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Male circumcision for protection against HIV infection in sub-Saharan Africa: The evidence in favour justifies the implementation now in progress

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Abstract

This article responds to a recent 'controversy study' in *Global Public Health* by de Camargo et al. directed at three randomised controlled trials (RCTs) of male circumcision (MC) for HIV prevention. These trials were conducted in three countries in sub-Saharan Africa (SSA) and published in 2005 and 2007. The RCTs confirmed observational data that had accumulated over the preceding two decades showing that MC reduces by 60% the risk of HIV infection in heterosexual men. Based on the RCT results, MC was adopted by global and national HIV policy makers as an additional intervention for HIV prevention. Voluntary medical MC (VMMC) is now being implemented in 14 SSA countries. Thus referring to MC for HIV prevention as 'debate' and viewing MC through a lens of controversy seems mistaken. In their criticism de Camargo et al. misrepresent and misinterpret current science supporting MC for HIV prevention, omit previous denunciations of arguments similar to theirs, and ignore evidence from ongoing scientific research. Here we point out the flaws in three areas de Camargo et al. find contentious. In so doing we direct readers to growing evidence of MC as an efficacious, safe, acceptable, relatively low cost one-off biomedical intervention for HIV prevention.

Keywords

Male circumcision; HIV prevention; sub-Saharan Africa; scientific evidence; public health policy and practice; controversy studies

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The first two authors contributed equally to this work.

Introduction

The present article sets out to critically examine the veracity of claims made in a recent article in *Global Public Health* on male circumcision (MC) for HIV prevention (de Camargo, de Oliveira Mendonça, Perrey, & Giami, 2013). The claims were directed mostly at the findings from three randomised controlled trials (RCTs) conducted in sub-Saharan Africa (SSA) showing that voluntary medical MC (VMMC) provides to men a 60% reduction in risk of being infected with HIV during heterosexual intercourse (Auvert et al., 2005; Bailey et al., 2007; Gray et al., 2007). On the basis of the evidence the RCTs provided, VMMC was adopted by normative global health organisations as a new policy for HIV prevention (World Health Organization [WHO]/Joint United Nations Programme on HIV/AIDS [UNAIDS], 2007; UNAIDS, 2008). Since then, 14 countries in SSA have adopted and are implementing this medical intervention as part of an overall strategy to stem heterosexual transmission of HIV with an initial goal of 20 million circumcisions by 2015, representing 80% coverage (UNAIDS, 2013; WHO, 2013; Dickson et al., 2011; Wamai et al., 2011). UNAIDS has recently identified two additional target countries (UNAIDS, 2013). As of December 2012 over three million circumcisions had been completed in the 14 scale-up countries under assured quality standards (Bertrand et al., 2013; UNAIDS, 2013). Coverage has ranged from 4% in Malawi to 63% in Kenya (UNAIDS, 2013). The differences between countries can be attributed to multiple factors, including adoption of policies, health system challenges, strategies for demand generation, as well as socio-cultural and individual factors (Wamai et al., 2011; Mwanga et al., 2012; Dionne & Poulin, 2013; Gray, Wawer, & Kigozi, 2013; Plotkin et al., 2013; UNAIDS, 2013; WHO, 2013; Chinkhumba, Godlonton, & Thornton, 2014; Weintraub et al., 2014).

de Carmago et al. suggest in their ‘controversy study’ the need for better evidence. They make statements of questionable relevance and argue erroneously that the RCTs and supporters of MC have ignored ‘values’ (culture, behaviour and ethics). de Camargo et al. misrepresent the design, execution and analysis of findings from the trials. In so doing they make several critical mistakes in the interpretation of the evidence, confusing efficacy and effectiveness. Further, the authors ignore newer evidence from MC research and implementation studies and seem unaware of published critiques that have dismissed claims by MC opponents on this issue. Belabouring repudiated criticisms of the evidence favouring MC as a potentially effective tool against HIV infection weakens their arguments. As the strength of the evidence continues to grow, claims by opponents have become increasingly untenable (Wamai, 2012). Scholars and policy makers who value high quality scientific evidence appreciate the value of evidence more so than rhetoric or ideology as a basis of public health policies (Russell, Greenhalgh, Byrne, & McDonnell, 2008; Banks, 2009; Behague et al., 2009; Brownson, Chriqui, & Stamatakis, 2009; Collins, 2009; Chan, 2012; Das & Samarasekera, 2012; Kim, 2012).

In settings of high HIV prevalence, as applies in many SSA countries (UNAIDS, 2013), research has established that the predominant mode of transmission (MOT) of HIV is heterosexual intercourse (Schmid et al., 2004; Gouws, White, Stover, & Brown, 2006; Colvin, Gorgens-Albino, & Kasedde, 2008; Wamai et al., 2011). Modelling shows MC has potential for an enormous population-level impact in reducing HIV incidence and the costs

of HIV/AIDS in these settings (Nagelkerke, Moses, de Vlas, & Bailey, 2007; UNAIDS/WHO/SACEMA Expert Group on Modeling the Impact and Cost of Male Circumcision for HIV Prevention, 2009; United States Agency for International Development [USAID], 2009; Hallett et al., 2011). Hence, to ignore or deny the evidence and policy support for VMMC in HIV prevention serves to undermine attempts to stem the tide of the HIV epidemic (Center for Global Health Policy, 2010; Banerjee et al., 2011; Morris et al., 2011; Wamai et al., 2011; American Academy of Pediatrics (AAP) Task Force on Circumcision, 2013). Since de Camargo et al. have expressed their views in a peer-reviewed journal, in the interests of scholarship and policy determination it is important that fundamental flaws in their arguments be identified and readers directed to the growing evidence of the utility of VMMC as a valid biomedical intervention for HIV prevention. The 'seventeen puzzles' or 'anomalies' invoked by de Camargo et al. about the evidence for MC in HIV prevention have been rebutted point-for-point previously (Klausner et al., 2008; Wamai et al., 2008, 2012; Morris et al., 2011, 2012a;). Hence, rather than repeat the already published repudiation of their claims, our criticisms instead focus on three main areas encompassing the 'puzzles'. We first address the evidence supporting VMMC as a biomedical intervention noting current data on efficacy and potential effectiveness in SSA. Next we assess behavioural and contextual considerations in proposals to adopt VMMC. Our last section addresses public health policy considerations in adopting VMMC, including cost-effectiveness, cultural acceptability and ethics.

