. The U.S. government, for example, has pledged to reallocate PEPFAR resources to ensure support for at least 4.7 million VMMC procedures in 2012 and 2013. WHO, UNAIDS, PEPFAR, national health ministries and VMMC task forces, and other stakeholders have joined together to launch a new strategy to intensify joint action to accelerate VMMC scale-up (WHO/UNAIDS, 2011), although the absence of clearly defined annual milestones undermines the impact of this joint strategy.

“Strong collaboration between political, traditional and religious leadership will be critical to the safe and effective scale-up of [voluntary medical male circumcision] services.”

Festus Mogae
Former Botswana President
Addis Ababa, Dec. 5, 2011

Recommendations: Leadership and Commitment

- *National political leaders should provide vocal, visible and consistent support for expedited VMMC scale-up, actively exhorting their countrymen to undergo the procedure and positioning VMMC as a national social norm.*
- *Regional bodies should actively embrace the goal of 80 percent coverage in priority countries and promote accountability and South-South collaboration on VMMC scale-up. Key regional bodies that have potentially important roles to play in scale-up include the Southern Africa Development Community, the East African Community, and the African Union.*
- *VMMC scale-up should become a visible, high-priority item on the global political agenda, with visibility comparable to the global push to eliminate mother-to-child HIV transmission. In particular, VMMC should be highlighted and promoted in such global forums as the 2012 International AIDS Conference, periodic reviews of progress by the United Nations (i.e., UNGASS process), and the annual World Health Assembly.*
- *Civil society in priority countries should actively endorse and promote VMMC scale-up. Donors and international agencies should provide support for civil society advocacy on VMMC, and global civil society networks should also embrace the goal of achieving 80 percent VMMC coverage of men ages 15-49 in priority countries.*

National Ownership of the VMMC Agenda

The push to achieve 80 percent coverage in 14 priority countries in a timeframe that maximizes impact will require new social and cultural norms in many settings, as well as difficult decisions regarding resource allocation and relative prioritization of HIV strategies. Only strong and genuine national ownership of VMMC scale-up can address these challenges. Although the international community has an important stake in capturing the prevention potential of male circumcision, care needs to be taken to support national efforts and to avoid overriding national sentiment with donor preferences. As Kenya's experience indicates (see p. 16), the time taken to involve diverse national stakeholders is time well spent, enabling diverse national constituencies to move forward together in a common effort to promote VMMC as a new social norm.

Regional leaders are also speaking out. For example, the Champions for an HIV-Free Generation, a group of former African heads of government and thought leaders on the continent, has embraced the cause of VMMC scale-up and urged African leaders to take steps to promote the procedure. Through outreach from the Champions, African musicians in 2011 created a popular pro-VMMC song to be used in marketing and promotion efforts.

Although global and regional action is needed, the ultimate test of political commitment for VMMC scale-up will occur at national and local levels. In Kenya, strong political support from senior-most political leaders and from the leadership of the Ministry of Health played a critical role in the country's pioneering efforts to increase VMMC coverage.

Recently, a number of national leaders have stepped forward to endorse VMMC. In 2011, South African President Jacob Zuma announced plans for expedited scale-up of VMMC services. In Zimbabwe, President Robert Mugabe and vocal parliamentarians have similarly embraced VMMC scale-up. The number of procedures performed in the country has nearly quadrupled between 2010 (11,176) and the first ten months of 2011 (41,712). Swaziland has launched a national campaign to circumcise at least 80 percent of all men, with King Mswati III actively encouraging his countrymen to accept the procedure. Tanzanian political leaders also have expressed strong support for VMMC scale-up, while certain countries that previously lagged in embracing the approach, such as Botswana, took steps in 2011 to expedite service expansion.

The true reflection of political leadership is the willingness to make difficult decisions to elevate the priority and visibility of VMMC on the national agenda. In some countries that have formally endorsed VMMC for HIV prevention, national VMMC task forces seldom meet and the issue continues to garner little visibility or traction.

Presidents, prime ministers, health ministers and parliamentary leaders are only some of the individuals whose leadership is needed to spur greater progress on VMMC. Community leaders—such as religious leaders, elders of ethnic groups and other community gatekeepers—also have a pivotal role to play, an issue addressed in greater depth in the discussion of demand creation and of cultural considerations in VMMC scale-up.

Scaling up in Kenya: Proof that Rapid Success is Possible

Kenya demonstrates both the feasibility of rapid scale-up but also the critical elements of success. Since the country began implementing VMMC services for HIV prevention in 2008, it has performed more than 420,000 VMMCs. Most of these services have occurred in Nyanza Province, where the prevalence of male circumcision was 45 percent (compared with national prevalence of more than 80 percent).

