

The US President's Emergency Plan for AIDS Relief's (PEPFAR's) guidelines ("PEPFAR 2020 Country Operational Plan Guidance for all PEPFAR Countries") propose to continue the so-called voluntary medical male circumcision (VMMC) in Africa, while mostly discontinuing its support of childhood or early infant male circumcision. While we support this latter decision on both medical and ethical grounds, we argue that the broader VMMC program has serious inbuilt flaws that are not adequately addressed within the current draft of the guidelines. This draft, including section 6.2.5.1 of the guidelines, which focuses on VMMC as applied to youths 15 years of age and older, rests on a distorted understanding of the medical evidence and is economically inadvisable. But more than this—and we do not make these claims lightly—the draft, if finalized in its current form, would put the U.S. government in the untenable position of violating core principles from medical ethics and human rights law.

The VMMC program is undoubtedly well-motivated. But in its conception and implementation, it has failed to achieve its goals and has caused considerable collateral damage, as is now being documented in the peer-reviewed literature. One problem is the intensive pursuit of "demand creation" to meet quotas, relying on advertising and other publicity that has misled African youths into thinking that circumcision alone is a reliable safeguard from contracting HIV. [Gilbertson 2019; Luseno 2019] Some of these advertisements have relied on misleading, unsubstantiated, or non-generalizable claims, suggesting for example that women will reject men sexually if the men are not cut (amounting to body-shaming of genitally intact males); and local officials have resorted to outright misrepresentation that circumcision effectively immunizes a person from HIV. [Gathura 2019; Gwaambuka 2019]

We do appreciate the guidelines' recommendation that the VMMC program be discontinued for most African youths 14 years of age and younger. This is a long overdue step that must be taken on grounds of human rights, law, and ethics, as well as cost-effectiveness.

Regarding African males 15 years of age and older, the most critical aspects of the guidelines lie in what PEPFAR leaves out. Medical ethics require doctors to use the most effective, least invasive treatment or prevention method for any condition. For primary HIV prevention, this remains condom use and other behavioral factors such as reduction in the number of concurrent sexual partners. [Kaufman 2017] For secondary prevention, the most effective, least invasive interventions are condoms, "treatment-as-prevention," pre-exposure prophylaxis and post-exposure prophylaxis.

Studies of general populations support this view. The only populations in which male circumcision may show a substantial benefit are those at high risk of infection, namely those with HIV-infected sexual partners and those who engage in unprotected sexual contact with multiple partners of unknown HIV status. Given this, circumcision, if it has a role at all in HIV prevention, might be a potential intervention for such high-risk subgroups; however, given the effectiveness of condoms, "treatment-as-prevention", and pre-exposure prophylaxis, it would be unethical for a healthcare worker to recommend circumcision generally. Even if offered, very few men, given accurate disclosure, would choose circumcision over these other proven interventions, which should be invested in

and made more widely available.

For an irreversible surgical procedure, the ethical bar for intervention is especially high. As a recent international consensus statement by leading scholars in ethics, law, medicine, and other specialist fields makes clear, medically unnecessary genital cutting can only be undertaken with the free and informed consent of the affected person [Brussels Collaboration on Bodily Integrity 2019]. Such consent obviously cannot be given by infants or young children; but even in the case of older boys or men, the coercive atmosphere in which the VMMC program is being imperative undermines this ethical imperative.

Securing proper informed consent, particularly providing proper information to make an informed consent possible, has not been at the core of the VMMC program [Schenk 2012; Luseno 2019; Schenk 2014] Yet it is completely essential. Stuart Rennie et al. called the world's attention to this issue near the beginning of the VMMC program in the world's premier journal on medical ethics, yet this was sadly ignored in the intervening dozen-plus years. [Rennie 2007] More recently, it has been shockingly reported that limited information is being provided to adolescents about HIV prevention and care, that adolescents are rarely provided with condoms, and providers report spending little time talking about either HIV prevention or condom use. [Kaufman 2017] Moreover, according to another study, most VMMC participants believe there is "no risk" to circumcision, and are confused about the difference between the risk of the procedure and the risk of HIV! [Friedland 2013] Genital cutting of adults is legally and ethically permissible as long as they are properly and fully informed and provide their informed consent prior to the procedure. In the case of VMMC, men were not properly informed that circumcision does not completely protect anybody, but at most reduces the probability of transmission from female to male, which is very different. [Schenk 2012; Luseno 2019; Schenk 2014]. Even more alarming, an estimated 35,000 young boys have been circumcised in Kenya alone without their own valid consent nor even the consent of their parents [Luseno et al. 2019]. A medically unnecessary surgery that is not consented to either by the individual or a valid proxy decision maker is simply criminal assault and battery.

HIV is no longer an untreatable condition; it is now considered a chronic illness. [Deeks 2013] Thus the emergency mentality that has in the past driven the VMMC program should be reconsidered, with greater attention paid to paramount ethical and legal principles. Permanently excising healthy, functional tissue from a psychosexually significant part of the body is a serious matter, and it is a massive misdirection of effort. Vast sums have been spent on circumcision that could have been better used on condoms, education and post-exposure prophylaxis and lifetime treatment of affected people that reduces to zero their risk of transmitting HIV to their sexual partners. VMMC advocates warn that circumcision is only effective if accompanied with extensive education about, for example, avoiding sex during the wound-healing period and the continued need to consistently wear condoms despite the genital surgery. But if African men and their partners can be effectively educated about such matters, as VMMC proponents insist they can and must be, then, a fortiori, they could be effectively educated to simply consistently wear condoms in the absence of surgery (with no wound healing period), which would

eliminate the need for circumcision. Proper use of condoms, with or without circumcision, near-fully protects both men and women from HIV sexual transmission.

Even were there to be overwhelming evidence for a net health benefit of VMMC in real-world situations, which there certainly is not, it should still be the personal decision of the man himself whether to have surgery on a part of the body recognized as the most intimate, private and erogenous part of his body.

In Africa, traditional circumcision was never associated with lower HIV prevalence: there were as many situations where it was associated with more HIV than situations with less HIV, due to a variety of confounding factors. [Van Howe 2015] In Zambia, VMMC campaigns were not associated with lower HIV prevalence among men age 15-29, despite declining prevalence among their partners. [Garenne 2019] In Zambia, men who underwent VMMC tended to have riskier sexual behavior. [Garenne 2019] In African countries where VMMC campaigns were conducted on a large scale, HIV prevalence did not decline significantly compared with previous trends. For example, Uganda, which had seen a 47% decrease in HIV incidence after implementing the ABC program [Low-Beer 2004], saw an increase in HIV following the VMMC rollout. Some 10 years after onset, VMMC campaigns have not shown any appreciable benefits, despite the massive investment and the millions of men circumcised. [Gathura 2019; Gwaambuka 2019]

The time is right to stop the ill-conceived, Western-centric VMMC program. We are more than a dozen years on from the three randomized controlled trials (RCTs) and still their results have not been replicated despite being widely questioned. Mainstream HIV experts now regularly fail to mention circumcision as a worthwhile intervention [Workowski 2015] We call on PEPFAR to modify its guidelines to request full cancellation of the VMMC program for all ages before further harm occurs and to divert the funds that are thereby saved to programs of more surely proven effectiveness. The law and medical ethics require no less.