Biomedical evidence of randomised controlled trials of male circumcision for HIV prevention

de Camargo and colleagues are correct in pointing out that RCTs are the gold standard for epidemiological evidence—in the present case supporting a biomedical intervention for disease prevention. The three RCTs from South Africa, Kenya and Uganda (Auvert et al., 2005; Bailey et al., 2007; Gray et al., 2007) were the culmination of a large body of earlier observational data that had suggested an ability of MC to reduce risk of HIV (Weiss, Quigley & Hayes, 2000; Siegfried, Muller, Deeks, & Volmink, 2003; Siegfried et al., 2005; Drain et al., 2006; WHO & UNAIDS, 2007a; UNAIDS & WHO, 2012). The RCTs showed relative risk-reductions of 61%, 51% and 53% in the studies in South Africa, Kenya and Uganda, respectively (Auvert et al., 2005; Bailey et al., 2007; Gray et al., 2007). These were subsequently affirmed in two meta-analyses (Byakika-Tusiime, 2008; Mills, Cooper, Anema, & Guyatt, 2008) and a Cochrane systematic review (Siegfried et al., 2009). One of the meta-analysis found the protection afforded by MC was higher than that seen in the observational studies (53% for general populations and 69% for high-risk populations, compared to 61% from observational studies [cohort studies 71% and case control 46%]) (Byakika-Tusiime, 2008). These levels of risk-reduction have withstood the test of time and have in fact increased since publication of the RCTs (Bailey et al., 2010; Gray et al., 2012; Auvert et al., 2011, 2013).

This evidence weakens arguments by de Camargo et al. that are built on selectively chosen publications by MC opponents. The claims that have now been discredited appear in Boyle & Hill (2011), Green, McAllister, Peterson, & Travis (2008), Green et al. (2010), Van Howe

(1999), Van Howe and Storms (2011), and other articles by opponents. Repudiation of the claims can be found in Moses, Nagelkerke, and Blanchard (1999), O'Farrell and Egger (2000), Castellsague, Albero, Cleries, and Bosch (2007), Wamai et al. (2008), Klausner et al. (2008), Morris et al. (2011), Banerjee et al. (2011), Wamai and Morris (2011), Wamai et al. (2012) and Morris et al. (2012a). de Camargo et al. do not cite any of these scholarly critiques. Furthermore, the fact that many of these—with the exception of Morris et al. (2011), Wamai and Morris (2011) and Wamai et al. (2012)—pre-date March 2011, undermines their claim of having conducted an adequate search of literature published up until March 2011. Thus de Camargo et al. provide a partial one-sided presentation of a thesis on MC and protections against HIV infection. The 'debate' is much more extensively enunciated in scholarly articles they omit. Researchers who countered previous criticisms of the RCTs addressed issues related to the methodological design, implementation of the studies, and interpretation of their findings (see for example Auvert, Sobngwi-Tambekou, Taljaard, Lagarde, & Puren, 2006; Klausner et al., 2008; Banerjee et al., 2011; Morris et al., 2011; Wamai et al., 2008, 2012). Furthermore, as a result of the ongoing accumulation of additional research findings in support of MC (Bailey et al., 2010; Center for Global Health Policy, 2010; Gray et al., 2012; Auvert et al., 2011, 2013) the field has moved well beyond the argument presented by de Camargo et al. Nevertheless, it is important to address six biomedical issues raised by de Camargo et al.

First, de Camargo et al. point to an RCT in Uganda that found MC increased risk of HIV transmission from HIV-positive men to HIV-negative women (Wawer et al., 2009). It must, however, be appreciated that this study by Wawer et al. (i) investigated the reverse effect, i.e., male-to-female transmission of HIV, whereas the three RCTs focused on male acquisition of HIV infection, (ii) found no statistically significant difference, and (iii) found HIV infections occurred in couples who ignored advice to refrain from sexual intercourse during the healing period (Wawer et al., 2009). It is also noteworthy that all men in this trial were HIV-infected, whereas in the three RCTs not all women were HIV-infected. Following Wawer et al. (2009) one systematic review and meta-analysis of 19 epidemiological analyses found 'little evidence' of 'direct' risk reduction for MC in male-to-female transmission of HIV (Weiss, Hankins, & Dickson, 2009). Although a large RCT to definitively assess a 'direct effect' may be 'logistically unfeasible' (Weiss, Hankins, & Dickson, 2009), since then, two large studies have been published of relevance to this issue. One multinational prospective study among HIV-1-serodiscordant couples in SA found a '40% lower risk of HIV-1 acquisition by the female partner', although the effect did not reach statistical significance (Baeten et al., 2010). The other, a modelling study, found MC would confer a 46% reduction in risk of HIV acquisition in women (Hallett et al., 2011). Thus MC indirectly benefits women as well, resulting in substantial population effects (Quinn et al., 2000; Hankins, 2007).

Secondly, De Camargo et al. note the biological mechanisms proposed by the trial authors for the protective effect of MC against HIV infection by citing two biological studies (Patterson et al., 2002; O'Farrell et al., 2006), but fail to recognise subsequent findings from newer biological studies (Ganor et al., 2010; Ganor & Bomsel, 2011). Morris and Wamai (2012) detailed the cellular, chemical and biological mechanisms responsible for foreskin-

mediated HIV infection, and since then additional biological studies have appeared (Schneider et al., 2012a; Liu et al., 2013).