Kenya's push to implement VMMC for HIV prevention benefited from strong political support—from the very top of the government, extending through the Ministry of Health (Mwandi et al., 2011). Especially influential was Prime Minister Raila Odinga, whose advocacy of VMMC proved persuasive to his fellow Luo tribesmen (personal communication, M. Stalker, 2011).

Strong political support for VMMC has translated into concrete policies and a strong oversight body: the national VMMC task force. Kenya has adopted recommended approaches to improve the efficiency of VMMC services, including dedicated sites for VMMC services, strategic configuration of surgical sites and approval of nurses to perform VMMC procedures.

Much of the action on VMMC has occurred at the provincial level. Nyanza Province formed its own VMMC task force to oversee implementation. Elders from the Luo ethnic group initially resisted VMMC scale-up. Respectful, persistent dialogue with these leaders convinced them that all services would be voluntary and that the procedures were intended to confer a medical benefit rather than alter cultural traditions.

Kenya has demonstrated considerable flexibility in its implementation of VMMC. In addition to providing VMMC in established sites, the country also undertakes an annual Rapid Results Initiative in Nyanza. This time-limited campaign, which coincides with school holidays, involves extensive promotional activities and results-oriented outreach to tens of thousands of men in a matter of weeks.

For a review of Kenya's experience, see Mwandi et al., 2011.



VMMC campaign advertisements from Uganda and Swaziland

Efficiency-Promoting Policies

In an era of flattening or declining HIV assistance, it is vital that all available funding for VMMC be used as efficiently as possible to reduce the burden on fragile health systems and accelerate progress toward 80 percent coverage.

In 2010, WHO published “Considerations for implementing models for optimizing the volume and efficiency of male circumcision services”. The purpose of this document was to outline various considerations and options for organizing VMMC surgical services so as to improve the efficiency and service volume while assuring a safe service of high quality. The document provides guidance to programme managers involved in setting up or strengthening VMMC services (WHO, 2010). It is projected that implementation of these measures would increase by four-fold the number of men undergoing the procedure in a given time period by a single surgical team (from 2,200 per year to 8,800 per year) (personal communication, E. Njeuhmeli, 2011). In dedicated VMMC settings in Tanzania, the monthly number of procedures performed rose from around 300 to more than 1,400 after MOVE (Models for Optimizing the Volume of Efficiency) of VMMC procedures were implemented (personal communication, E. Njeuhmeli, 2011).

Efficiency-promoting steps include use of optimal procedures to stop post-operative bleeding, use of validated surgical techniques that minimize time required for surgery, and strategic configuration of surgical settings and allocation of clinical staff (WHO, 2011). Given such dire shortages of human resources for health (WHO, 2011), VMMC scale-up requires innovative use of task sharing (i.e., peeling off key steps in the surgical process, enabling nurses to perform and preserve the precious time of surgeons for activities that demand enhanced medical skill) and task-shifting (i.e., wholesale delegation to the nurse to perform the entire procedure).

Several countries have taken steps to implement innovative human resource strategies. Zimbabwe, for example, has implemented task sharing, while Kenya and Tanzania allow trained nurses to perform procedures. Several countries, however, have yet to adopt formal policies on human resources for VMMC.

In addition, temporary redeployment of public-sector health staff during time-limited campaigns has proven successful, as has recruitment of new health graduates and recently retired health workers (Curran et al., 2011).



Woman outreach worker provides VMMC information in Njombe, Tanzania.
Credit: Jhpiego/MCHIP/Tanzania

Recommendations: Coordination

- *National governments should take steps to strengthen the functioning, visibility and capacity of national VMMC task forces.* These task forces should be ultimately responsible for overseeing the coordination, adaptation, implementation, monitoring and evaluation of national strategies for VMMC scale-up. Donors and international technical agencies should, where indicated and requested, provide support to build the capacity of national task forces.
- *Donors, international agencies, international NGOs and sub-national units should harmonize and align their activities with national operational plans.* Activities should be regularly reported to, and coordinated with, national VMMC task forces.

