Ethical Considerations Surrounding Voluntary Medical Male Circumcision (VMMC) in South Africa as an Intervention for HIV Prevention

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Abstract

In efforts to combat the global HIV/AIDS pandemic, the WHO/UNAIDS published the *Joint Strategic Action Framework to Accelerate the Scale-up of Voluntary Medical Male Circumcision for HIV Prevention in Eastern and Southern Africa* which outlines the aim of a VMMC (voluntary medical male circumcision) prevalence of 80% among males 15-49 year old in 14 countries by 2016 (WHO/UNAIDS, 2011). In line with this directive, South Africa has launched a national VMMC campaign.

However, a lot of ethical issues remain unaddressed surrounding VMMC. These can be categorised as individual considerations (autonomy and informed consent; non-maleficence and unintentional, unforeseen harm; risk compensation in circumcised men; risk of undermining current HIV prevention strategies; age of circumcision), community considerations (cultural considerations; justice: the gender divide and female subjugation; distributive justice; social stigmatisation as a result of VMMC), national considerations (adverse events and complications on a macro level; cost saving and unforeseen expenditure of VMMC; the implications of international funding for VMMC; the public health ethics of VMMC; risks of "de-medicalisation" of a surgical procedure; the ever present danger of corruption), global considerations (female genital mutilation; non-sexual HIV transmission; a dangerous shift in focus) and other considerations (a statistical perspective on VMMC; circumcision technique; lack of ethical awareness; dealing with medical uncertainty).

Finally, I shall consider neonatal circumcision, which is in itself a contentious issue, and has no role to play in VMMC.

The unresolved issues raised by these ethical considerations cast doubt on the moral status of VMMC and I conclude that the VMMC campaign as it stands in South Africa currently is morally indefensible. There is, undeniably, a pressing need for HIV/AIDS prevention strategies in South Africa and other developing countries but the role of circumcision has been overemphasised to the detriment of more holistic approaches. While there are no easy answers to any of the ethical dilemmas presented in this thesis, it is imperative to raise ethical awareness surrounding VMMC.

Abstrak

In 'n poging om die globale MIV/VIGS-pandemie te bekamp, het die WHO/UNAIDS in 2007 die *Joint Strategic Action Framework to Accelerate the Scale-up of Voluntary Medical Male Circumcision for HIV Prevention in Eastern and Southern Africa* gepubliseer wat 'n aksie-plan is wat poog om 'n voorkoms van VMMC (vrywillige mediese manlike besnyding) van 80% in 14 lande onder 15-49 jaar oue mans in 2016 (WHO/UNAIDS, 2011) te bewekstellig. In ooreenstemming met dié riglyn, het Suid-Afrika 'n nasionale VMMC veldtog geinnisiëer.

Maar baie van die etiese kwessies verbonde aan VMMC is nie bevredigend aangespreek nie. Hierdie kwessies kan geklassifiseer word onder individuele oorwegings (outonomie en ingeligte toestemming; nie-kwaadwilligheid en onbedoelde, onvoorsiene skade; risiko vergoeding in mans wat besny is; VMMC ondermyn die huidige MIV-voorkoming strategieë; ouderdom van besnyding), gemeenskap oorwegings (kulturele oorwegings; geregtigheid: die oorweging van die geslag verdeel en vroulike onderdanigheid; distributiewe geregtigheid; sosiale stigmatisering as gevolg van VMMC), nasionale oorwegings (newe-effekte en komplikasies op 'n makro-vlak; kostebesparing en onvoorsiene uitgawes van VMMC; die implikasies van internasionale befondsing vir VMMC; die openbare gesondheid etiek van VMMC; risiko's van "de-medikalisering" van 'n chirurgiese procedure; die alomteenwoordige gevaar van korrupsie), globale oorwegings (vroulike genitale verminking; nieseksuele oordrag van MIV; 'n gevaarlike verskuiwing in fokus) en ander

oorwegings ('n statistiese perspektief op VMMC; besnyding tegniek; die gebrek aan bewustheid van hierdie etiese kwessies; die hantering van mediese onsekerheid) bespreek.

Ten slotte, sal ek neonatale besnyding ondersoek, wat op sigself 'n omstrede kwessie is, en geen rol behoort te speel in VMMC nie.

Die onopgeloste kwessies wat deur hierdie etiese oorwegings aan die lig gebring word veroorsaak twyfel oor die morele status van VMMC. Ek lei dus af dat die VMMC veldtog soos dit tans bestaan in Suid-Afrika moreel onverdedigbaar is. Daar is ongetwyfeld 'n dringende behoefte vir MIV/VIGS-voorkoming strategieë in Suid-Afrika en ander ontwikkelende lande, maar die rol van besnydenis word oorbeklemtoon ten koste van 'n meer holistiese benadering. Hoewel daar geen maklike antwoorde op enige van die etiese dilemmas wat in hierdie skripsie verken is nie, is dit noodsaaklik dat etiese bewustheid rondom VMMC verhoog word.

Dedication

For Dr Kok

Who inspired me with his cries of "Save the foreskin!"

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Chapter 1: Introduction

Circumcision can be defined as the surgical removal of all or part of the foreskin of the penis and it may be incorporated into religious rituals, a medical procedure for various pathological conditions or traditionally as part of a ritual for initiation into manhood (Siegfried *et al.*, 2011).