Thirdly, in challenging the adoption of VMMC programmes de Camargo et al. refer to other 'anomalies' of biomedical importance such as 'sexual satisfaction', 'infection in men who have sex with men' (MSM) and 'adverse effects'. Besides their failure to cite newer research on these issues, flaws in their arguments include the following: (i) Their assertion that researchers need to obtain more data on such questions. But this is not an argument discounting current evidence, especially that from high quality studies such as RCTs and meta-analyses. (ii) Their claim that there are 'substantial complications' or adverse events arising from the RCTs includes only a single retrospective cross-sectional study of hospital data based on infant MC in Nigeria (Okeke, Asinobi, & Ikuerowo, 2006), while ignoring the extensive data showing that risks are low. For example, the three large, well-designed high quality RCTs found adverse events to be uncommon, minor and easily and immediately treatable (Auvert et al., 2005; Bailey et al., 2007; Gray et al., 2007). A systematic review of studies of VMMC complications in SSA reported no more than 'average risk' and that the majority were 'of minor clinical consequence' (Muula, Prozesky, Mataya, & Ikechebelu, 2007). The higher complication rate for neonatal or infant MC reported in Nigeria by Okeke, Asinobi and Ikuerowo (2006) is an anomaly that stemmed from inferior training (Ekenze, & Ezomike, 2013). Done under clinical standards, MC is safe. A recent analysis by the Centers for Diseases Control and Prevention of 1.4 million infant circumcisions found adverse events were only 0.5% and virtually all of these were minor and easily and immediately treatable with complete resolution (El Bcheraoui et al., 2014). This study found rates were 10–20 times higher in older children and men. VMMC is being implemented using validated clinical standards (WHO & UNAIDS, 2008, 2011; WHO, 2012; Bertrand et al., 2013; PEPFAR, 2013). Nigeria is not one of the 14 VMMC scale-up countries.

Fourthly, further contradicting de Camargo et al., the review by Weiss and colleagues (2010) noted there was 'little evidence' of any adverse effect on sexual satisfaction or function following MC and that MC 'may also protect against' HIV in MSM. The RCTs reported no evidence of adverse effects of MC on sexual function, sensitivity and satisfaction (Auvert et al., 2005; Bailey et al., 2007; Gray et al., 2007; Kigozi et al., 2008; Krieger et al., 2008), a finding validated in a large systematic review (Morris & Krieger, 2013) and a meta-analysis (Tian et al., 2013). In MSM, MC would not likely provide protection against HIV acquisition during receptive anal intercourse, but a Cochrane systematic review (Wiysonge et al., 2011) and other studies (Millett, Flores, Marks, Reed, & Herbst, 2008; Templeton et al., 2009; Templeton, Millett, & Grulich, 2010; Schneider et al., 2012b) found that MC had a protective effect in MSM who engaged exclusively in insertive anal intercourse. In MSM other research has found that MC for HIV prevention may be cost-effective (Anderson et al., 2009).

Fifthly, in light of the relative protection of 61% conferred by VMMC against HIV infection in the South African RCT, Auvert et al. (2005) compared the procedure to a 'vaccine.' de Camargo et al. assert that this is 'hyperbolic and possibly misleading.' However, the vaccine comparison has been logically made and defended by numerous scholars (Morris, 2007; Rennie, Muula, & Westreich, 2007; Schoen, 2007; Klausner et al., 2008; Wamai et al., 2008;

Ben et al., 2009; Morris et al., 2012b; Halioua & Lobel, 2014). In noting the urgency and value of MC implementation, U.S. Global AIDS Coordinator, Eric Goosby, stated, 'it will look like a vaccine has entered the community' (Center for Global Health Policy, 2010). Would de Camargo et al. similarly dismiss the worth of common vaccines that possess a similar level of efficacy?—e.g., influenza vaccines (Kelly et al., 2009; Grohskopf et al., 2013), whose estimated efficacy in children aged 6–23 months and 24 months was found to be 66% in a RCT in 1999–2000 (Hoberman et al., 2003) and 40% in a Cochrane systematic review (Jefferson, Rivetti, Di Pietrantonj, Demicheli, & Ferroni, 2012). Thus a 60% efficacy of MC against HIV seen in the RCTs by 1.5 years, rising to 63% by 4.5 years in Kenya (Bailey et al., 2010), 73% by 4.8 years in Uganda (Gray et al., 2012) and 76% in preliminary data from South Africa (Auvert et al., 2011) might lead one to conclude that there is no question that MC can be compared in efficacy to at least some common vaccines.

In making a sixth point, de Camargo et al. repeat the common criticism by MC opponents that the effect of MC in HIV prevention seen in the RCTs is 'decontextualized' from 'real-world effectiveness' (de Camargo et al., 2013). Such concerns fail to recognize the effectiveness of MC seen in numerous observational and ecological studies over several decades (e.g., Fink, 1986; Cameron et al., 1989; Moses et al., 1990, 1994; Halperin & Bailey, 1999; Weiss, Quigley & Hayes, 2000; Buvé et al., 2001; Siegfried, Muller, Deeks, & Volmink, 2003; Siegfried et al., 2005; Drain et al., 2006). As one early estimate based on Halperin and Bailey (1999) pointed out, MC could have prevented '8,000,000 or more adult HIV infections' in 15 countries in Africa and Asia (Potts, 2000). Thus, the cumulative evidence of effectiveness cannot be restricted to the RCTs. In fact RCTs are not completely decontextualised or fully devoid of 'real world' significance (Stephenson, 1998; Rosen, Manor, Engelhard, & Zucker, 2006). Effectiveness may also change over historical time as cultures adopt MC or stop doing so for cultural, political or practical reasons as described in multiple studies (Gollaher, 2000; Aggleton, 2007; Angulo & Garcia-Diez, 2009; Cox & Morris, 2012; Timberg & Halperin, 2012; Darby & Cozijn, 2013).