The Importance of Counseling on Sexual Behaviors in Delivery of VMMC

High-quality counseling constitutes a central component of service provision for VMMC. Clients need to be fully informed regarding the partial effectiveness of VMMC and counseled to avoid increasing sexual risk behavior, as risk compensation could potentially diminish or offset the public health impact of circumcision scale-up (Eaton & Kalichman, 2009; Cassell et al., 2006). Although the South Africa randomized controlled trial found some evidence of increase sexual activity among circumcised men (but no increase in the number of sex partners), the bulk of follow-up evidence has failed to detect risk compensation among men who have undergone VMMC as adults (Kong et al., 2011; Mattson et al., 2008; Agot et al., 2007). Given the potential negative impact of risk compensation and uncertainty regarding the validity of self-reported sexual behavior, intensified risk-reduction counseling needs to be complemented by robust, ongoing monitoring of reported sexual behaviors among recipients of VMMC services. These programs should ideally provide education and dialogue addressing broader issues of male sex and sexuality and gender roles, as these are fundamental to choices about sexual behavior. VMMC programs can play a unique role in fostering these conversations with healthy men who might otherwise be hard to reach through the health services.

In addition, clients require counseling on the need to abstain from sexual intercourse for at least six weeks following their procedure. For HIV-negative men, sexual abstinence during the healing period is necessary to avoid exposure to the virus, while HIV-positive men should refrain from sex in order to prevent transmission to their sex partners. One study in Kenya found that nearly one-third (31 percent) of men over age 18 resumed sexual activity within six weeks of being circumcised (Herman-Roloff et al., 2010). While premature resumption of sexual activity poses potential risks in individual cases, modeling exercises suggest that it is unlikely to meaningfully diminish the community-level protection for men (Hewett et al., 2011; UNAIDS/WHO/SACEMA Expert Group, 2009). However, the risk to women is highly sensitive to the prevalence of sexual activity during the healing period, as modeling indicates that VMMC would generate more new infections among women than are averted over one year if at least 30 percent of men resume sex within six weeks of their surgery (Hewett et al., 2011).

Demand Creation

As a relatively new prevention tool—and one that currently requires surgery as well as a departure from cultural norms in some settings—success of VMMC depends on demand for the procedure by adolescent and adult men. Several studies indicate that VMMC is widely acceptable in sub-Saharan Africa, among both sexually active men and their female partners (Wambura et al., 2011; Westercamp & Bailey, 2007; Lukobo & Bailey, 2007; Ngalande et al., 2006).

In the real world, however, demand to date appears to be mixed across priority countries. In some countries—such as Kenya, South Africa and Tanzania—robust demand has been reported (Mwandi et al., 2011; Lissouba et al., 2011; Bridges et al., 2011; Mahler et al., 2011). In Swaziland, by contrast, strong early demand in 2010 was followed by a decline in the number of men seeking VMMC in 2011. In some settings where early demand for the procedure has been observed, heaviest demand appears to be among teenagers rather than men in their 20s who are most likely to be sexually active and most likely to be at risk of HIV infection (see Mwandi et al., 2011).

Based on experience to date, experts in the field agree that demand creation should be regarded as an essential element of VMMC promotion. However, the optimal approach to demand creation remains the subject of some debate. Although media campaigns undoubtedly have a role to play in increasing awareness of VMMC services, evidence suggests that interpersonal communication is critical to service uptake. According to surveys, the support of family members, friends and sex partners is often central to a man's decision (Lissouba et al., 2011). In particular, women (mothers, spouses, girlfriends and friends) are often highly influential with respect to men contemplating VMMC (Obure et al., 2011). Experience in Kenya indicates that outreach programs are highly effective in building demand for VMMC services (Donnelly, 2011).

Regardless of the communication channel (e.g., mass media, interpersonal, community mobilization), it is important that programs select messages that have been evaluated for their impact and appeal, as well as their accuracy. In Kenya, emphasis on the HIV prevention benefits of VMMC played an important role in assuaging initial resistance of Luo tribal elders in the early stages of VMMC scale-up in Nyanza Province (personal communication, M. Stalker, 2011).³ Surveys in South Africa also suggest that the HIV-protective effect of VMMC is the most consistently resonant message across all ethnic groups (Bridges et al., 2011). However, there are also indications that some men are less motivated by HIV prevention than by the perceived benefits of VMMC with respect to personal hygiene, penile appearance, personal sexual satisfaction and the preferences of sex partners (Lissouba et al., 2011; Bridges et al., 2011).



A mass media campaign, organized by Sonke Gender Justice in South Africa, encourages men to undergo VMMC and stresses the importance of continued condom use and respectful, equitable relationships. Credit: Sonke Gender Justice Network

3. A majority of men in virtually all ethnic groups in Kenya are circumcised. A notable exception is among the Luo, who are concentrated in Western Kenya and comprise one of the country's largest ethnic groups.

