

REVIEW ARTICLE



A review of public health, social and ethical implications of voluntary medical male circumcision programs for HIV prevention in sub-Saharan Africa

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Ideally, the benefits of public health interventions should outweigh any associated harms, burdens, and adverse unintended consequences. The intended benefit of voluntary medical male circumcision (VMMC) programs in eastern and southern Africa (ESA) is the reduction of HIV infections. We review the literature for evidence of reductions in HIV incidence, evaluate the extent to which decreases in HIV incidence can be reasonably attributed to VMMC programs, and summarize social harms and ethical concerns associated with these programs. Review findings suggest that HIV incidence had been declining across ESA since before the large-scale rollout of VMMC as a public health intervention, and that this decline may be due to the combined effects of HIV prevention and treatment interventions, such as expanded antiretroviral therapy. The independent effect of VMMC programs in reducing HIV infections at the population level remains unknown. On the other hand, VMMC-associated evidence is increasing for the existence of negative social impacts such as stigmatization and/or discrimination, and ethically problematic practices, including lack of informed consent. We conclude that the relationship between the benefits and burdens of VMMC programs may be more unfavorable than what has been commonly suggested by proponents of global VMMC campaigns.

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INTRODUCTION

In 2007, the World Health Organization (WHO) and Joint United Nations Program on HIV/AIDS (UNAIDS) recommended voluntary medical male circumcision (VMMC) be offered as part of a comprehensive package of HIV prevention interventions in high prevalence settings, particularly in eastern and southern Africa (ESA) [1]. The recommendation was based on results from three randomized controlled trials (RCTs) conducted during the early to mid-2000s in Kenya, South Africa, and Uganda which showed reductions of 50–60% in the risk of female-to-male transmission of HIV among circumcised men compared with non-circumcised men [2–4]. In addition to medical male circumcision, WHO and UNAIDS recommended that the comprehensive HIV prevention package include safer sex education, condom education and provision, HIV testing, linkage to care and treatment if found positive, and management of sexually transmitted infections (STIs) [1]. Currently, 15 ESA countries are targeted as priorities for VMMC programs (Botswana, Eswatini, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Namibia, Rwanda, South Africa, South Sudan, Uganda, Tanzania, Zambia, and Zimbabwe) [5].

The goal of the rapid and urgent scale-up of VMMC programs in these 15 priority ESA countries was to reduce HIV infections in sub-Saharan Africa [1]. In this paper, we review the literature for evidence that VMMC has led to realized reductions in HIV incidence. We also evaluate the extent to which decreases in

HIV incidence can be attributed to VMMC versus other interventions (e.g., antiretroviral therapy [ART]). Additionally, we summarize findings of the societal “side-effects” of VMMC, as well as the main ethical challenges associated with these programs.

Previous reviews have focused on the barriers and facilitators of VMMC uptake to inform the development of effective interventions to increase service uptake [6], analyzed the effectiveness of economic compensation and incentives to increase VMMC uptake among older men to inform VMMC demand creation programs [7], and synthesized the evidence on best practices for the delivery of adolescent VMMC services [8]. Our paper builds on a recent review [9], which examined the impact of circumcision on the risk of HIV infection among heterosexual men in varying epidemic contexts, including men in high HIV incidence cohorts, community-based cohorts with stable circumcision prevalence, and community-based cohorts during VMMC scale-up. In this paper, we provide a ‘contextual’ or ‘realistic’ evaluation of VMMC programs in ESA priority countries that takes a balanced approach in considering the benefits and harms of the public health intervention. This is in keeping with recent recommendations for program evaluation to examine a range of factors, including those that are external to program intentions and activities, that may have contributed to the outcome. Failure to do so may misleadingly magnify the contribution of the program to the intended outcome [10, 11].

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METHODS

We conducted systematic and non-systematic searches, including gray literature, to identify publications to include in our review. We divided our review of the literature into four sections as follows: Evidence of HIV infections decreasing in the priority ESA countries; role of VMMC in reductions in HIV incidence; The unintended consequences of VMMC as a public health intervention in ESA; Main ethical dimensions of VMMC programs. For the section on the evidence of reductions in HIV incidence, we used epidemiological reports from UNAIDS and the Global Burden of Diseases, Injuries, and Risk Factors (GBD) Study. For the section on the role of VMMC in reducing HIV incidence, we used UNAIDS data and relevant peer-reviewed papers in the published literature. The peer-reviewed papers were obtained through literature searches in PubMed and EBSCOHOST for VMMC-related studies conducted in the 15 ESA priority countries. EBSCOHost included the databases Biomedical Reference Collection: Corporate; E-Journals; GreenFILE; Library, Information Science & Technology Abstracts; MEDLINE Complete; APA PsycArticles; Psychology and Behavioral Sciences Collection; APA PsycInfo; and SocINDEX with Full Text. Our searches were conducted in December 2020 and limited to articles published in English between 2009 and 2020. We excluded studies published in 2008 or earlier because those would have probably used studies/data prior to VMMC being implemented as policy and therefore would not tell us whether reductions in HIV incidence observed in priority countries can be attributed to the VMMC campaign. We retained five articles from longitudinal studies that contained primary data on HIV incidence in heterosexual men by circumcision status.