The claims by de Camargo et al. in making their sixth point ignore evidence of emerging effectiveness seen in post-trial MC implementation, the protective effect having been found to be sustained at levels similar to or higher than the RCTs several years later (Bailey et al., 2010; Gray et al., 2012; Auvert et al., 2011, 2013). A further point related to this is the inherent value of RCTs as the gold standard for 'best evidence' in biomedicine (Sackett et al., 1996; Rosen, Manor, Engelhard, & Zucker, 2006; Padian et al., 2008; Padian, McCoy, Balkus, & Wasserheit, 2010; UNAIDS & WHO, 2012). The prevailing scientific evidence shows that the 60% level reported by the RCTs makes VMMC more efficacious in HIV prevention than other biomedical interventions such as microbicides, vaccines and treatment of sexually transmitted infections (STIs) (Padian, McCoy, Balkus, & Wasserheit, 2010; Marrazzo & Cates, 2011; UNAIDS & WHO, 2012), the efficacy of these being 39%, 31% and 42%, respectively (Karim & Karim, 2011). In comparison, studies of pre-exposure prophylaxis and anti-retroviral therapy (ARVs) for 'treatment as prevention' (TasP) show efficacies of 63–73% and 96%, respectively (Granich, Gilks, Dye, & De Cock, 2009; Cohen et al., 2011; Karim & Karim, 2011). The latter interventions suffer, however, from inherent problems of adherence and availability, which reduce their effectiveness below the level seen for MC (Marrazzo & Cates, 2011; Piot & Quinn, 2013). They are, moreover, less cost-

effective than VMMC (Bärnighausen, Bloom, & Humair, 2012; Gomez et al., 2013). Given this, can the RCTs by themselves be used as a basis for the formulation of policies? The conduct of public health research is to inform policy (Baltussen & Niessen, 2006; Brownson, Chriqui, & Stamatakis, 2009; Collins, 2009; Lie & Miller, 2011; Chan, 2012; Das & Samarasekera, 2012; Kim, 2012). The RCTs served this goal and solidified already existing evidence, so resulting in policy recommendations and commencement of implementation (WHO & UNAIDS, 2007b; UNAIDS, 2008; Center for Global Health Policy, 2010; UNAIDS & WHO, 2012; Wamai et al., 2012). As such, contrary to de Camargo et al., MC for HIV prevention was not ill-advised.

Behavioural and contextual considerations in adopting VMMC

While rigorous scientific evidence shows that MC is an efficacious biomedical intervention, its potential effectiveness is nevertheless mediated by behavioural and structural-contextual factors that determine acceptability, adoption and diffusion by policy makers and administrators (Merson et al., 2008; Weiss et al., 2008; Behague et al., 2009; Rotheram-Borus, Swendeman, & Chovnick, 2009; de Wit, Aggleton, Myers, & Crewe, 2011; Aboud & Singla, 2012;). Among outstanding ‘anomalies’ presented by de Camargo et al. are a number of ‘confounding factors’ or ‘externalities’ they cite to criticise the VMMC RCTs—specifically socio-economics, politics, culture and religion (de Camargo et al., 2013). The sociological literature advises the need for framing promises of biomedical and public health interventions with warrants because they tend to ‘underestimate the complexity of the social world’ (Timmermans, 2013). We therefore concur that the issues raised are important to consider when assessing whether to adopt a proven biomedical intervention.

The question here is whether (i) the efficacy registered by the experimental studies considered these factors and (ii) similar levels are, or can be, maintained outside trial settings. An affirmative answer is apparent since:

1. The RCTs took into account nearly all of these factors, with the exception of politics and religion, a policy and implementation issue we consider below. For instance, with regard to behavioural risk reduction, during the pre-trial and trial processes both the MC and non-MC groups received very similar instructions (Auvert et al., 2005; Bailey et al., 2007; Gray et al., 2007).
2. The results of the RCTs were similar to those found in a meta-analysis of 15 observational studies (conducted before the trials) that adjusted for potential confounders and found a strong risk reduction (adjusted RR = 0.42, CI 0.34–0.54) (Weiss, Quigley, & Hayes, 2000). An even larger systematic review of 34 observational studies by the Cochrane collaboration had confirmed the observational results (Siegfried, Muller, Deeks, & Volmink, 2003).
3. New studies conducted in the ‘real world’ contexts continue to provide evidence of risk reduction, the level strengthening to as much as 76% at the community level 4 to 9 years after the official 1.5 year end-point of the trials (Bailey et al., 2010; Gray et al., 2012; Auvert et al., 2013, 2011). The evaluation of the first

RCT showed that interventional VMMC was ‘associated with a significant reduction of HIV levels in the community’ (Auvert et al., 2013).

4. Researchers involved in the trials and other MC scholars have addressed criticisms by opponents other than de Camargo et al. about ‘confounding factors’ and ‘externalities’ (Auvert et al., 2006; Klausner et al., 2008; Wamai et al., 2008, 2012; Banerjee et al., 2011; Morris et al., 2011, 2012b; Wamai & Morris, 2011). As an example, de Camargo et al. cite the MC critics Dowsett and Couch (2007) who, in light of the results of the RCTs, seem puzzled that some ecological studies show higher prevalence of HIV in circumcising compared to non-circumcising communities. Scholars with expertise in MC and HIV have, however, discussed the operational dynamics, using as a basis a critical examination of demographic data in the context of socio-economic and cultural issues (Deeks, & Volmink, 2003; Siegfried, Muller, Gersovitz, 2005; Wamai et al., 2008, 2011). MC could be a proxy for knowledge, behaviour or socio-economic status (Siegfried, Muller, Deeks, & Volmink, 2003). Thus, it is not surprising that HIV prevalence would be higher where MC is higher among relatively wealthier and more educated men who also tend to have more sex partners, as applies in Tanzania and Zimbabwe (National Bureau of Statistics (NBS) [Tanzania] and ICF Macro, 2011; Wamai et al., 2011; Zimbabwe National Statistics Agency & ICF International, 2012).

de Camargo et al. point to the ‘effectiveness’ of condoms in prevention of HIV infections in San Francisco, but fail to consider (i) a systematic review that included a trial, showing condom efficacy was 85% for consistent use (Weller & Davis, 2002) and (ii) the lack of consistent condom use and demonstrated effectiveness in generalized HIV epidemics in SSA (Bankole, Ahmed, Neema, Ouedraogo, & Konyani, 2007; Potts et al., 2008; Maticka-Tyndale, 2012). Although the 100% condom programme among sex workers in Thailand showed success (UNAIDS, 2000), a recent Cochrane systematic review of the seven RCTs of condoms found ‘little clinical evidence of effectiveness’ and no ‘favourable results’ for HIV (Lopez et al., 2013). The reality is that, for various reasons, use of condoms in both high and low prevalence settings remains at a level that is below that required to reach significant prevention thresholds at a population level (Agha, Kusanthan, Longfield, Klein, & Berman, 2002; Foss, Hossain, Vickerman, & Watts, 2007; Agius, Pitts, Smith, & Mitchell, 2010; Kennedy, Medley, Sweat, & O’Reilly, 2010; Warner, 2010; Scott-Sheldon, Huedo-Medina, Warren, Johnson, & Carey, 2011; WHO/UNAIDS/UNICEF, 2011; Geibel, 2013; Jones et al., 2013), and is declining in countries with high HIV prevalence such as Uganda, Côte d’Ivoire and South Africa (UNAIDS, 2013; Shisana et al., 2014).