Innovative Civil Society Engagement

Civil society engagement is critical to the success of virtually any public health campaign—and VMMC is no exception. Given the complexity of the messages, questions and concerns around this strategy which is both powerful and partially effective; directly beneficial to men, but indirectly (over the long term) to women, it is essential that civil society organizations and individuals be engaged as leaders and partners in implementation.

This can take many forms. Starting in 2008, women in East and Southern Africa initiated grassroots dialogues and evidence-gathering to document the impact of VMMC on their communities. This work stemmed from concerns that rollout of VMMC would shift resources from other interventions and have adverse effects on women's ability to negotiate condom use, sexual decision making and other issues. The Women's HIV Prevention Tracking (WHiPT) project (www.avac.org/whipt) was launched to both gather information on and respond to these concerns.

In Uganda, several civil society groups developed a coalition-based approach to document successes and gaps in service provision in 2010. This coalition included the Uganda Network of AIDS Service Organization, Mama's Club, the Health Rights Action Group and HEPS Uganda. Members of this coalition led civil society dialogues, pressured government officials to take action through the national VMMC task force, and laid out an agenda for further action. The work is detailed in their report *Male Circumcision: Too Little, Too Slow*, available at www.avac.org/toolittletooslow.

Launched in 2012, the pan-African campaign Africans Telling the Truth About VMMC (www.truthabout-vmmc.org) uses grassroots action and social-medial platform to define and amplify the views and concerns of Africans claiming the intervention as a tool that is African-researched, -led, -implemented and -chosen.

Recommendations: Community Engagement

- *Communities should embrace VMMC as an advocacy issue and request donors, national governments and VMMC delivery sites that allocate substantial resources to these activities. Civil society partners have a key role to play in education about VMMC and related issues, such as gender equality, domestic violence, the need to continue risk reduction via partner reduction and condom use and the importance of abstaining from sex until wound healing. In the context of resource-constrained service delivery, it is critical to work with community partners to create and share comprehensive messages that optimize the benefit of VMMC.*
- *National and local governments should work with community gatekeepers, including traditional and religious leaders, to implement inclusive community dialogues on VMMC for HIV prevention. It is critical to ensure that social, cultural and community leaders—including those engaged in traditional male circumcision rituals—are engaged as active partners in designing VMMC programs.*

Traditional and religious leaders often have an important effect on local demand for VMMC services. In Orange Farm, South Africa, ethnic group was strongly associated with men's intention to undergo VMMC (Lissouba et al., 2011). Surveys of community leaders have identified resistance to VMMC among traditionally circumcising tribes (WHO, 2009), although experience indicates that this need not function as a permanent obstacle to scale-up. In Kenya, for example, health officials, community activists and other stakeholders held repeated respectful discussions with Luo elders, emphasizing the medical purpose and voluntary nature of the intervention and eventually obtaining their support for program implementation (Mwandi et al., 2011). In Zimbabwe, leaders of some ethnic groups have agreed to integrate VMMC into traditional circumcision rituals.

Recommendations: Demand Creation

- *National governments, clinical sites, community leaders, international agencies and donors should collaborate on the formulation and implementation of operational research to inform demand-creation activities. Such research should investigate the reason why men do or do not access VMMC services, optimal messages and communications channels, and key message carriers to motivate VMMC uptake.*
- *Demand-creation activities should be adequately budgeted and regarded as an essential component of VMMC services.*
- *Demand-creation activities should focus particular efforts on reaching key stakeholder groups, including men in their 20s and 30s; women and girls; and traditional and religious leaders. As described above, these groups should be engaged as partners in communication and education.*

Resources

As a relatively inexpensive partially-effective intervention that need not be repeated for any single client, VMMC is not associated with extraordinary resource demands in comparison with more expensive biomedical tools, such as antiretroviral therapy or prevention of mother-to-child transmission (Schwartlander et al., 2011). Nevertheless, sufficient resources are needed to move from low-level implementation to rapid scale-up. Indeed, in countries such as Tanzania and Zimbabwe, where political support for VMMC is robust, national and non-governmental stakeholders report that lack of resources appears to be the primary impediment to immediate service expansion. It is estimated that US\$2 billion will be needed between 2011 and 2025 to achieve and maintain 80 percent VMMC coverage in priority countries (Njeuhmeli et al., 2011).

Quantifying the resource gap for VMMC remains something of a challenge, as reliable data are not available in all countries on amounts allocated toward VMMC services. It is essential for countries to develop costed plans and to quantify the resource gap, if any, that exists in meeting ambitious targets. Efforts to scale up VMMC will face the same challenges as many other prevention strategies, in terms of competition for scarce resources.