For the sections on the unintended consequences of VMMC and ethical considerations, we conducted a review of publications with findings suggesting potential harms associated with program implementation. To capture social science literature related to VMMC programs, we made searches of PubMed and Google Scholar over the period of 2005–2021 using relevant search terms in addition to the research databases we have from working for 14 years in the field. Additional studies were identified by reviewing articles' bibliography sections.

Review of the evidence

Evidence of HIV infections decreasing in the priority ESA countries. Overall, although trajectories differ across countries, HIV incidence in sub-Saharan Africa peaked in 1997 and has since trended downward [12]. Until 2007, infection rates decreased in most of sub-Saharan Africa, including among (at the time) nine priority ESA countries, while rates increased in eSwatini, Lesotho, Mozambique, Namibia, South Africa, and South Sudan (see Table 1) [13]. By 2017, rates of new infections were declining in all 15 priority countries, although at slower rates in Ethiopia, Kenya, Tanzania, and Zimbabwe [13]. These trends are supported by data from UNAIDS which show declines in HIV incidence trajectories between 2000 and 2019 in almost all the priority countries. Between 2010 and 2019, new infections decreased in almost all priority countries, except South Sudan, by 15–66% (see Table 1) [14]. In South Sudan, although rates of new infections declined between 2007 and 2017, the data suggest an overall 17% increase of new HIV cases in the country since 2010.

Although new HIV infections have remained consistently higher among women than men in sub-Saharan Africa, UNAIDS data show that new infections among both groups have been declining since 2000 [14]. Data from almost all the priority ESA countries show declines in new HIV infections among women and men between 2010 and 2019. The exception is South Sudan, where HIV incidence among women and men increased during that period [14].

Role of VMMC in reductions in HIV incidence

The roll-out of VMMC programs began in 2008 in five priority countries: eSwatini, Kenya, Malawi, South Africa, and Zambia (see

Table 1. Change in new HIV infections in the priority ESA countries.

Country	Annualized rate of change in new infections (95% uncertainty interval) ^a		Change in new HIV infections since 2010 ^b
	1990–2007	2007–2017	
Botswana	–3.1% (–4.5 to –1.8)	–5.3% (–9.1 to –1.7)	–34%
eSwatini	14.2% (8.5–19.5)	–21.8% (–36.1 to –15.1)	–66%
Ethiopia	–18.9% (–21.5 to –16.3)	–1.3% (–7.6 to 4.1)	–46%
Kenya	–6.1% (–7.5 to –4.8)	–3.5% (–6.3 to –0.5)	–44%
Lesotho	2.8% (1.1–4.5)	–7.1% (–10.7 to –4.4)	–45%
Malawi	–7.0% (–8.5 to –5.5)	–10.8% (–18.9 to –5.3)	–41%
Mozambique	5.4% (3.5–7.5)	–5.2% (–9.5 to –1.7)	–17%
Namibia	2.4% (0.8–5.1)	–5.8% (–10.8 to –1.2)	–36%
Rwanda	–6.1% (–9.3 to –2.1)	–7.2% (–11.7 to –2.5)	–47%
South Africa	12.8% (11.3–14.2)	–5.7% (–7.9 to –3.8)	–53%
South Sudan	0.2% (–5.4 to 9.5)	–5.7% (–15.6 to –2.9)	17%
Tanzania	–8.3% (–10.8 to –6.0)	–6.6% (–41.9 to 7.7)	–19%
Uganda	–3.8% (–7.7 to 0.2)	–11.4% (–35.9 to 2.5)	–43%
Zambia	–5.4% (–6.7 to –4.2)	–8.3% (–12.2 to –4.2)	–15%
Zimbabwe	–8.5% (–11.0 to –6.3)	–3.0% (–40.1 to 7.9)	–44%
Sub-Saharan Africa	–2.8% (–3.8 to –1.9)	–5.9% (–8.2 to –3.6)	
Global	–0.4% (–1.2 to 0.3)	–3.0% (–4.5 to –1.5)	

Sources: ^aGBD 2017 and ^bUNAIDS 2020.

Table 2) [5]. By 2012, the number of priority countries implementing VMMC programs had increased to 14. South Sudan was included in 2018 as the 15th priority country.

The success of VMMC programs among the 15 priority countries is typically presented in terms of the numbers of males medically circumcised, prevalence or coverage of VMMC, and new HIV cases averted. Between 2008 and 2018, an estimated 22.6 million men were medically circumcised in the 15 priority ESA countries [5]. By 2018, South Africa, Uganda, Tanzania, and Zambia had each circumcised over two million males. During the same period, Kenya, Mozambique, Rwanda, and Zimbabwe each circumcised between one to two million males. The remaining countries had each circumcised less than one million males (see Table 2).