Concerns by authors such as Berer (2007) and Green et al. (2010) that promoting MC jeopardises condom use, while important, are not borne out by the current evidence. The RCTs did not find a decrease in condom use (Auvert et al., 2005; Bailey et al., 2007; Gray et al., 2007). A meta-analysis of sexual behaviour in the trials found no significant difference between intervention and control groups (Siegfried et al., 2009). Furthermore, most studies continue to show neither evidence of disinhibition, nor of risk-compensation (Agot et al., 2007; Mattson et al., 2008; Mehta et al., 2009; Ayiga and Letamo, 2012; Crosby, Ricks, &

Young, 2012; Grund & Hennink, 2012; Kong et al., 2012; Wilson, Xiong & Mattson, 2012). Although a qualitative study in Swaziland did identify contexts in which risk compensation may arise, the authors of that study noted that MC is 'likely to foster protective behaviour change among men' (Grund & Hennink, 2012). Because of the complex nature of sexual behaviour, continued vigilance and ongoing improvements in methodological designs has been advocated (Crosby et al., 2012; Underhill, 2013). To this end, one study from the VMMC rollout in Kenya showed minimal risk compensation (Westercamp, Agot, Ndinya-Achola, & Bailey, 2012), while more recent findings show men understand that MC provides partial protection and therefore need to continue other protective measures (L'Engle, Lanham, Loolpapit, & Oguma, 2014). It is also well recognised that risk compensation and disinhibition are not just concerns for MC but also for pre-exposure prophylaxis and many other public health interventions (Holt et al., 2012; Lockman & Sax, 2012; Kalichman et al., 2010, 2013).

MC researchers have long emphasised the need to continue advocating interventions that work in HIV prevention with greater investment in those exhibiting evidence of stronger effectiveness (Potts et al., 2008; Wamai et al., 2008, 2012; Center for Global Health Policy, 2010; Morris et al., 2012b; Rosario and Kasabwala, 2013). Thus the suggestion by de Camargo et al. that biomedical interventions (MC and anti-retrovirals) have 'relegated to the background' the promotion of the condom as part of the individual responsibility of managing 'sexuality' [sic] is not borne out by the evidence. The use of multiple approaches, now termed 'combination prevention', is advocated by HIV authorities in the light of growing evidence of the value of synergising interventions in combination to populations for optimal effectiveness in saving lives and costs (Potts et al., 2008; UNAIDS, 2010, 2013; Kurth, Celum, Baeten, Vermund, & Wasserheit, 2011; Shattock, Warren, McCormack, & Hankins, 2011; Wamai et al., 2011; Bärnighausen, Bloom, & Humair, 2012; Cohen & Baden, 2012; Goosby et al., 2012; Long & Stavert, 2013; Rosario & Kasabwala, 2013; Nsubuga Jones et al., 2014; White, Mayanja, & Shafer, 2014). Combination prevention provides more options to individuals and communities, aligning with Sen's notion of expanding capabilities for people to live the life they value (Sen, 1999), and offers the prospect of effectively reducing HIV 'from a pandemic to low-level endemicity' (Jones et al., 2014). Aral and Peterman (1998) define effectiveness as outcomes realised under normal conditions in regional or whole populations. To achieve effectiveness, an efficacious tool requires correct use every time (Kippax, 2012). As a once-and-for-all procedure MC is unique compared to interventions requiring consistent, constant and correct use to be effective.

Public health policy considerations in adopting VMMC

Even when behavioural factors can be overcome, translating science into policy and then structural implementation can be a complex process as a result of various underlying important societal considerations (Gostin & Hankins, 2008; Behague et al., 2009; Gebbie, 2009; Rotheram-Borus, Swendeman, & Chovnick, 2009; Heidari, Harries, & Zachariah, 2011; Hunsmann, 2012; Kippax, 2012; Gray, Wawer, & Kigozi, 2013; Timmermans, 2013). Several programmatic aspects of VMMC for HIV prevention have been criticised. The criticisms question the inclusiveness of discussion and consideration of cultural

acceptability, cost, cost-effectiveness and ethical issues prior to adoption of policy. Indeed, to ensure success in implementation, these are critical issues policy-makers and decision-makers should keep in mind. And the evidence from the countries adopting VMMC in SSA contradicts the claims by opponents of VMMC that the process of policy development and implementation was flawed. To start with, the argument that in adopting MC as policy, global and national institutions were mistaken and therefore there should have been a 'more reasoned discussion' (de Camargo et al., 2013) ignores several important matters:

1. There were extensive discussions, spanning at least two decades, about the evidence from observational and ecological studies after MC for HIV prevention was proposed by Fink (1986) and later in analyses of data available up to that time by Cameron et al. (1989), Moses et al. (1990, 1994) and Halperin and Bailey (1999) that MC could help prevent HIV infection. During this time, even as evidence accumulated, policy makers largely disregarded MC for various reasons (Halperin & Bailey, 1999; Aggleton, 2007).

2. Policy recommendations were formulated and adopted by the WHO and UNAIDS (2007b, 2008, 2012) only after results from all the three RCTs establishing beyond reasonable doubt that MC does reduce HIV infection in heterosexual men were available (Auvert et al., 2005; Bailey et al., 2007; Gray et al., 2007; Mills, Cooper, Anema, & Guyatt, 2008; Siegfried et al., 2009). The prior observational studies, including a review of 37 of these (Siegfried et al., 2005), plus the first RCT (Auvert et al., 2005) were not considered sufficient to recommend adoption of VMMC as an intervention. It was only after results from two additional RCTs became available that extensive discussions, led by international normative agencies, that VMMC was recommended as an addition to the limited armamentarium of weapons available to fight the HIV epidemic.