VMMC refers to voluntary medical male circumcision and has been brought to prominence in the last decade by renewed interest in this surgical intervention for the purpose of human immunodeficiency virus (HIV) prevention, which has spawned a wealth of research on the subject. In 2007, the World Health Organisation (WHO), in conjunction with UNAIDS (the Joint United Nations Programme on HIV/AIDS), published a policy document on VMMC, followed by the Joint Strategic Action Framework to Accelerate the Scale-up of Voluntary Medical Male Circumcision for HIV Prevention in Eastern and Southern Africa in 2011. This document outlines the aim of a VMMC prevalence of 80% in 14 countries among 15-49 year old males by 2016 (WHO/UNAIDS, 2011) which implies 20.3 million circumcisions will have to be carried out in order to meet this goal. South Africa has followed the initiative issued by the WHO by drawing up the National Strategic Plan on HIV, STIs and TB 2012 - 2016 (2012, p.14) in which it states the aim of "increasing access to a package of sexual and reproductive health services", including medical male circumcision for adults and neonates.

Circumcision has been practiced since antiquity. Some of the earliest records are depictions of male circumcisions on Egyptian sarcophagi, dating back to 2345 – 2182 BC (Aggleton, 2007). According to the Greek historian Herodotus, circumcision was practised in Egypt as early as the fifth century BC (Aggleton, 2007). It is also an integral part of Semitic tradition, where circumcision forms part of a covenant with God dating back to Abraham (Aggleton, 2007).

In the modern world, circumcision has always had a rather controversial history, with advocates on both sides feeling very strongly on the matter. It gained popularity in the 1800s under the auspices of doctors such as Ricketts (1894 cited in Aggleton, 2007, p19), who claimed circumcision could cure maladies as diverse as "eczema, oedema, elephantiasis, gangrene, tuberculosis, hip joint disease, enuresis, general nervousness, impotence, convulsions and hystero-epilepsy". Remondino (1891 cited in Aggleton, 2007, p19) believed the prepuce exerted a malign influence on a man in general and was responsible for "making him a victim to all manner of ills, sufferings and tribulations; unfitting him for marriage or the cares of business; making him miserable and an object of scolding in childhood... beginning to affect him with all kinds of physical distortions and ailments, nocturnal pollutions, and other conditions... calculated to weaken him physically, mentally and morally; to land him, perchance, in jail or even in a lunatic asylum", while Kellogg viewed circumcision as a cure for masturbation as well as the social ills he believed stemmed from masturbation (Aggleton, 2007). Miller (2002) demonstrates that these Victorian physicians were remarkably influential in the creation of social and cultural norms that demonise the foreskin as the root of moral and physical decay and attach values of being polluted, chaotic, and bad.

With the medical advances of the 20th century, circumcision lost its popularity in the medical community due to increasing concerns about risks and complications, the widespread use of antibiotics, changing attitudes regarding sexual enjoyment and the de-vilification of masturbation (Darby, 2005). In his study of circumcision in Anglophone countries, Darby (2005, p.35) states that "routine circumcision began as a doctor-driven innovation, became established in the medical repertoire, spread rapidly, and then declined slowly as doctors ceased to recommend it." However, the advice had created a social norm and following generation continued to ask for circumcision for their children, especially circumcised fathers (Darby, 2005). Today, some developed countries like the United States of America have high circumcision rates due to majority preference, quite unrelated to religious or cultural beliefs. In Australia, Hutson (2004, p.238) reports "the commonest reason for requesting circumcision is the father's desire for the baby to look like himself." Darby (2005, p.35) concurs that "the fundamental reason for the circumcision of boys is a population of circumcised adults." The medical community is subject to the same social conventions as the rest of the general population, as doctors continue to perform circumcisions despite the lack of medical indications which Dristas (2001) suggests may be due to the apprentice model in which doctors are taught and also because changing their practices may be perceived as calling into question past practices and admittance of error.

Circumcision is widely practised for religious purposes as it plays a prominent role in Islam and Judaism, while in Africa the practice also holds cultural

significance as a rite of passage, predominantly in northern and western Africa, as well as locally in several southern African cultures.

All aspects of medical practice carry with them ethical dilemmas at one point or another. Circumcision is no different, and the matter becomes even more complex when we consider conflicting medical evidence on whether circumcision is beneficial or harmful, the need for a respectful attitude towards different religious and cultural beliefs and the issues behind neonatal circumcision, where the infant cannot voice an opinion. The ethical quandary becomes even further complicated when we add the agenda of HIV prevention to the surgical act of circumcision. It is almost unprecedented that a surgical procedure should be undertaken for prevention of a lifestyle disease with myriad and poorly understood behavioural, social, cultural and personal intricacies. And yet, while VMMC has received considerable attention these past few years both in medical and non-medical settings, the ethical considerations of VMMC have remained somewhat murky and, to date, largely unexplored.

A serious study of the ethical considerations surrounding VMMC requires finding a rational path between the two extremes. Detractors argue for the complete dismissal of VMMC on the basis of a rejection of male circumcision as a form of genital mutilation (Rennie *et al.*, 2007). Proponents, on the other hand, may harbour an overly optimistic interpretation of the evidence from the three RCTs that downplays the scientific, social, cultural and ethical uncertainties and makes the assumption that the transition of circumcision

research into health policy and practice will be straightforward and risk-free (Rennie *et al.*, 2007).

This thesis is an attempt to explore some of these ethical considerations. Firstly I shall consider the scientific evidence, both internationally and locally, of VMMC and its interpretation and then look at the media perceptions of VMMC. I shall move on to the ethical considerations, which I have considered on several levels, from individual, to community, to national, to global, followed by a discussion of neonatal circumcision and its role in VMMC campaigns and finally, share an anecdote from my personal experiences.

Chapter 2: Literature Review

There are three landmark RCTs that have effectively demonstrated that VMMC reduces the risk of female-to-male HIV infection. It was in light of these three studies that WHO/UNAIDS (2007) released a press release in March 2007 that recommended the inclusion of male circumcision into current HIV prevention measure guidelines in countries with low circumcision rates and generalised epidemics. So let us turn our attention first to these three studies.