In 2011, UNAIDS and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) set a target goal of at least 80% VMMC

Table 2. Yearly country performance of voluntary medical male circumcisions in 15 priority countries from eastern and southern Africa: 2008–2018.

	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	Total 2016–2018	Total 2008–2018
Botswana	-	5,424	5,773	14,661	38,005	46,793	30,033	15,722	24,042	19,756	24,207	68,005	224,416
Eswatini	1,110	4,336	18,869	13,791	9,977	10,105	12,289	12,952	17,374	18,138	14,316	49,828	133,257
Ethiopia*	-	769	2,689	7,542	11,961	16,393	11,831	9,744	10,306	15,789	23,009	49,104	110,033
Kenya	11,663	80,719	139,905	159,196	151,517	190,580	193,576	207,014	219,086	233,879	286,899	739,864	1,874,034
Lesotho	-	-	-	-	10,835	37,655	36,245	25,966	34,157	25,150	26,448	85,755	196,456
Malawi	589	1,234	1,296	11,881	21,250	40,835	80,419	108,672	129,975	166,350	199,399	495,724	761,900
Mozambique	-	100	7,633	29,592	135,000	146,046	240,507	198,340	253,079	315,380	311,891	880,350	1,637,568
Namibia	-	224	1,763	6,123	4,863	1,182	4,165	17,388	27,340	30,134	34,942	92,416	128,124
Rwanda	-	-	1,694	25,000	138,711	116,029	173,191	138,216	137,218	264,973	327,904	730,095	1,322,936
South Africa	5,190	9,168	131,117	296,726	422,009	514,991	482,474	485,552	497,186	511,191	572,442	1,580,819	3,928,046
South Sudan**	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	1,147	1,147	1,147
Uganda	-	-	21,072	77,756	368,490	801,678	878,109	556,546	411,459	847,633	619,082	1,878,174	4,581,825
United Republic of Tanzania	-	1,033	18,026	120,261	183,480	329,729	573,845	435,302	548,390	730,435	885,599	2,164,424	3,826,100
Zambia	2,758	17,180	61,911	85,151	173,992	294,466	315,168	222,481	311,792	483,816	482,183	1,277,791	2,450,898
Zimbabwe	-	2,801	11,176	36,603	40,755	112,084	209,125	188,732	205,784	301,366	326,012	833,162	1,434,438
TOTAL	21,310	122,988	422,924	884,283	1,710,845	2,658,566	3,240,977	2,622,627	2,827,188	3,963,990	4,135,480	10,926,658	22,611,178

Source: 2019 Global AIDS Monitoring.

*In Ethiopia, implementation of VMMC is in the Gambela region.

**South Sudan has only recently initiated a pilot VMMC program, and its data were reported for the first time in 2018.

prevalence or coverage among males aged 15–49 years in the priority countries [1]. Evidence indicates that by 2017, only three priority countries (Ethiopia, Kenya, and Tanzania) had achieved the 80% coverage goal at the national level; all other priority countries had not achieved the goal [15]. In 2014, priority countries, including Kenya, started providing VMMC to boys as young as 10 years old [16]. Since then, a large proportion of VMMCs has been conducted among males under the age of 15 years [17]. However, WHO guidance no longer prioritizes this age group due to concerns about safety and informed consent [18].

Based on epidemiological modeling studies, it was expected that the 22.6 million circumcisions performed in ESA priority countries would potentially avert about 250,000 new HIV infections; 78% among men and 22% among women [5]. These estimates suggest that VMMC has a significant role in reducing HIV incidence in priority ESA countries. However, estimates of the impact of VMMC on HIV incidence have declined over time as technical aspects and assumptions of the models have changed, underscoring the limitations of basing key policy decisions on modeling studies [19, 20]. For example, early models incorrectly assumed uniform uptake of VMMC among males of different age groups and a steady or gradual decline in HIV incidence in priority ESA countries. Also, the early models did not account for the impact of the expanding use of ART and pre-exposure prophylaxis (PrEP) on HIV incidence [19]. Limitations of modeling studies continue to be identified in recent publications with attendant declines in the estimated effect of VMMC on HIV incidence [21].

As summarized above, surveillance data indicate that HIV incidence was declining in most of the priority ESA countries before the large-scale rollout of VMMC began [12–14]. Moreover, these data provide no evidence of substantial changes in the downward trending trajectories of HIV incidence to support the argument that VMMC has had a significant role in reducing HIV infections in priority countries. Although a recent systematic review and meta-analysis concluded that VMMC is “an important evidence-based intervention for the control of generalized HIV epidemics”, [9] as presented below, we did not find convincing evidence that VMMC has had a significant effect on reducing HIV incidence at the population level.