PEPFAR finances roughly 70 to 80 percent of VMMC currently performed for HIV prevention in priority countries (personal communication, E. Njuehmel, 2011). To achieve its target of supporting 4.7 million VMMC in 2012 and 2013, PEPFAR country programs will need to reallocate resources, directing funds from lower-priority interventions to VMMC and other high-priority strategies. Increased funding for PEPFAR would substantially strengthen efforts to scale up VMMC, although President Barack Obama has proposed to cut PEPFAR bilateral outlays by 11 percent in Fiscal Year 2011, a request that was still pending in Congress at the time of publication (Henry J. Kaiser Family Foundation, 2012).

Only three countries—Rwanda, South Africa and Tanzania—have requested and received approval for financing from the Global Fund for the delivery of VMMC services. Most priority countries, however, have not requested Global Fund support for VMMC services. With Round 11 cancelled, the Global Fund has invited countries to reprogram their grants to emphasize high-priority strategies such as VMMC.

In general, priority countries have failed to allocate domestic resources for VMMC scale-up. South Africa is an important exception, having budgeted US\$40 million for VMMC services, although provinces in the country are reportedly having varying levels of success in actually programming this money on the ground. Budget allocations that result in VMMC scale-up services is money well spent and an important indication of political commitment.

Recommendations: Resources

- *All priority countries should make meaningful domestic budget allocations for VMMC services.*
- *National governments should use their costed VMMC plans to determine national budget allocations and to mobilize resources from in-country donors to ensure that funding gaps are met. National governments quantifying their resource gaps should urge PEPFAR, the leading funder for circumcision scale-up, to ensure that needs are met. Where the resource needs have not been quantified, civil society should advocate for government to show leadership and donors to provide technical and financial assistance.*
- *Countries should prioritize VMMC scale-up in proposals to the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), and analyze country needs and priorities to ensure that existing funds are aligned with the GFATM's new strategy for iterative support to countries to maximize the public health impact of grant funding. The Global Fund Secretariat should provide technical support to countries to assist with rational reprogramming.*

Integrating VMMC with Other Services

Bi-directional linkages and referral mechanisms are needed both to maximize VMMC scale-up and to capture the ancillary benefits of these new services. VMMC programs provide an excellent platform for HIV counseling and testing, couples testing and counseling, and referral of HIV-positive men for follow-up treatment and care. They represent a key point of contact with men who might otherwise not seek health services. As such, there is a unique opportunity for engagement around male sex, sexuality, gender roles and shared sexual decision making. Community-based testing and counseling programs, prevention outreach and other health services should routinely inform male clients of the availability of VMMC services.

National Operational Plans

To achieve the ambitious target of 80 percentage coverage, countries need to develop and adhere to clear, time-bound plans for scale-up. Detailed, costed operational plans can unite all stakeholders in a common endeavor and increase accountability for results. Ideally, national plans should specify delivery modes for VMMC services, quantify needs for financial and human resources, and establish annual coverage targets. If such information is not readily available, the national plan can specify the steps needed to obtain it. Such plans also serve as excellent platforms for mobilizing the resources needed to reach national scale-up targets.

Several countries still lack detailed, costed national operational plans for VMMC (Dickson et al., 2011). Zambia is currently working to develop its operational plan, with expectation of launching it by the end of 2012.

Many countries lack the capacity to develop operational plans on their own. Donors and international agencies can help national processes by supplying needed technical support and compensating for limited national capacity. PEPFAR and the Bill & Melinda Gates Foundation have provided financial and technical support for the development of detailed national operational plans, and WHO also has expressed its readiness to provide technical support. The Global Fund has invited countries to consider reprogramming their grants to prioritize high-impact, high-value interventions such as VMMC, but additional efforts are needed (either through the Global Fund itself or through its technical partners) to deliver needed support to facilitate recommended reprogramming.

Operational plans need to specify the modes of delivery for VMMC and provide clear guidance on the relative prioritization of delivery options. In most countries, it will be neither feasible nor wise to adopt only one delivery strategy, given the diverse needs of clients. In developing operational plans, countries should weigh the relative benefits off different delivery options, including dedicated, stand-alone sites; mobile services; time-limited national or local campaigns; and integration of VMMC into mainstream health facilities. With the support of international technical experts, countries should determine the mix of delivery strategies that will permit the most efficient and expedited scale-up of services.