The first, conducted by Auvert *et al.* (2005) in Orange Farm in South Africa, showed a 60% protection against HIV infection in the circumcised group as opposed to the control group. The other two studies, which took place in Rakai, Uganda (Gray *et al.*, 2007) and Kisumu, Kenya (Bailey *et al.*, 2007) showed that circumcision reduced the incidence of HIV infection in the circumcised group compared to controls by 51% in Uganda and 53% in Kenya. After adjustment for non-adherence, those participants found to be HIV positive at baseline and crossovers, the calculated protective rate was 76% in South Africa, 60% in Kenya and 60% in Uganda. These were all three very large trials of 3 274, 4 996 and 2 784 participants respectively. Interestingly, all three of these trials were stopped early by the data and safety monitoring boards when interim reviews revealed these results and all control group participants in all trials were offered circumcision at the end of the trials, making long term follow up impossible. Participants in the South African trial were only followed up until 21 months and in the other two trials until 24 months.

Based on the results of the South African RCT, simulation models suggest a predicted average of 2.0 (between 1.1 and 3.8) million new HIV infections and 0.3 (between 0.1 and 0.5) million deaths could be averted over the next 10 years in sub-Saharan Africa, assuming 100% uptake of male circumcision (Williams *et al.*, 2006). In the following ten years, a further 3.7 (between 1.9 and 7.5) million new HIV infections and 2.7 (between 1.5 and 5.3) million deaths could be averted, with about one quarter of these being in South Africa (Williams *et al.*, 2006). However, Williams *et al.* (2006, p.1032) also found that VMMC "will increase the proportion of infected people who are women from about 52% to 58%" and "where there is homogenous mixing but not all men are circumcised, the prevalence of infection in circumcised men is likely to be about 80% of that in uncircumcised men". They concluded that VMMC "is equivalent to an intervention, such as a vaccine or increased condom use, that reduces transmission in both directions by 37%" (Williams *et al.*, 2006, p.1032).

It is well known that when trials are stopped early the efficacy could be overestimated when compared to subsequent studies and it is essential to undertake long-term post-circumcision trial surveillance to determine the effectiveness of circumcision in populations with varying HIV prevalence, to assess the durability of any benefits observed in the trials and to monitor attitudes of risk compensation (Gray *et al.*, 2007). The claim that circumcision confers lifelong protection from HIV infection is certainly a stretch, and cannot be inferred from any of the RCTs done to date (Ncayiyana, 2011). And yet, the South African Medical Research Council (MRC) has adopted the position that "research on the effectiveness of male circumcision for preventing HIV acquisition in heterosexual men is complete. No further trials are required to

establish this fact" and that HIV infection rates are reduced in heterosexual men for at least the first two years after circumcision (Siegfried *et al.*, 2011, p.12).

The South African MRC's Cochrane Review (Siegfried *et al.*, 2011) metaanalysis combined the above three trials and concluded that there is strong evidence that VMMC reduces HIV infection in heterosexual men between 38% and 66% over 24 months. Under these conditions, the incidence of adverse effects was low and it can be considered a safe procedure. While they advised inclusion of circumcision into HIV prevention programs, they also advised that further research is necessary to assess feasibility, desirability and costeffectiveness in local contexts (Siegfried *et al.*, 2011).

However, the MRC's Cochrane Review also found that in the South African trial, men in the circumcised group practised more risky sexual behaviour, while in the Kenyan group circumcised men were consistently more sexually active and consistently engaged in unprotected sex (Siegfried *et al.*, 2011). Similarly in the Ugandan trial, circumcised men were consistently more sexually active (Siegfried *et al.*, 2011). All these findings are suggestive of behavioural disinhibition among circumcised men and yet selective quoting of this trial often leads circumcision proponents to reach different conclusions. While circumcision remained protective during the 24 month follow up period, it is not known whether this protective effect will last long term (Siegfried *et al.*, 2011). Each trial employed early stopping rules acceptable in statistical

practice, but this led to high attrition rates in each trial and possibly has caused an over-estimation of the treatment effect (Siegfried *et al.*, 2011).

These three landmark studies have not been without controversy. Van Howe and Storms (2011, p.e4) are vehemently opposed to, as they call it, "the circumcision solution" and claim that it will actually increase HIV infections. They build a strong argument against VMMC, as follows:

1. Questionable scientific evidence

They question the methodology of the three RTCs which were almost identical in execution, citing "expectation bias (both researcher and participant), selection bias, lead-time bias, attrition bias, duration bias and early termination that favoured the effect that the investigators were hoping for".

2. Lack of biological plausibility

While there are theories of why circumcision may decrease the risk of HIV infection, to date, this hypothesis that the foreskin is a predisposing factor to HIV infection has not been proven by any direct scientific evidence.

3. Lack of consistent epidemiological evidence

If circumcision did provide a 50-60% protection from sexually transmitted HIV infection, this should be apparent in the general population, especially in countries where men have traditionally circumcised, like Malawi, Rwanda, Cameroon, Ghana, Zimbabwe, Lesotho, Swaziland and Tanzania. As we shall see later, the observational studies done in the general population have found mixed results. In fact, a South African study showed no real difference, with 12.3% of

circumcised men testing HIV positive compared to 12.0% of intact men (Connolly *et al.*, 2008).

4. Risk compensation

Risk compensation occurs when people believe that an intervention provides additional protection and, due to the false sense of security that this creates, engage in higher risk behaviour. As a consequence of the increase in higher risk behaviour, the intervention either has no effect or actually increases the number of targeted events that it was put in place to avoid. This has been demonstrated empirically (Bailey, Neema & Othieno, 1999; Bonner, 2001; Seed *et al.*, 1995).