Two population-based prospective studies in Uganda [22] and South Africa [23] assessed the impact of combination interventions on HIV incidence. Findings from both studies indicate that ART use, viral load suppression, and VMMC coverage all increased in the study settings over their respective research periods. HIV prevalence and incidence also decreased in both settings among men and women (see Table 3). Additionally, regression analysis using data from Uganda found that male circumcision was associated with decreased HIV incidence among men [22]. Another study to assess the impact of VMMC on male HIV risk in Uganda also found that male circumcision was associated with a lower risk of incident HIV infection [24]. However, although reductions are larger among men who are circumcised, study findings indicate that HIV incidence rates are also declining among men who are non-circumcised [23, 24]. While the reductions in HIV incidence among women and non-circumcised men may be due to indirect protection afforded by VMMC (i.e., circumcised men not acquiring and transmitting HIV), it is also possible that other factors (e.g., expanded ART coverage) may be contributing to the reduction of new HIV cases in the priority countries.

Borgdorff et al. [25] used data from a health and demographic surveillance system (HDSS) in Kenya to determine trends in HIV prevalence and incidence between 2011 and 2016. They found that, overall, HIV incidence declined over the surveillance period. They also found that while having a circumcised male partner was protective for women and girls, the protective effect of circumcision was not significant for incident HIV infection among men and boys. Borgdorff et al. [25] concluded that “the decline of HIV

Table 3. Summary of findings from studies examining the effectiveness of VMMC and ART in reducing HIV incidence.

First author (year)/study purpose	Country/ study period	Research design/sample	Results
Kagaayi et al. (2019) [22] To assess the impact of combination HIV interventions on HIV incidence in four HIV-hyperendemic communities.	Uganda 2011–2017	Open population-based prospective cohort study Males and females aged 15–49 years N = 8942 (52% male)	<p>↑ ART use from 16% at baseline to 82% at final survey.</p> <p>↑ Population viral load suppression among HIV+ from 34% at baseline to 80% at final survey.</p> <p>↑ Male circumcision coverage from 35% at baseline to 65% at final survey.</p> <p>↓ HIV prevalence from 41% at baseline to 37% at final survey.</p> <p>↓ HIV incidence from 3.43 per 100 person-years (95% CI, 2.45–4.67) at baseline to 1.59 per 100 person-years (95% CI, 1.19–2.07) at final survey.</p> <p>Male circumcision associated with decreased HIV incidence.</p>
Loevinsohn et al. (2020) [24] To assess the impact of a PEPFAR-supported VMMC program on the risk of male HIV acquisition over time.	Uganda 2008–2016	Open population-based prospective cohort study Analytical sample restricted to non-Muslim HIV uninfected and uncircumcised men at study entry N = 3916 men Five survey rounds denoted as 13–17	<p>34% of eligible men were circumcised between 2008 and 2016.</p> <p>↓ HIV incidence in circumcised men (0.86 infections per 100 person-years for survey rounds 13–14 vs 0.30 infections per 100 person-years for survey rounds 15–17; men who were non-circumcised (1.33 infections per 100 person-years for survey rounds 13–14 vs 0.74 infections per 100 person-years for survey rounds 15–17).</p> <p>VMMC associated with 51% lower risk of incident HIV infection.</p>
Makhema et al. (2019) [26] To determine whether and to what degree a community-based intervention to maximize HIV testing and case identification, linkage to care, early (expanded) ART, and male circumcision could reduce the population-level incidence of HIV infection.	Botswana 2013–2018	Pair-matched community-randomized trial Residents from random sample of ~20% of households in each community. N = 4,487 enrolled in HIV incidence cohort in each group (intervention and control); 60% were female.	<p>↓ HIV incidence ratio in intervention group compared with standard-care group.</p> <p>↑ (Nonsignificant) effect of intervention than standard care on incidence of HIV infection among men.</p> <p>↑ Increase in percentage of virally suppressed HIV-positive participants in intervention communities (from 70 to 88%) than in standard-care communities (from 75 to 83%) (relative risk, 1.12; 95% CI, 1.09–1.16).</p> <p>Among HIV+ not receiving ART at enrollment, median time to initiation of ART was 69 days in the intervention group compared to 367 days in the standard-care group.</p> <p>↑ in % of HIV– men aged 16–49 years who reported being circumcised from 30% at baseline to 40% at trial end in the intervention group, as compared with an increase from 33 to 35% in the standard-care group (relative risk, 1.26; 95% CI, 1.17–1.35).</p>
Vandormael et al. (2019) [23] To quantify sex-specific trends in HIV incidence following changes in ART coverage, prevalence of detectable viremia, condom use, and male circumcision.	South Africa 2005–2017	Prospective cohort of repeat HIV testers in a population-based HIV testing platform N = 22,239; 57% women	<p>↓ HIV incidence rates (IRs) when opposite-sex ART coverage surpassed 35% and ART eligibility criteria were removed in 2016.</p> <p>↓ HIV incidence between 2012 and 2017 among men from 2.49 (95% CI, 1.83–3.37) to 1.01 (95% CI, 0.58–1.76) seroconversion events per 100 person-years.</p> <p>↓ HIV incidence between 2014 and 2017 among females from 4.89 (95% CI, 4.09, 5.84) to 3.06 (95% CI, 2.38–3.94) seroconversion events per 100 person-years.</p> <p>↑ ART coverage among HIV+ women from 2.1% in 2005 to 54.6% in 2017 and among HIV+ men from 1.5% in 2005 to 38.4% in 2017.</p> <p>↓ Population prevalence of detectable viremia among women from 72.8% in 2011 to 55.3% in 2014 and among men from</p>