3. Policy development for implementation of VMMC was not confined to international agencies. Debate and open discussion with a multitude of stakeholders from a broad spectrum of backgrounds took place in every country and contributed to the policy guidelines and legislative actions that were developed (WHO & UNAIDS, 2007b, 2008; Mwandi et al., 2011; Wamai et al., 2011; UNAIDS & WHO, 2011; Tumwesigye, Nakanjako, Wanyenze, Akol, & Sewankambo, 2013). Ensuing discussions on development of policy guidelines since completion of the RCTs in 2007 have considered contextual, cultural and religious issues (UNAIDS, 2007). Evaluations that have discussed the biomedical and cultural ethics have led to conclusions that underscore the value placed on MC in disparate settings of HIV epidemiology and social, cultural and political traditions (UNAIDS & WHO, 2011; AAP Task Force on Circumcision, 2012; American Jewish Committee Berlin Office, 2012; Ben-Yami, 2013).

4. de Camargo et al. ignore pro-MC policies of countries outside of SSA. The AAP Task Force on Circumcision (2012) produced a policy based on 'current evidence' strongly supporting infant MC, as did the Centers for Disease Control and Prevention (Smith et al., 2010), and there has been a call for safeguarding it (Lancet, 2012). In Australia a policy statement by the Royal Australasian College

of Physicians (RACP) Paediatrics & Child Health Division (2010) did not engage the breadth of the current evidence and was subjected to a withering critique in a peer-reviewed article published in an official journal of the RACP (Morris et al., 2012c). In the Netherlands the Royal Dutch Medical Association (KNMG) published a 'viewpoint' which failed to endorse infant MC and which stated that the view expressed was not based on prevailing evidence (KNMG, 2010). A statement by the Royal College of Paediatrics and Child Health in the UK was, by its own admission, 'not evidence based on a consensus' (http://www.bapu.org.uk/wp-content/uploads/2013/03/circumcision2007.pdf).

There have been various challenges to the legality of circumcision of male minors. In each instance the arguments used have been exposed as legally and ethically flawed (Bates et al., 2013; Morris & Tobian, 2013) and bans have never been instituted. For example, a report by the Tasmanian Law Reform Institute posted on the Internet led to an outcry by medical practitioners, followed in due course by a critique by a lawyer, a bioethicist, paediatricians, STI academics and public health advocates (Bates et al., 2013). In the USA the so-called 'MGM Bill' presented to the US Congress every year for over a decade has been repeatedly rejected (Morris & Tobian, 2013). In Germany a decision by a regional court in Cologne questioning the legality of childhood MC stimulated passionate debate, and ultimately Government legislation upheld the right of parents to have their minor male children circumcised (American Jewish Committee Berlin Office, 2012). This has been followed by a similar trend validating the rights of parents to make medical decisions on the behalf of their children in other European countries. After weighing the benefits of MC against risks, policy makers have recognised that legal and ethical considerations support the right of parents to make decisions about circumcision of their infant boys, much as they do vaccinations, and of adult men to choose to undergo the procedure (Clark, Eisenman & Szapor, 2007; UNAIDS, 2008; AAP Task Force on Circumcision, 2012; Morris et al., 2012a; Ben-Yami, 2013; Morris, Bailis, & Wiswell, 2014).

Although the biomedical evidence shows benefits outweigh risks (AAP Task Force on Circumcision, 2012; Morris et al., 2012a; Morris, Bailis, & Wiswell, 2014) this has not guaranteed the adoption of policies in all jurisdictions. In light of this, the call by de Camargo et al. for a 'more reasoned discussion' would actually entail opinions being set aside and would instead involve a thorough engagement with multiple scholarly evidence now available. This process has indeed been undertaken in numerous MC scale-up countries throughout SSA (UNAIDS & WHO, 2011, 2012; Wamai et al., 2011; UNAIDS 2013), in the USA (AAP Task Force on Circumcision, 2013), Australia (Morris et al., 2012c), in Germany by the Federal Parliament (American Jewish Committee Berlin Office, 2012) and Norway (Xinhua News Agency, 2014). Of the utmost importance is establishing guidelines that are context specific within the prevailing epidemiological, socio-demographic, and health system needs (UNAIDS, 2008; Dickson et al., 2011; Lie & Miller, 2011; AAP Task Force on Circumcision, 2013; Rosario and Kasabwala, 2013).

Besides questioning the nature of adoption of VMMC for HIV prevention, de Camargo et al. state that this concept was proposed 'by European and North American researchers' and therefore has 'echoes of a colonial past.' A similar notion was repeated by Bell (2014) in the

present journal. The argument has two main problems. First, if by ‘researchers’ they mean the authors of the three RCTs then the claim is misleading because many of the total of 23 authors were in fact from the countries in which the trials were conducted (Auvert et al., 2005; Bailey et al., 2007; Gray et al., 2007), as previously noted by Wamai et al. (2012). Secondly, having also considered the local context (cultural acceptability, HIV epidemiology), the circumcision policy proposal has broad support from all global health organisations as well as governments and local authorities of the countries where the intervention is being carried out (WHO & UNAIDS, 2007; UNAIDS, 2008; Mwandi et al., 2011; Tumwesigye, Nakanjako, Wanyenze, Akol, & Sewankambo, 2013; WHO, 2013). Additionally, if endorsement of a scientifically proven approach to alleviate a serious global infectious disease is cast in such a light then all international interventions, including alleviation of poverty and rollout of vaccination programmes, should also be questioned. This context acknowledges the importance of considering the concept of ‘bio-power’ in global health policy implementation (Kleinman, 2010). External or international health and social policies that have no acceptance by policy makers at the national level and by local target communities would be an imposition and can hardly be adopted or be effective. However, regardless of who produces it, rejection of compelling scientific evidence with strong population health benefits would be, as Collins (2009) argues, ‘too awful to contemplate.’