Delivery approaches should be tailored to local conditions. For working adults, for example, programs should consider flexible service hours (e.g., weekend, evening) and outreach to employers to ensure that workers are not at risk of termination or loss of pay for accessing VMMC services. Especially in rural and semi-urban areas, programs should take steps to address clients' transportation needs.



VMMC provider at Usokami Health Center in Njombe district, Tanzania.
Credit: Jhpiego/MCHIP/Tanzania

Ensuring the Safety of VMMC Services

In randomized controlled trials, the incidence of adverse events has been extremely low. As services are scaled up nationally, a continued focus on safety remains essential. All providers of VMMC services should complete rigorous training in safe VMMC procedures, and all service sites should ensure workers' access to universal precautions and make arrangements for the safe disposal of medical waste.

Safety considerations justify concerted efforts to encourage communities to either transition from traditional to medical circumcision or to incorporate VMMC into traditional rituals. In one study in Kenya, the rate of adverse events was found to be 25 percent for traditional circumcision but only 1.7 percent for VMMC (Bailey et al., 2008). Other studies have detected even higher complication rates for individuals undergoing traditional circumcision (Wilcken et al., 2010).

Operational plans should specify mechanisms for coordination of effort by multiple stakeholders. In some countries, more than a dozen different providers are currently engaged in the delivery of VMMC services. Depending on the setting, such services are often funded by multiple donors, with varying protocols governing routine reporting and service delivery. Coordination of diverse partners has proven challenging in many countries.

Effective coordination of partners is essential to national ownership, programmatic efficiency and accountability for results. Donors, international agencies, international and local NGOs, and sub-national units need to harmonize and align their efforts, establishing clear, detailed national operational plans and participating appropriately in national coordinating bodies for VMMC.

Recommendations: Country Implementation

- *All countries should have in place by the end of 2012 a detailed, costed, timeline-driven operational plan for circumcision scale-up.* Donors, international technical agencies, and international NGOs should provide requested support to countries that currently lack an operational plan or that need to update their existing plan.
- *Countries should establish and publicize annual scale-up targets for VMMC.* Ambitious annual gains should build toward the ultimate goal of 80 percentage coverage.
- *Diverse, adaptable delivery strategies should be pursued toward the goal of 80 percent.* Based on national circumstances, countries should consider a combination of delivery strategies, including stand-alone, dedicated sites; mobile services; time-limited campaigns; and integration of male circumcision into mainstream health care delivery sites.
- *Countries should adopt a comprehensive policy framework to accelerate progress toward 80 percentage coverage.* Formal policies should provide for task shifting and task sharing, infection control and waste management, and strategic configuration of clinical sites and surgical teams to promote efficiency. Policies should also mandate and guide needed education and counseling for circumcision clients.

Monitoring and Evaluation

At national, regional and global levels, effective scale-up depends on the availability of timely and accurate data. Currently, however, strategic information on circumcision scale-up is exceedingly scarce. Although the Male Circumcision Clearinghouse (malecircumcision.org) serves as an excellent resource for certain VMMC-related information, there is a disturbing lack of clarity regarding mechanisms and responsibilities for tracking service utilization, differentiating between medical and traditional circumcisions in monitoring implementation, and tracking implementation of recommended policies and practices across priority countries. As a result, well-intentioned decision-makers engaged in VMMC scale-up are forced to base their approaches on anecdote rather than hard evidence.

International partners should provide requested assistance to strengthen national capacity for monitoring and evaluation, including adverse event surveillance systems. All partners involved in the provision of VMMC services should make timely and reliable reports to national authorities.

As part of the joint circumcision strategy involving priority countries and international partners, a working group is being formed in 2012 to agree on standardized indicators and reporting protocols for VMMC scale-up. WHO and UNAIDS have indicated that the two agencies will provide annual reports of progress toward agreed targets, and PEPFAR will report regularly on progress toward achievement of its goal of supporting 4.7 million procedures in 2012 and 2013. VMMC data should also be collected in the biennial UNGASS reporting on targets set by the UN General Special Session on HIV/AIDS.