- 5. Leap of faith from RTC to real-life implementation
 The participants recruited for these RCTs were required to want to be circumcised. This introduced a selection bias and selected for high risk men. Thus, these results are not transferrable onto the general public.
- 6. The existence of more attractive, less invasive, less expensive, more effective alternatives

The "test and treat" model could reduce HIV infections by 55-73% and this intervention is directed at those most likely to benefit whereas the vast majority of men who are circumcised will not benefit from the procedure. Proponents of circumcision argue that a once-off surgical procedure is more cost-effective than supplying people with condoms indefinitely, however, this misses the point that circumcision *does not* remove the need for continued condom use. Moreover, the prevention rate of condoms can be as high as 99% which would make circumcision redundant.

They conclude that "the circumcision solution is a wasteful distraction that takes resources away from more effective, less expensive, less invasive

alternatives" and "by diverting attention away from these more effective interventions, circumcision programs will likely increase the number of HIV infections" (Van Howe & Storms, 2011, p.e4).

Boyle & Hill (2011, p.316) have also questioned the scientific validity of the three RCTs as "the trials were compromised by inadequate equipoise, selection bias, inadequate blinding, problematic randomisation, trials stopped early with exaggerated treatment effects and not investigating non-sexual transmission". They also question why trials were carried out in countries with a higher incidence of HIV in intact men as opposed to those where more circumcised men were HIV positive, why only certain ethnic groups were sampled, why large numbers of participants were lost to follow up and why intervention groups received additional counselling on safe sex practices compared to controls (Boyle & Hill, 2011). Wamai et al. (2012, p.93) have responded to these concerns by arguing for "the quality, consistency and robustness of the scientific evidence that underpins the public health recommendations, guidance and tools on VMMC". They claim that "millions of HIV infections will be averted in the coming decades as VMMC services scale-up to meet demand, providing direct benefits for heterosexual men and indirect benefits for their female partners" (Wamai et al., 2012, p.93).

Locally, VMMC has also come under intense scrutiny and criticism. Myers and Myers (2008, p.728) point out that while the RCTs are theoretically strong designs, their discordant findings compared to observation studies may imply that the results are not generalisable beyond research settings and have

concluded that "given the epidemiological uncertainties and the economic, cultural, ethical and logistical barriers, it seems neither justified nor practicable to roll out MC as a mass anti-HIV/AIDS intervention". Dan Ncayiyana (2011, p.775) has argued that "the illusive promise of circumcision to prevent female-to-male transmission of HIV infection is not the way to go for South Africa". He asks, "what man would want to accept circumcision and the associated risks, if he were made clearly to understand the need to continue to abstain, be faithful and/or condomise? What then would be the benefit?" (Ncayiyana, 2011, p.776)

In the debate that ensued following Dan Ncayiyana's editorial in the South African Medical Journal, Kesinger and Millard (2012, p.123) have defended the three RCTs that support VMMC stating that "there are few medical or public health interventions that are based upon evidence as strong and consistent as that for the effectiveness of male circumcision in preventing female-to-male transmission of HIV". Furthermore, they defend the decision to stop all three RCTs early as being made on ethical grounds by independent data and safety monitoring boards because evidence was considered strong enough to deem withholding circumcision unethical (Kesinger & Millard, 2012). Proponents of VMMC such as Kesinger and Millard (2012) consistently downplay the idea of risk compensation and defend the idea of cost savings through massive VMMC rollout (which shall be discussed later under ethical considerations). Ncayiyana (2012, p.125) has responded to these claims by urging a critical and cautious attitude as VMMC is essentially "the envisaged mass roll-out of a surgically invasive prophylactic intervention without historical parallel, and it is only appropriate that the project is deliberated within the medical profession

beyond the immediate circles of the panels and committees driving the initiative". While the science behind the three RCTs may in fact be sound, it is still vulnerable to "considerable interpretation creep along the way, with inferences of 'lifelong protection', and of benefits of neonatal circumcision that are not self-evident from the RCTs" (Ncayiyana, 2012, p.125).

Then there is also the question of what role traditional circumcisions should play, if any, with regards to HIV prevention. Several communities in South Africa have traditionally circumcised, and previously, these traditional circumcisions were strongly discouraged for many reasons, which is that they exposed people to HIV infection (Gwandure, 2011; Kepe, 2010). In the Eastern Cape, where the Xhosa population traditionally circumcises, the HIV prevalence rate is 11%, almost double that of the Western Cape, where circumcision is not routinely practised, at 6% (Ncayiyana, 2011). A South African survey found 12.3% of circumcised men tested HIV positive as opposed to 12% of uncircumcised men which would suggest circumcision has had no protective effect against HIV infection (Connolly et al., 2008). Circumcision proponents such as Venter et al. (2012) have criticised this finding, arguing that these statistics relied on self-reporting which is unreliable as the amount of foreskin removed in culturally performed circumcision varies. It is difficult to know how to take this criticism, as the amount of foreskin removed in a medical circumcision is similarly operator dependant, which would make this criticism equally valid against VMMC.