Another noteworthy policy question raised by de Camargo et al. is that of the cost and cost-effectiveness of MC as an intervention. They cite MC critics McAllister et al. (2008) who claim that use of condoms or anti-retrovirals (ARVs) is ‘more cost-effective.’ McAllister et al. did not, however, provide any data to support their claim, nor has any evidence in support emerged since their publication. On the other hand, economic evaluations have strongly supported adoption of MC (Williams et al., 2006; Bärnighausen et al., 2012; Verguet, 2013). The first Cochrane review of MC data following the initial RCT in 2005 and the second, which followed the publication of the second and third RCTs in 2007, stated the need for cost-effectiveness studies for guiding policy (Siegfried et al., 2005, 2009). Since then multiple modelling studies and systematic reviews have demonstrated that MC is highly cost-effective in comparison with other biomedical or behavioural interventions (Galarraga, Colchero, Wamai, & Bertozzi, 2009; UNAIDS/WHO/SACEMA Expert Group on Modeling the Impact and Cost of Male Circumcision for HIV Prevention, 2009; USAID, 2009; Njeuhmeli et al. 2011; Bärnighausen et al., 2012; Duffy, Galukande, Wooding, Dea, & Coutinho, 2013; Kahn & Marseille, 2013; Long & Stavert, 2013; Verguet, 2013). In comparison to treatment of infected individuals, one of these recent cost-effectiveness analyses found that, ‘the most cost-effective HIV prevention strategy is to expand MMC coverage and then scale up ART, but the most cost-effective HIV-mortality reduction strategy is to scale up MMC and ART jointly’ (Bärnighausen et al., 2012).

de Camargo et al. seem to agree with the provocative argument by Aggleton (2007) that MC is ‘enacted upon others by those with power.’ This argument is fallacious. It does not apply to the RCTs, nor does it apply to the current implementation of VMMC scale-up in countries with high HIV epidemics and where proper guidelines and clinical standards are followed (WHO & UNAIDS, 2008; Bertrand et al., 2013; PEPFAR, 2013). VMMC is not forced on subjects: the ‘V’ in ‘VMMC’ stands for ‘voluntary’.’ Thus contrary to assertions by

opponents, VMMC neither ignores nor breaches consideration of ethics or human rights (Lie, Emanuel, & Grady, 2006; Morris, 2007; Rennie et al., 2007; UNAIDS, 2008; AAP Task Force on Circumcision, 2012; Ben-Yami, 2013). In response to the issue of MC acceptability raised by Sawires et al. (2007), de Camargo et al. correctly note that Westercamp and Bailey (2007) had examined it. The high median level of MC acceptability (65%) in the study by Westercamp and Bailey (2007) in nine SSA countries counters the claim by de Camargo et al. of MC being 'enacted upon' others as though they had no choice.

The authors also fail to observe numerous other studies showing high cultural acceptability among men and women in multiple non-circumcising settings (Lukobo & Bailey, 2007; WHO & UNAIDS, 2007a; Mugwanya et al., 2011; Gasasira et al., 2012; Morris et al., 2012a; Waters et al., 2012; Westercamp, Agot, Ndinya-Achola, & Bailey, 2012; Jones, Weiss, Arheart, Cook, & Chitalu, 2013; Layer et al., 2013; Plotkin et al., 2013). Failing to consider the extensive evidence of high acceptability of MC leaves the reader with the impression that the proposals for acceptability studies by the South African RCT study team (Auvert et al., 2005) and the Cochrane Collaboration (Siegfried et al., 2005,2009) have not yet been addressed. In fact, a 'keyword' search for 'acceptability' in the database of the Clearinghouse on Male Circumcision, a collaborative effort supported by multiple HIV/AIDS institutions such as UNAIDS and WHO, yields 122 studies as of July 2014 (http://www.malecircumcision.org/wikindx3/index.php?action=searchDisplay). Overall, the studies show high acceptability for VMMC by both men and women, despite fear of pain, culture, and information gaps having been cited for slow uptake in certain locations (Mavhu et al., 2011; Dionne & Poulin, 2013; Plotkin et al., 2013; Chinkhumba, Godlonton, & Thornton, 2014). It should therefore be self-evident that the acceptability now apparent shows a change in societal attitudes and practice of MC over time across numerous cultures in SSA, a fact not without historical precedent elsewhere in Africa, Europe, Asia and the United States of America (Kenyatta, 1965; Gollaher, 2000; Aggleton, 2007; Frederiksen, Kenyatta, Bonaparte, & Malinowski, 2008; Madhivanan et al., 2008; Angulo & Garcia-Diez, 2009; Kaicher & Swan, 2010; Schneider et al., 2010; Cox & Morris, 2012; Timberg & Halperin, 2012; Yang et al., 2012; Darby & Cozijn, 2013).

Additionally, de Camargo et al. challenge experimental evidence and biomedical interventions seemingly in favour of behavioural change and policy procrastination. Promotion of behavioural change by mass media communication, testing and peer education has had mixed success in heterosexual and MSM populations in SSA and elsewhere, especially among those uninfected (Darbes et al., 2002; Bertrand et al., 2006; Kennedy, Medley, Sweat, & O'Reilly, 2010; McCoy, Kangwende, & Padian, 2010; Lorimer et al., 2013). Behavioural change interventions require unrealistic targets to be effective (Nsubuga, White, Mayanja, & Shafer, 2014) and are less cost-effective (Galarraga, Colchero, Wamai, & Bertozzi, 2009; Hsu et al., 2013). Given the high quality of the evidence for the protective effect of MC against HIV and its cultural acceptability, should the public health community withhold this proven intervention in order to instead pursue other strategies whose effectiveness has been proven to be lower and more costly? As an example, should recent evidence showing that TasP can be highly effective (Granich, Gilks, Dye, & De Cock, 2009; Cohen et al., 2011) be ignored in favour of behavioural change or MC? We think not. Or should vaccination against sexually transmitted human papillomavirus types 16 and 18 to

help reduce cervical cancer (Agosti & Goldie, 2007; WHO, 2009; Knaul, Frenk J., & Frenk S., 2011) be withheld and replaced by policies to reduce risky sexual behaviour instead? Certainly not where those targeted also favour it. Rather, effective policy decisions are informed by the highest quality scientific evidence available (Baltussen & Niessen, 2006; Brownson, Chriqui, & Stamatakis, 2009; Collins, 2009; Chan, 2012; Das & Samarasekera, 2012; Kim, 2012). Policy procrastination over proven and acceptable interventions can cost lives, as happened in South Africa due to failure to provide ARVs (Chigwedere et al., 2008).