Table 3 continued

First author (year)/study purpose	Country/ study period	Research design/sample	Results
			77.8% in 2011 to 67.2% in 2014. ↑ Self-reported circumcision among men from 3.0 to 32.9% between 2009–2016. ↓ HIV IR between 2012 and 2016 from 1.24 (95% CI, 0.57–2.69) to 0.5 (95% CI, 0.16–1.57) events per100 person-years among circumcised men and from 3.01 (95% CI, 2.16–4.18) to 1.73 (95% CI, 1.01–2.97) events per100 person-years among uncircumcised men. ↓ Adjusted incidence rate ratio among circumcised men compared with uncircumcised men and among circumcised and uncircumcised men compared with women.
Borgdorff et al. (2018) [25] To determine the trends in HIV prevalence and incidence.	Kenya 2011–2016	Secondary analysis of data from a health and demographic surveillance system (HDSS) in which home-based counseling and testing (BCT) surveys have been done since 2011, to increase coverage of HIV control interventions. Age 13 and older N = 12,606 included in HIV incidence analysis	↓ HIV incidence from 11.1 (95% CI, 9.1–13.1) per 1000 p-ys in 2011–12 to 5.7% (95% CI, 4.6–6.9) per 1000 p-ys in 2012–16. ↓ Adjusted HIV incidence ratio (0.5, 95% CI, 0.2–1.0) among females with a circumcised male partner than with uncircumcised male partner. ↓ (Non-significant) unadjusted HIV incidence ratio (0.7, 95% CI, 0.4–1.1) among circumcised males compared to uncircumcised males.

prevalence and incidence cannot be directly attributed to increasing ART and VMMC coverage. Other explanatory factors might include the natural history of the HIV epidemic in eastern Africa, which showed declines of HIV incidence even before the onset of large-scale ART use and expanding VMMC coverage". This claim is consistent with the data presented in the preceding section and, as further illustrated below by Makhema et al. [26], suggests that there are likely many factors responsible for reductions in HIV incidence where they occur, and it is simplifying and misleading to assert (since the evidence is weak) that VMMC initiatives are a major determinant among these factors.

Makhema et al. [26] conducted a pair-matched community randomized trial to examine whether and to what degree a combination intervention to maximize HIV testing and case identification, linkage to care, early (expanded) ART, and male circumcision could reduce the population-level incidence of HIV infection in Botswana. Compared to baseline, at study conclusion, they found a significantly greater increase in the percentage of virally suppressed HIV-positive participants and shorter time to ART initiation in intervention communities than in standard-care communities. They also observed a larger increase in the percentage of HIV-negative men who reported being circumcised in the intervention group than the standard-care group. However, in the Discussion section, the authors state that while the reduction in HIV incidence in the intervention group may be due to the intervention, they were "...unable to directly determine which specific intervention or interventions were most important in reducing the incidence of HIV infection". Additionally, "[g]iven the small number of men who underwent circumcision (approx. 50%) by trial end, it is unlikely that male circumcision contributed substantially".

A key limitation of studies conducted to date is that none were designed to measure the independent effect of VMMC programs on population-level HIV incidence. The studies indicate that combination HIV interventions are effective in reducing HIV incidence. However, the studies do not contribute knowledge about the specific effect of VMMC on the reduction of HIV incidence at the population level, suggesting a need for

appropriately designed, rigorous studies to address this knowledge gap.

The unintended consequences of VMMC as a public health intervention in ESA

Our literature review not only revealed weak evidence for the benefit commonly associated with VMMC programs (lowered HIV incidence), it also exposed various concerns associated with VMMC program implementation. Divided into three categories, these unintended consequences include adverse events, risk compensation, and social/cultural impacts.