The idea that circumcision could somehow be related to HIV transmission is by no means a new one. It was first hypothesised by an American circumciser in 1986 (Fink, 1986) and leading up to the three RCTs, many observational studies were done that yielded mixed results. Large scale Demographic and Health Surveys were conducted between 2003 and 2007 to determine the relationship between male circumcision and HIV prevalence and incidence in sub-Saharan African countries that have generalised epidemics. A metaanalysis of all the data showed no effect of circumcision (Garenne, 2008). Among individual countries, "eight of those countries (including South Africa) showed no significant difference in seroprevalence in circumcised and uncircumcised groups, while two countries (Kenya and Uganda) showed lower HIV prevalence among circumcised groups, and three countries (Cameroon, Lesotho and Malawi) showed higher HIV prevalence among circumcised groups" (Garenne, 2008, p.1). Among observational studies conducted in the general population, six studies (Serwadda et al., 1992; Barongo et al., 1994; Seed et al., 1995; Kelly et al., 1999; Gray et al., 2000; Auvert et al., 2001b) found circumcision to be beneficial in HIV prevention while seven found no benefit (van der Perre et al., 1987; Barongo et al., 1992; Pison et al., 1993; Barongo et al., 1995; Grosskurth et al., 1995; Kisesa, 1996; Auvert et al., 2001a). However, all the studies done among high risk groups favoured of a protective effect of circumcision (Carael et al., 1988; Greenblatt et al., 1988; Simonsen et al., 1988; Cameron et al., 1989; Dialio et al., 1992; Gilks et al., 1992; Pépin et al., 1992; Telzak et al., 1993; Bwayo et al., 1994; Vaz et al., 1995; Mehendale et al., 1996; Nasio et al., 1996; Sassan et al., 1996; Tyndal et al., 1996; Lankoande et al., 1998; Lavreys et al., 1999; MacDonald et al., 2001).

A systematic review and meta-analysis published in 1999 found that circumcised men were at greater risk of acquiring and transmitting HIV than uncircumcised men (van Howe, 1999) while another systematic review and meta-analysis of all literature published by 1999 concluded that male circumcision is associated with a significantly reduced risk of HIV infection among high risk men in sub-Saharan Africa (Weiss *et al.*, 2000). While the mixed results from these observational studies clearly demonstrated the need for RCTs, the marked discrepancy in results between trials done in the general population versus those done in high risk groups should clearly demonstrate that data obtained from high risk groups is not generalisable to the general population. The three RCTs are considered to have been conducted in the general population, however, as van Howe and Storms (2011) point out, the fact that the trials required men to want to be circumcised could have selected for a high-risk population.

The conflicting conclusions drawn from the literature that I have presented here are what have created an ethical dilemma with regards to how we should proceed, or indeed should have proceeded, with scale up for VMMC. I shall discuss this later under ethical considerations of dealing with medical uncertainty. Even if the science behind the VMMC campaign is not at issue, the unresolved debate at the heart of the matter remains what the evidence means and what its role should be in the greater HIV prevention strategy (Ncayiyana, 2012). This central, burning question is ethical in nature. Is what we are doing to these young men and boys right? The fact that mass VMMC rollout has occurred despite any resolution to this question and continues daily all over South Africa is a cause for concern.

Chapter 3: VMMC in the media

With non-medical newspapers such as the online *Bloomberg News* screaming headlines like "Circumcision reduces HIV infections 76% in South Africa, researchers find" (Bennett, 2011 [online]), the VMMC debate is no longer confined to the medical fraternity but has spread into the communities and households of all South Africans. But unlike the medical fraternity, which has access to all of the evidence behind VMMC which allows each of us to reach our own conclusions, the general population often receives a more one-sided view of things and, due to low education and literacy levels in the communities worst affected by HIV/AIDS, are often less well-equipped to reach fully informed decisions.

Often, proponents of VMMC may seem overly enthusiastic, singing the praises of circumcision while omitting or downplaying the possible disadvantages and cultural or ethical barriers. A WHO Bulletin quoted Venter as saying, "Male circumcision is the most powerful intervention we have at this point in time. It is phenomenally effective. One of the beauties of circumcision is that it is a one-off operation which takes 16–20 minutes but then has a profound effect on the rest of a man's life. Whereas to promote condom use or microbicides, repeated long-term promotion is needed" (Wise, 2006, p.509). At a 2011 AIDS conference, Auvert was quoted as saying: "We are changing the social norm. It's the first time in the world that we have a successful intervention in a community to reduce the sexual transmission of HIV between adults" (Bennett, 2011). On another occasion, Venter et al. (2012, p.125) have made such

sweeping claims as "This intervention is regarded as a game changer in South Africa's HIV prevention efforts".

Locally, several prominent political figures have also taken a pro-circumcision stance, such as President Jacob Zuma who was quoted as saying he had been circumcised and had encouraged his sons to undergo the procedure and Zulu King Goodwill Zwelithini who made a public announcement heralding the reinstatement of the tradition of circumcision — though performed medically, rather than by traditional practitioners — in December 2009 (Dugger, 2010).

Even more worryingly, sometimes South African government officials make announcements that are factually incorrect! Minister of Health Aaron Motsoaledi has also encouraged men to be circumcised to reduce their chances of contracting HIV, saying "We have proof that male circumcision reduces the chance of the virus being transmitted from a *man* to a *woman*. We will call on every man who has not been circumcised to make sure he is circumcised" (Motsoaledi urges circumcision, 2011, [online]). This is coupled with the message that state health facilities provide free circumcisions (Motsoaledi urges circumcision, 2011). Kwazulu-Natal MEC Dr Sibongiseni Dhlomo, in the same speech in which plans were announced to include neonates as part of the VMMC campaign in Kwazulu-Natal, said, "I guess we are all in one with the most ardent crusaders for universal male circumcision in the late nineteenth century, Dr Peter Charles Remondino who in 1891 said, 'Circumcision is like a substantial and well-secured life annuity; every year of life you draw the benefit, and it has not any drawbacks. Parents cannot make a

better paying investment for their little boys, as it insures them better health, greater capacity for labour, longer life, less nervousness, sickness, loss of time, and less doctor-bills, as well as increases their chances for an euthanasian death'" (Dhlomo, 2010 [online]). The fact that this kind of out-dated and factually incorrect sentiment is being expressed by our country's leaders, who should be setting an example to the public instead of misinforming them, is deeply disturbing.