Thus denying access to provision of MC in the face of community acceptability and demand can be regarded as failing to meet human rights to better health from a proven medical intervention that can save millions of lives and reduce suffering and costs of health care (Potts, 2000; Lie et al., 2006; Potts et al., 2008; UNAIDS/WHO/SACEMA Expert Group on Modeling the Impact and Cost of Male Circumcision for HIV Prevention, 2009; USAID, 2009; Sansom et al., 2010; UNAIDS, 2010; Dickson et al., 2011; Lie & Miller, 2011; Njeuhmeli et al., 2011; Shattock et al, 2011; American Jewish Committee Berlin Office, 2012; Bärnighausen et al., 2012; Kacker, Frick, Gaydos, & Tobian, 2012; Morris et al., 2012a, 2012b, 2012c; Wamai et al., 2012; AAP Task Force on Circumcision, 2013; Auvert et al., 2013; Bates et al., 2013; Long & Stavert, 2013; Rosario & Kasabwala, 2013; Morris, Bailis, & Wiswell, 2014). There is a need to safeguard VMMC everywhere (Center for Global Health Policy, 2010; Templeton, 2010; Lancet 2012; Jones et al., 2014; Morris, Bailis, & Wiswell, 2014). The world cannot afford the cost of inaction. The Global Fund for HIV/AIDS, TB and Malaria (2013) estimates that the cost of inaction over scale-up of HIV prevention services, would result in a total of 3.9 million new HIV infections in 2014–2016 and US$47 billion in costs throughout the lifetimes of those whose infections could have been avoided.

Likewise, the cost for inaction in meeting a target of 20 million VMMCs in the 14 SSA countries would be 4 million (22% of the estimated) new infections and US$20.2 billion lost during 2009–2025 (UNAIDS/WHO/SACEMA Expert Group on Modeling the Impact and Cost of Male Circumcision for HIV Prevention, 2009; USAID, 2009). To achieve the estimated population-level impact of MC in the now 16 ‘priority’ SSA countries (UNAIDS, 2013) this biomedical intervention needs to be scaled up rapidly, especially in high-risk groups in which it would be even more cost-effective (Chinkhumba, Godlonton, & Thornton, 2014). We agree with Gostin and Hankins (2008) that to realise this goal MC has to be ‘acceptable, available, and safe; sensitive to cultural and religious values; respectful of patients’ rights to consent and confidentiality; and defend the human rights of girls and women’. The overall evidence from the 14 scale-up countries in SSA is that these ‘socio-legal barriers’ (Gostin & Hankins, 2008) are being overcome and countries are now accelerating VMMC. The latest reports are that by March 2014 the number of circumcisions has reached six million (30% of the target), with coverage in Kenya (87%) being highest (Z. Mwandi and R.C. Bailey, personal communication), which is considered as a ‘success’ (Galbraith et al., 2014). The goal of achieving 20 million circumcisions by 2015 was overly ambitious, especially because most countries, with the exception of Kenya and South Africa, had not commenced major programming as of mid-2011 (Wamai et al., 2011). This was not, however, unexpected (Justman et al., 2013). Although a strategy that works in one country may not work in another, ongoing experience shared between countries, innovative diffusion

and health systems models, and sustained funding to meet demand and eliminate cost and informational barriers (Goosby et al., 2012; Gray, Wawer, & Kigozi, 2013; Justman et al., 2013; WHO, 2013; Chinkhumba, Godlonton, & Thornton, 2014; Galbraith et al., 2014; Stone, 2014; Weintraub et al., 2014), can ensure the progress being made in implementation of safe, acceptable, high quality VMMC programs in these countries is accelerated.

Conclusion

Despite having been challenged by sceptics, the evidence that VMMC is a safe, acceptable, efficacious, cost-effective intervention for reducing risk of HIV infection in heterosexual men in SSA justifies its implementation. Criticisms of the evidence of MC for HIV prevention raised by de Camargo et al. (2013) and Bell (2014) are flawed. It appears the critics are either unfamiliar with, or choose to ignore, much of the growing scientific literature, particularly studies conducted subsequent to the completion of the RCTs. The post-trial studies have now answered many of the questions raised by the trial authors and others. The policy process has involved careful consideration and acceptance of the scientific evidence, including the biological efficacy and the relevant social and economic elements. This process has been broadly collaborative and inclusive, spearheaded by international normative agencies and local Ministries of Health. The service infrastructure in scale-up countries is being strengthened and progress towards the goal of high coverage is accelerating, with Kenya already surpassing the target a year ahead of schedule. The potential effectiveness of VMMC should not be assessed on the basis of the RCTs alone, but should consider the numerous observational studies that provided initial contextual evidence and the studies subsequent to completion of the trials.

In light of the continuing accumulation and strengthening of evidence of the efficacy and emerging effectiveness of MC for HIV prevention, risk-benefit and cost-effectiveness analyses of behavioural, pharmaceutical and VMMC approaches, policy recommendations by global health institutions and ethical considerations, we consider that withholding of VMMC in settings experiencing high generalised HIV epidemics is unethical (Clark, Eisenman, & Szapor, 2007; Ben-Yami, 2013; Morris et al., 2014). As Clark, Eisenman, & Szapor (2007) emphasise, ‘to deny individuals access to this effective therapy is to deny them the dignity and respect all persons deserve’. Consideration of the totality of research on the health benefits of MC to date supports the adoption, promotion and advocacy of this procedure for prevention of heterosexually acquired HIV, as well as several other common STIs, other adverse medical conditions and genital cancers in both sexes (Morris, 2007; Golden & Wasserheit, 2009; Tobian, Gray, & Quinn, 2010; Morris et al., 2012a, 2014). Adoption and implementation of VMMC as a component of the HIV prevention tool kit thus has merit and is fully in line with conventional considerations used for adoption of evidence-based policies that underscore public health programmes (Hill 1965; Baltussen & Niessen, 2006; Brownson, Chriqui, & Stamatakis, 2009; Collins, 2009; Lie & Miller, 2011). Continued monitoring and vigilance to safeguard high clinical and ethical standards can ensure the goal of population-level effectiveness of VMMC in stemming the tide of HIV in SSA is realised.

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