Recommendations: Monitoring and Evaluation

- *Countries, donors, international agencies and other stakeholders should develop a set of core, standardized indicators to guide monitoring and evaluation efforts for VMMC scale-up. Countries should have the leeway to adapt indicators to national conditions and reporting structures, preserving in all instances the ability to provide regionally comparable reporting on core indicators.*
- *Donors, international agencies and international NGOs should take steps to harmonize and align their program reporting protocols and systems based on standardized indicators and national reporting structures.*
- *Individual countries, regional bodies and the global community (through WHO and UNAIDS) should issue annual reports on progress toward the goal of 80 percentage coverage by 2015. These reports should identify lessons learned, including best practices and implementation bottlenecks.*
- *All countries should implement routine, standardized, comprehensive reporting of adverse events relating to VMMC services. Donors, international agencies and international NGOs should provide countries with financial and technical support to build adverse-event surveillance systems.*

A New Frontier: Innovative Devices to Accelerate Circumcision Scale-Up

The world is on the cusp of a major advance—the availability of one or more innovative devices that have the potential to reduce impediments to VMMC uptake and significantly accelerate scale-up. By simplifying the procedure and precluding the need for sutures, these new devices might persuade many men who currently have reservations about VMMC to come forward to receive services. And by minimizing the need for surgical expertise in performing procedures, the new experimental tools could sidestep important human resource challenges and expedite scale-up.

PrePex has been championed by the Rwandan government, which envisions the device as the mainstay of national circumcision scale-up. Manufactured by a company incorporated in the British Virgin Islands, PrePex is a disposable device that uses two rings to compress the foreskin, cutting off blood circulation to the foreskin and allowing its bloodless removal after several days. PrePex obviates not only the need for sutures but for any cutting of live tissue at all, as the foreskin is left in place to desiccate and is removed at the same time as the device. A study in Rwanda indicates that PrePex is safe, effective and suitable for use in mass circumcision programs (Bitega et al., 2011).



The Shang Ring, made by a Chinese manufacturer, is a disposable device available in 22 sizes and can be used in males of all ages, from neonatal to adult. The device is comprised of two rings that compress the foreskin, minimize bleeding, and eliminate the need for sutures. The use of the Shang Ring reduces procedure time and requires less surgical skill than surgical VMMC procedures that are currently used. Studies suggest that the Shang Ring is safe and acceptable (Barone et al., 2011; Barone et al., 2012).



PrePex and Shang Ring, novel devices to eliminate the need for sutures

Studies to confirm the results of early evaluations of PrePex and Shang Ring are currently ongoing. Because these innovative devices may allow VMMC to be performed more quickly and require less skill, they have the potential to spur swifter progress toward ambitious coverage goals that may be difficult to achieve through relying solely on surgical procedures (McIntyre, 2011). By eliminating the need for sutures—and, in the case of PrePex, for any surgical cutting of vital tissue—these novel devices are likely to increase acceptance of VMMC and help generate more robust demand for services. Because they speed the procedure, their use may also result in cost savings.

Because most countries in sub-Saharan Africa have limited national regulatory capacity, they typically look to WHO for certification and prequalification of new medical devices for widespread use in public health programs. WHO has specified the clinical data needed for consideration of such devices, which includes a field study, a study comparing the device to surgery and evidence of efficacy from at least two countries (WHO, 2012). The agency does not recommend products by their brand name. It has however advised the Rwandan government that an elastic ring-controlled radial compression device for adult VMMC can be used in men ages 18 years and over when placed by appropriately trained physicians and nurses, with active surveillance of adverse events for the first 1,000 patients (WHO, 2012). Studies are currently underway in Zimbabwe to obtain required clinical data from a second country.

WHO Prequalification Process

WHO's prequalification process involves a scientific assessment, which includes a review of existing data, consistent testing or performance evaluation, and site visits to manufacturers. The purpose of this process is to ensure that diagnostics, medicines, vaccines and immunization-related equipment and devices for high-burden diseases meet global standards of quality, safety and efficacy. Low- and middle-income countries that lack robust national drug regulatory infrastructure typically look to WHO prequalification decisions for guidance on whether to integrate innovative new tools into national health guidelines. Entities like UNICEF, the Global Alliance for Vaccines and Immunization, the Global Fund and many others use WHO prequalification to guide decisions about purchasing. If one or more male circumcision devices were to receive WHO prequalification, it would open up the possibility of large-scale procurement and rollout of devices as part of the global strategy for scaling up voluntary medical male circumcision.

Due to the urgent need for accelerated VMMC scale-up, WHO has committed to expedited review of available data in 2012. The earliest that WHO might issue a global recommendation for a suture-free VMMC device is late 2012. In the meantime, pilot introductory studies are needed to prepare for rapid implementation of such devices in VMMC programs if and when they are prequalified by WHO.