Then there are several organisations that have been very active in the promotion of VMMC, such as Brothers For Life, the South African National AIDS Council and the Treatment Action Campaign, among others. In 2011, the Sonke Gender Justice Institute launched a VMMC promotion campaign, which included brochures, posters, T-shirts and murals in addition to the taxis that served commuters in Johannesburg and Cape Town bearing slogans such as "Less skin, we win" and "Don't give HIV a chance to settle. Remove that foreskin". A range of posters (see Appendix A) were also distributed, bearing similar messages such as "Clean is sexy #nuffsaid" and "Give me one good reason why you shouldn't..." They also aimed to expand their efforts in social media and cellphone-based technologies, even going so far as a teen fiction novel to reach younger audiences. To find out where the nearest free circumcision clinic is, one has to SMS the word "proud" to their SMS service. Advertising of this nature is clearly hopelessly biased toward VMMC and does not seek to inform and promote VMMC as one aspect of a holistic HIV prevention campaign, but rather is designed to create an idealised idea of circumcision in and of itself as being desirable, physically attractive and something in which to take pride.

Given the amount of attention VMMC has received in the media, the promotions and advertising have all been almost entirely one sided. As we have seen in the literature review, the medical proof for VMMC is far from black and white and there has been a strong feeling in certain parts of the medical community that mass VMMC rollout is not the way to go for South Africa. Unfortunately, media coverage of these negative findings has been worryingly absent thus far.

While these community awareness efforts aimed at HIV prevention are certainly praiseworthy and it is definitely important to bring HIV out into the open and get people talking in communities, the danger in these campaigns is that if the information provided is entirely one-sided, they are likely to do more harm than good. It is no easy feat to convey the real message behind VMMC – that circumcision decreases the risk of HIV infection but every unprotected sexual encounter can still potentially lead to HIV infection – in a few phrases on a poster or billboard. The issues surrounding circumcision are complex, as we shall see in the discussion following, and these advertising efforts, while well intentioned, are dangerously reductionist. Being exposed to these messages every day might lead people in the community to make up their minds on circumcision before they have received the full message. Even if the men and boys who attend their local clinics and circumcision centres are being, as we would hope, fully informed, there are no proper educational opportunities regarding VMMC for those already circumcised or those too old to qualify for VMMC as well as girls and women. This has led to unfounded

beliefs regarding VMMC, especially among women (Layer *et al.*, 2013). For this reason these campaigns, as they stand presently, may actually be detrimental.

Furthermore, while the three RTCs that gave rise to the whole medical male circumcision movement did not demonstrate any statistically significant change in risk-taking behaviour (see later under risk compensation), it should be borne in mind that this was *before* the widespread advertising and promotion of VMMC. There is always the possibility that the considerable media attention that VMMC has received has created on-going changes in patterns of risk-taking behaviour ahead of the literature and that it may be a much larger problem today than was previously demonstrated. For this reason, the focus in VMMC promotion and advertising should be *not only* on the benefits of circumcision but *equally importantly* that circumcision does not offer full protection from HIV infection.

While circumcision does have a role to play in the fight against the HIV/AIDS epidemic, the recommendation by Bailey *et al.* (2007, p.655) following the Kenya RCT was that "circumcision will be most effective if it is *not* perceived as a stand-alone clinical procedure, but as one component of a full suite of HIV prevention and reproductive health services, including HIV testing and counselling, diagnosis and treatment of sexually transmitted infections, condom promotion, behavioural change counselling and promotion, and other methods as they are proven effective". The Cochrane Review ultimately concludes that "male circumcision can be considered an effective measure to *partly* prevent HIV acquisition in heterosexual men" (Siegfried *et al.*, 2011,

p.12) (Emphasis added by author). This sentiment has been echoed by local VMMC proponents such as Venter *et al.* (2012, p.125) who state "No one argues that any one HIV prevention intervention will work alone, or that VMMC is 100% protective. Drivers of the HIV epidemic are complex and there is no 'one size fits all' prevention". I believe this is really the gist of the research that had been overlooked and under-publicised in the VMMC mass media campaigns. Overemphasis on this one step will threaten to derail the whole HIV prevention programme.

While the literature has been crystal clear and the medical fraternity is well aware that circumcision forms only one facet of a holistic HIV prevention programme, the problem that arises is when this message gets distorted by the broken telephone of the media on its way to the lay population. And as inevitably happens in the children's game of broken telephone, the message at the end comes out horribly garbled.

Chapter 4: Ethical considerations surrounding VMMC

In an attempt to approach the myriad ethical considerations surrounding VMMC, I am going to consider the issues on a number of levels, from individual, to community, to national, to global. While this is not a sharp delineation or categorisation, it suffices as a means for approaching this huge issue in a coherent fashion.

4.1 Individual considerations

4.1.1 Autonomy and informed consent

South African law has been drawn up with the protection of South Africans in mind and demands very high standards for informed consent. The National Health Act (2003) states:

- 1. Every health care provider must inform a user of
 - a. the user's health status except in circumstances where there is substantial evidence that the disclosure of the user's health status would be contrary to the best interests of the user;
 - the range of diagnostic procedures and treatment options generally available to the user;
 - c. the benefits, risks, costs and consequences generally associated with each option; and
 - d. the user's right to refuse health services and explain the implications, risks, obligations of such refusal.