Adverse events. Adverse events are negative health outcomes associated with accident or provider error [27]. Concerning VMMC, adverse events are generally rare. Within the three RCTs [2–4] that provided the basis for the recommendation that VMMC be implemented as an HIV prevention intervention [28], the rate of adverse events was 1.5–7.6% [29]. As reported, these included pain, wound reopening, bleeding, hematoma, swelling, issues with anesthetics, erectile dysfunction, unhappiness with appearance, and infection [29]. For adolescents, the risk of urethrocutaneous fistulas resulting from circumcision is an additional concern [30]. Rarer, but more serious injuries include damage to or amputation of the glans [31], Fournier's gangrene [32], and deaths resulting from tetanus infections [33, 34]. To avoid or mitigate adverse events in VMMC programs, researchers have pointed out the need to improve the quality of VMMC services. Their suggestions include increasing parental engagement among adolescent clients [35, 36], managing targets to ensure service providers are not overwhelmed by demand [36, 37], enhancing preoperative screening [36, 38], ensuring consistent and thorough counseling to ensure patients know how to care for themselves [39], and improving patient access to post-operative medical care [40].

Risk compensation. From early in the drive to promote VMMC, there existed concerns about risk compensation [3, 4, 29, 41–44]. Risk compensation (or disinhibition) refers to the worry that those who undergo a preventive intervention may engage in behaviors

that put them at risk because they feel protected [45]. Much evidence exists suggesting that post-medical male circumcision risk compensation concerns are unfounded [3, 4, 42, 46–49]. This includes results from studies that analyzed self-reported data and did not find statistically significant changes in risk compensation among men at three [50] months and at one [42, 51], two [52, 53], and three years post-circumcision [54]. Researchers have also reported decreases in risk behaviors following VMMC [4, 51, 52], including increased condom use [55, 56]. These findings are expected [57] given that the RCTs and subsequent implementation efforts provided HIV risk behavior education as an intervention component. In Kenya, a decrease in risk behaviors was observed among both men who became circumcised and those who chose to remain non-circumcised [51]. Another study reported no significant risk compensation, even when the potential effects of risk reduction education were excluded [46].

Other studies, however, report having found evidence of risk compensation. For instance, in Zambia circumcised men aged 15–29 have been found to engage in riskier behaviors in terms of having more extramarital partners compared to non-circumcised men (11.1% circumcised vs 8.7% non-circumcised; relative risk: 1.278; $p=0.045$) [58]. Although the differences were not statistically significant, rates were higher among circumcised than non-circumcised men of having two or more partners (circumcised 24.5% vs non-circumcised 22.4%) and using commercial sex services (circumcised 2.1% vs non-circumcised 1.9%) [58]. Interestingly, one study found increased risk-taking among those who underwent circumcision, but also that belief in the protectiveness of circumcision led to less risky behaviors [59]. Even in the early study conducted by Auvvert et al. [2], statistically, significant increases in the mean number of sex partners among those who underwent circumcision were observed (5.9 versus 5.0, $p < 0.001$ between months four and 12 and 7.5 versus 6.4, $p = 0.0015$ between months 13 and 21), suggesting at least the potential for risk compensation.

Nonetheless, a recently published systematic review and meta-analysis of risk compensation among heterosexual men [48] have led some to conclude definitively that concerns about risk compensation associated with VMMC are unfounded [49]. Yet, even if we leave aside the well-known issues related to social desirability bias [60–62] associated with measures that rely on self-reported sexual behaviors (as these studies do), this systematic review shows a range of effects on post-circumcision risk compensation (positive, negative, and neutral), depending on context. In other words, the data presented by Gao et al. [48] show that risk compensation is an issue of concern in some contexts, but not in others. This suggests that there are likely some factors, not yet well understood, that may foster post-circumcision risk compensation in some settings, while inhibiting it in other settings.

Added to this, smaller, qualitative, and survey-based studies provide greater context for how changes in behavior and attitudes post-medical male circumcision may affect risk behaviors [63]. For example, one study reported men engaging in unprotected sex too soon after VMMC due to cultural beliefs concerning sexual cleansing and/or misunderstandings related to what it meant to be fully healed [43]. Worryingly, a cross-sectional survey study conducted in Botswana, Namibia, and Swaziland found that 13% of young men and 10% of young women incorrectly believed that circumcision provides men with 100% protection from HIV [64]. Similarly, a study of risk perceptions among South African women suggested that women who were aware of VMMC's protective effect also believed circumcised men had less need for condoms and posed less HIV risk for women [65]. Finally, researchers have reported HIV behavioral risk compensation among *traditionally* circumcised South African men. As they explain, the influence of the promotion of VMMC for HIV prevention for non-circumcised men may have harmful impacts via increased risk behaviors

among men who were circumcised without the benefit of risk reduction counseling [66]. This suggests the need for risk reduction education for all circumcised men [67]. In summary, broad claims that VMMC does not lead to risk compensation should be examined critically, as behavioral responses to being medically circumcised may differ by setting, and some dimensions of sexual behavior (such as the number of partners) may be less affected by VMMC than others (such as condom use).