The potential impact of new devices, were they to be prequalified by WHO, would depend on several factors. While the manufacturer of PrePex has asserted that the device would be less costly than the surgical procedure, the company has yet to assign a specific cost to the device, although press reports have suggested that per-unit costs could be comparable to per-patient costs for surgery (McNeil, 2012). Countries will require clear, timely advice from WHO on how best to introduce new tools, and additional funding will be required to ensure that these new tools accelerate efforts to bring VMMC to scale.

Recommendations: Innovative Devices

- *Data from ongoing efficacy studies on non-surgical devices for VMMC (the Shang Ring and PrePex are two such devices under evaluation) should be analyzed without delay and used to guide normative agency recommendations with broad applicability by mid-2013. Gaps left by current research, including operations research and additional confirmatory studies should be clearly defined and filled in a strategic, coordinated manner. Donors and international agencies should provide appropriate technical and financial support to ensure timely implementation, completion and analysis of these studies.*
- *Decision-making tools should be developed to help priority countries evaluate the suitability and relevance of new devices. These tools should be in place by mid-2013. WHO should ensure that regional and national consultations are held to begin implementing these tools and analyze results.*
- *All countries seeking program efficiencies should investigate the feasibility of implementing new devices and make ambitious implementation plans accordingly. WHO and UNAIDS should provide technical support for the development of national rollout plans.*

Conclusion: The Time for Action

Scaling up of voluntary medical male circumcision in priority countries is essential to having a sustained impact on the AIDS epidemic. As with many of the components of combination prevention that are currently available, including treatment as prevention and prevention of pediatric infection, VMMC can be implemented today. Delays in implementation at ambitious scale will cost dearly—in terms of lives, new infections and resources that could otherwise be freed up in the context of declining HIV incidence. The authors of this report are committed to advocating for change based on the key recommendations framed in the *Call to Action* (p. 1 and throughout the document) and we will track progress on these activities on an annual basis. We urge all stakeholders to act on the evidence and join in this essential advocacy effort.

The time for action is now.



Collaboration of VMMC with traditionally circumcising communities in Southern Zimbabwe. Credit: Eric Gauss/PSI/Zimbabwe

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AVAC: Global Advocacy for HIV Prevention

www.avac.org

Founded in 1995, AVAC is a non-profit organization that uses education, policy analysis, advocacy and a network of global collaborations to accelerate the ethical development and global delivery of AIDS vaccines, voluntary medical male circumcision, microbicides, PrEP and other emerging HIV prevention options as part of a comprehensive response to the pandemic.

National Empowerment Network of People Living With HIV/AIDS in Kenya

www.nephak.org

NEPHAK's mission is to promote greater involvement of people living with HIV/AIDS (GIPA) in the national response to HIV/AIDS in Kenya. It envisions a nation where people living with HIV are on the frontline in the fight against HIV/AIDS and TB and where their rights are recognized and respected to support their meaningful involvement in TB and HIV/AIDS prevention, treatment, care and support towards an AIDS and TB free society.

Sonke Gender Justice Network

www.genderjustice.org.za

Founded in 2006, the Sonke Gender Justice Network is a South African-based NGO that works across Africa to strengthen government, civil society and citizen capacity to support men and boys in taking action to promote gender equality, prevent domestic and sexual violence, and reduce the spread and impact of HIV and AIDS.

Uganda Network of AIDS Service Organizations

www.unaso.or.ug

Founded in 1996, UNASO is a network organization that exists to provide coordination, representation and networking among civil society AIDS Service Organizations (ASOs) for enhanced quality HIV and AIDS service delivery. UNASO membership strength to date is over 2000 organizations and has facilitated the establishment of 50 district networks in Uganda.

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The Clearinghouse on Male Circumcision for HIV Prevention

www.malecircumcision.org

The Clearinghouse exists to expand global access to information and resources on male circumcision for HIV prevention. Initiated by WHO, UNAIDS, AVAC and FHI 360, it aims to provide current evidence-based guidance, information and resources to support the delivery of safe male circumcision services in countries scaling up male circumcision as one component of comprehensive HIV prevention services.

Africans Telling the Truth About VMMC

www.truthaboutvmmc.org

This is a growing network of African scientists, advocates and others, supporting the acceleration of VMMC in Africa. Members reaffirm the fact that VMMC is an African-led initiative with strong, consistent and undeniable evidence that VMMC is one of the best HIV prevention interventions available today.

A JOINT REPORT FROM
AVAC, NATIONAL EMPOWERMENT NETWORK OF PEOPLE LIVING WITH HIV/AIDS IN KENYA,
SONKE GENDER JUSTICE NETWORK AND UGANDA NETWORK OF AIDS SERVICE ORGANIZATIONS