2. The health care provider concerned must, where possible, inform the user as contemplated in subsection (1) in a language that the user understands and in a manner which takes into account the user's level of literacy.

The wording of the Act is very clear and it should be obvious that in order for a clinician to take fully informed consent, a significant investment in time and dialogue is necessary. However, it is no secret that South Africa's public hospitals are woefully under-resourced and overloaded. This, in combination with the ambitious goals that the Department of Health has set for VMMC in South Africa, leads one to wonder how often the consent that is taken prior to VMMC is fully informed, as the law would see it. This is an especial risk in rural communities with lower socioeconomic status and lower education levels, where even more time needs to be taken for the consent process, as well as instances of mass circumcisions as occurs in circumcision camps and at schools, where VMMC proceeds in a production line-like fashion. How are we to know that the men and boys that are currently being circumcised are fully informed, partaking autonomously and in possession of all the relevant facts?

In adults, there should be no moral concern over VMMC as long as consent is fully informed. But given the murkiness of the medical literature surrounding VMMC and the numerous unresolved ethical issues, Garenne (2012) asks, *how* do we inform participants properly? Gwandure (2011, p.93) recommends that "the public in sub-Saharan Africa should receive adequate education about HIV infection risk, bioethics, health law and human rights before they undergo

medical male circumcision". To educate men in this ideal manner would be far beyond the means of our current public health sector, even with the financial support of international agencies, as this would entail first bridging gaps and addressing deficiencies in education levels and literacy. Given the complexity of the nature of the protection that is gained from circumcision (which is addressed under a statistical perspective on VMMC later), which it is doubtful most doctors and nurses that have not received any special training in VMMC even fully understand, it is reasonable to assume that not very many men are actually *fully* informed.

As mentioned in the previous section, many high profile South Africans and political leaders have taken strong pro-circumcision positions and Gwandure (2011) has suggested that this raises issues of group or collective consent versus individual consent or refusal. By this he means that when a political or community leader publicly consents to being circumcised and openly supports VMMC, this makes men more likely to follow the course of action their leader has advised and less likely to verify health benefits and risks for themselves (Gwandure, 2011). This form of social marketing can be manipulative and even downright deceptive when these political leaders are not medically qualified to make these claims or even, as we have seen, provide misinformation (Gwandure, 2011).

4.1.2 Non-maleficence and unintentional, unforeseen harm

The intention to prevent HIV infection, the motivating force behind the VMMC campaign, is clearly beneficent in nature. However, as we have seen in the

literature review, different experts have interpreted the evidence differently, and some authors not only argue that VMMC is not beneficent, but in fact is clearly in violation of the principle of non-maleficence as it causes pain, mutilation, possible infections and even death (Garenne, 2012).

Even if we work from the assumption that VMMC is not in itself harmful, there are still, as with all surgical procedures, harms that can follow VMMC in the form of surgical complications and adverse events. Hutson (2004) states that the most fundamental ethical principle of surgery is that the risk of the surgery should be balanced by the risk of the disease. In the case of VMMC, there is no disease state and we are operating on perfectly healthy men, so no complications can be ethically justified (Hutson, 2004). The Cochrane Review of male circumcision for HIV prevention found that there are still significantly higher complication rates even in medical circumcisions (as opposed to traditional circumcisions) performed in the community (18%) versus 3.6% found under trial conditions (Siegfried et al., 2011). Siegfried et al. (2011, p.11) advised that promotion of male circumcision should be explicit: "the procedure should be conducted by an appropriate skilled practitioner in a sterile clinic environment and must include education about post-operative care". As it stands in South Africa, circumcisions are often performed by junior doctors or clinical associates, often in ill-equipped clinic setting, or worse, in mobile units and makeshift circumcision camps.

Another important harm that may come about following VMMC is a negative effect on sexual functioning, which has obvious implications for a man's quality

of life. A study done in Kenya following the RCT to assess this possibility did not demonstrate any association between sexual dysfunction and male circumcision (Krieger *et al.*.2008), however another study in South Korea found that adult circumcision adversely affects sexual function by decreasing masturbatory pleasure and sexual enjoyment (Kim & Pang, 2007). Easton and Kalichman (2009) suggest one possible reason for this discrepancy is that in clinical trial conditions, top of the line surgical practices and infection control standards were used which limited nerve damage and reduced scarring while medical practices in some resource poor settings rarely have the capacity to follow the gold standard. Another possibility is that satisfaction levels following circumcision may be culture specific, and thus, are not generalisable.

Negligence, or the failure to provide due care, is another harm that needs to be taken into consideration with VMMC. A recent case reported in the *Mercury* newspaper, in which the family of a boy who suffered complications following a circumcision in 2009 were awarded R2.2 million, expert witness plastic and reconstructive surgeon Dr Paul McGarr said, "In essence, nine minutes of a rushed, incompetent circumcision has significantly and severely impacted on the child for the rest of his life" (Regchand, 2013). Under no circumstances can medical negligence be tolerated, but in the case of VMMC, the boys and men that suffer from negligent acts were undergoing an optional procedure with questionable medical benefit, which makes it even less tolerable.

4.1.3 Risk compensation in circumcised men

There is a possibility that circumcised men who believe they are protected from HIV infection will compensate for their perceived risk reduction by engaging in higher-risk behaviours, thereby mitigating any benefits of circumcision in preventing HIV infections and possibly even increasing HIV infections. This phenomenon has been demonstrated by observational studies (Bailey, Neema & Othieno, 1999; Bonner, 2001; Seed *et al.*, 1995). Locally, one study done in Johannesburg has found that certain population groups do consider condom avoidance as a benefit of circumcision but that in the aggregate, condom avoidance is not perceived as a benefit of circumcision (Bridges *et al.*, 2011).