Social and cultural impacts. Social and cultural impacts ranging from the individual level to that of community and society are important, yet less widely considered potential unintended consequences of VMMC campaigns. For males who remain non-circumcised but live within contexts where VMMC campaigns have been successful, social impacts may include stigmatization and/or discrimination [35, 36]. Importantly, VMMC programs target traditionally non-circumcising communities, within which some people oppose circumcision for cultural reasons. The promotion of VMMC among these groups may constitute the advancement of a “new bodily norm”, which could impact people's sense of cultural or ethnic identity and autonomy [68], as well as how they are perceived as an ethnic group by others [69]. Additionally, some efforts to promote and implement VMMC frame tradition and culture as “barriers” to be overcome in the name of “progress.” As such, VMMC campaigns, both primarily funded and largely implemented by Western actors or surrogates, have been argued to represent a kind of “cultural imperialism” within which local customs and systems of meaning surrounding circumcision—or non-circumcision—are overridden by a narrow biomedical lens [69]. It seems hardly mere coincidence that the United States, where male circumcision is a more prevalent and accepted cultural practice compared to other countries in the global north [70, 71], is the country that has made the most significant contributions to the advent of VMMC as an HIV prevention intervention, as well as to its continued funding and implementation across much of sub-Saharan Africa [72].

Additionally, there is the issue of gender equity: while women are socially, politically, and physiologically more vulnerable to HIV infection, VMMC campaigns focus on men and prioritize the prevention of female-to-male transmission, with prevention among women existing as an assumed, secondary, “knock-on” benefit of this intervention [73–75], despite direct evidence to the contrary. For instance, the sole randomized trial designed to test the hypothesis that male circumcision will reduce male-to-female HIV transmission (see Wawer et al.) [76] was terminated early after the female partners of circumcised men were found to have a 8.3% greater risk of infection over 24 months compared to the female partners of non-circumcised men in the control group. It could be (and has) been argued that the increased risk for the partners of circumcised men observed in this study can be explained by the premature resumption of sex before the completion of post-circumcision healing and therefore, could be avoided within VMMC implementation by risk reduction counseling and educative efforts. However, it is important to note that risk reduction counseling, condoms, and repeated instructions were provided within this trial, yet there was still an observed increase in risk for the female partners of circumcised men [76]. It seems somewhat misguided to assume that risk reduction counseling will be better or more effective in the less controlled real-world conditions of VMMC scale-up than in a controlled clinical trial setting. Moreover, if counseling against risk behaviors is key to the effectiveness of the intervention, then why circumcise at all? Would it not make more sense to use sexual risk behavior counseling as the primary intervention, given that regular condom use, reduction in risk of partners, etc., is more effective than circumcision, and removes the need for surgery? Regardless of one's interpretation of the Wawer et al. trial [76], what seems clear is that HIV prevention efforts that do not

prioritize social, cultural, and political factors, including gender dynamics, may sidestep, obscure, or exacerbate many key structural factors known to drive the epidemic, or misdirect attention and funding in such a way as to result in more harm than good.

Furthermore, there exists the potential for a loss of public trust in the healthcare system, the institutions that exist to promote public health (e.g., PEPFAR, non-governmental organizations [NGOs], and their local implementation partners), and other future public health interventions [72]. The concern is that if people feel harmed, wronged, or misled by VMMC's proponents or implementers, they may become generally disinclined to engage with local healthcare or accept or participate in future public health campaigns. Such an outcome could be an unintentional, yet disastrous legacy of efforts to circumcise across ESA. Preservation of public trust has been shown to be crucial in Africa in relation to other infectious disease epidemics, including COVID-19 [77–79]. While no study has yet made a thorough assessment of the social/cultural impacts of VMMC for HIV prevention in Africa, these examples do suggest harms that may accumulate through continued efforts to promote this public health initiative given the ongoing uncertainty surrounding the independent contribution of VMMC to reducing new HIV infections, when considered alongside other measures.

Main ethical dimensions of VMMC programs

Ethical debates have arisen concerning the production of scientific evidence for VMMC reducing HIV transmission, including the RCTs in Africa [80–82], the process of transforming scientific evidence into HIV prevention policies [83, 84], and the translation of these policies in actual VMMC programs [36, 37]. Here we focus on four key ethical concerns in VMMC program implementation.

Voluntary informed consent. While some public health interventions are compulsory, the 'V' in VMMC implies that program participants can freely choose medical circumcision based on adequate information and understanding. However, the quality of consent in VMMC program implementation has been questioned on various grounds. As mentioned below, VMMC initiatives have targeted youths aged 15 and younger, sometimes without parental or guardian involvement. It is to be expected that youths may be challenged to freely choose and comprehend the significance of VMMC, particularly those from disadvantaged backgrounds who may lack familiarity with being asked to choose for medical procedures, as some studies have borne out [40]. Concerns have also been raised about aggressive persuasion strategies, including various forms of "demand creation" (including the use of economic incentives), peer pressure, and stigmatization of the non-circumcised [85, 86]. Results of studies on information disclosure and comprehension in VMMC consent processes are mixed, with some studies indicating that participants generally understand the nature and implications of VMMC [87], while others suggest the information provided emphasizes benefits over risks [88] and that participants have a poor understanding of key elements [35]. For example, prospective volunteers for VMMC are typically told that circumcision 'will reduce their risk of acquiring HIV by 60%', without further explaining that this is a 60% reduction in *relative risk*, i.e., relative to the absolute HIV risk where the original clinical trials were conducted nearly two decades ago. Volunteers are highly unlikely to know this key background information or that the absolute HIV risk may in fact now be quite small in their own communities.

Preventive genital surgery with minors. VMMC programs have followed international guidance in officially offering circumcision to adolescents [89], though in practice children from the age of 10 have been included [90]. Recently, safety issues in VMMC with boys under the age of 15 led PEPFAR to discontinue funding in its

programs for this age group [30], though it is likely that 'pre-adolescent' VMMC still takes place. Beyond the issue of physical (and potential psychological) [35] harm, most ethical issues revolve around the surgical removal of healthy genital tissue for HIV prevention purposes from adolescents in low- and middle-income country (LMIC) contexts. For reasons already given regarding informed consent, these adolescents (relative to adults) are likely less able to grasp the significance of the procedure or to decide autonomously in the face of influences from caregivers, peers, or other authorities [91]. Some adolescents are circumcised for prevention purposes without caregiver permission in jurisdictions where such permission is required [35, 92]; other studies suggest parental guidance in adolescent HIV prevention decision-making is often hindered by cultural and gender norms and lack of appropriate knowledge regarding HIV [93].

Program imperatives and unintended consequences. In VMMC programs, the ultimate goal of reducing HIV incidence is translated into specific numbers of circumcisions to be performed within a certain time period [36]. As mentioned above, vigorous pursuit of VMMC targets leads to several unintended and undesirable consequences. These consequences are also ethically questionable to the extent that they are unintended but not unexpected [94], and there are reasons to believe that some of these consequences should have been anticipated and mitigated.

First, it is well-known that purposive social actions regularly lead to unintended (including harmful) outcomes [95], and there is a substantial literature on unintended consequences connected with public health interventions [96]. Second, some effects connected to VMMC programs now being reported were identified by stakeholders prior to them being designed and implemented [97, 98]. VMMC programs are therefore vulnerable to the following ethical criticism: the strong focus on fulfilling circumcision targets led key stakeholders (e.g., funders and program implementers) to downplay the moral significance of reasonably expectable program-related harms. This contrasts with official WHO ethical guidance that states: "Taking a human rights-based approach to the development or expansion of male circumcision services requires measures that ensure that the procedure can be carried out safely, under conditions of informed consent, and without coercion or discrimination" [89].

Ethics of interventions that change social norms. VMMC differs significantly from traditional (ritual) circumcision in terms of its symbolic, cultural, and political significance. Promoting VMMC for HIV prevention, therefore, requires changing important norms for non-circumcising and traditionally circumcising communities and raises issues of social harm and justice. VMMC can disrupt meaningful distinctions and political relationships between ethnic groups, and can have adverse outcomes for women, and gender and sex dynamics, particularly if VMMC is promoted as a way of being a 'real' man [68, 99]. In general, deliberately attempting to change social norms for public health purposes is ethically controversial, not just because of likely unintended consequences (see above) but also due to the underlying assumption that public health goals should override traditional values. The assumption's soundness is unclear in the case of VMMC, particularly in LMICs where (increasingly) HIV is not the most pressing public health problem.

CONCLUDING REMARKS

Epidemiological data indicate that HIV incidence rates were already declining among both females and males in most ESA priority countries at the time VMMC programs were implemented in 2008. Incidence rates have continued to decline with limited evidence that the introduction of VMMC changed the rate of decline in priority countries. Additionally, we did not find

convincing evidence from studies assessing the effectiveness of combination HIV prevention interventions of a consistent, significant, and independent effect of VMMC on reducing population-level HIV incidence. This is not to say that VMMC programs have had no effect. Instead, we mean only to emphasize that clear evidence of the effect of VMMC on HIV incidence at the population level independent of other possible causal factors (e.g., expanded ART among HIV-infected individuals) does not currently exist.

According to influential public health ethics frameworks, ineffective public health interventions are ethically problematic because they have a poor risk/benefit profile and waste resources [100]. To the extent that their effectiveness in reducing HIV incidence remains unclear, the ethical justification of VMMC programs is more precarious than their proponents suggest. This precariousness opens the door for more general ethical critiques, e.g., that VMMC initiatives (especially in Africa) are manifestations of Western neocolonialism in global public health [69].

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WKL, SR, and AG contributed equally to conceptualizing the paper, conducting literature searches, identifying and reviewing articles to be included, writing the original draft, and editing and revising subsequent drafts.

COMPETING INTERESTS

The authors declare no competing interests.

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