In the South African RTC, it was found that circumcised men demonstrated slightly higher levels of risk-taking behaviour, specifically greater numbers of sexual contacts (Auvert *et al.*, 2005). Similarly, the Kenyan RTC found that men who had been circumcised had more unprotected sexual intercourse and less consistent condom use, however, they attributed these differences to increases in safer sexual practices in the control group, rather than risk compensation in the circumcised group (Bailey *et al.*, 2007). Other studies done in the same geographical area as the Kenya RTC found no significant differences in risky sexual acts in the circumcised group compared to controls (Agot *et al.*, 2007; Mattson *et al.*, 2008). It has to be borne in mind, though, that RCT conditions were unique in that the men participating received support and counselling on multiple occasions with significant amounts of time invested in addressing risk behaviours and risk decision making during counselling. This is in stark contrast to a real world setting where resources,

clinical attention and follow-ups are limited. Unless the rollout of VMMC includes persistent risk reduction counselling similar to what was used in the RCTs, which is both unfeasible and unrealistic, the behavioural implications cannot be inferred from those seen in the RCTs (Easton & Kalichman, 2009). Cassell *et al.* (2006, p.606) conclude that "the prospect of risk compensation should not deter us from pursuing promising methods of prevention or treatment, but it is imperative that we plan ahead to ensure that the benefits will significantly exceed any potentially offsetting limitations".

We also need to take into consideration, not just behavioural changes in men that are considering circumcision or have been circumcised, but also widespread opinions and beliefs regarding circumcision in the community as a whole. Even prior to the widespread publication and advertising campaigns promoting the benefits of circumcision, a study in Kenya found that preference for VMMC was strongly associated with belief that circumcision has a protective effect on HIV risk in women and uncircumcised males (Westercamp *et al.*, 2012). A few participants in that study expressed beliefs that suggest behavioural disinhibition with increased VMMC prevalence and awareness is a very real possibility (Westercamp *et al.*, 2012). The widely publicised results of the RCTs have further impacted social norms and protective beliefs. VMMC is a permanent procedure and may have long-term behavioural implications that are continuously evolving as the practice becomes more widespread and social norms and beliefs about VMMC change (Easton & Kalichman, 2009).

It is impossible to predict, at this point, what these future social norms and beliefs regarding VMMC will look like and similarly, what the sexual risk profiles of men who seek VMMC for HIV prevention will be. If high-risk men seek out VMMC then the concerns for risk compensation may be moot because if they are already at high risk, then in theory these men can only benefit from VMMC (Easton & Kalichman, 2009). However, if lower-risk men seek out VMMC then the effects of behavioural disinhibition could be far more devastating as these men may engage in more high-risk practices because of their lower perceived risk following VMMC and the false sense of security that this has created. Easton and Kalichman (2009) recommend that in order to maximise the protectiveness of VMMC, long-term monitoring of men seeking circumcision as part of a widespread rollout should be done in order to keep track of increases in sexual risk behaviours.

The danger of therapeutic misconception is not confined to men who wish to undergo or have undergone circumcision. A recent study in Kenya found that women had strong preferences for circumcised men because of the low-risk perception of HIV with circumcised men, social norms favouring circumcised men and perceived increased sexual desirability of circumcised men (Layer *et al*, 2013). The health benefits of male circumcision were generally overstated and many respondents falsely believed that women are also directly protected against HIV and that the risk of *all* STIs is greatly reduced or eliminated in circumcised men (Layer *et al*, 2013). This clearly demonstrates that we cannot aim education about VMMC at men alone and active steps need to be taken in order to counteract these dangerous rumours that have been established.

4.1.4 Risk of undermining current HIV prevention strategies

Given the continued spread of HIV infection, the alarming numbers of people affected and the sheer global scale of the HIV/AIDS pandemic, a sense of pessimism prevails regarding changing behaviour patterns. However, we must not lose sight of the fact that there have been successes in Thailand, Cambodia, Uganda, Kenya, Zimbabwe, and other settings which remind us that behaviour change is a feasible and effective approach to preventing new HIV infections (Cassell et al., 2006). VMMC supporters run the risk of promoting their intervention, not on the strength of the intervention alone, but by undermining current HIV prevention strategies. Venter (2012, p.125) states "the ABCs [abstain, be faithful, condomise] have proved insufficient in South Africa or elsewhere, in terms of reversing the HIV epidemic or addressing the complex drivers of HIV transmission". In the countries most affected by the HIV/AIDS pandemic, fewer than one in five people at highest risk for HIV infection have access to effective prevention interventions (Sawires et al., 2007), so it is unfounded to claim that HIV prevention strategies to date have failed, if they were never fully implemented.

Ncayiyana (2011, p.776) warns "there is a real risk that the roll-out of circumcision will dilute the standard prevention messages and undermine the gains already made in respect of condom use and behaviour modification" and I believe that claims such as Venter's are exactly the type of message that he is referring to. In a country that has had such a huge battle to change the mind-set and high-risk behaviours of its people, surely we cannot be willing to risk undermining what little progress we have made even slightly. Circumcision does not remove the need for abstinence and faithfulness or the ongoing need

to use condoms to prevent HIV infection and the need for the ABC message remains as strong now as ever.

The vital message that seems to have gotten lost along the way in the VMMC rollout drive is this: The full protocols of the RCTs included risk reduction counselling and follow up, not just the surgery. This is the model provided for VMMC that should be implemented in the rollout (Easton & Kalichman, 2009). In the Kenya RCT, it was found that there was a reduction in risk behaviours in both circumcised and uncircumcised participants from baseline to follow-up, indicating that the initial behavioural counselling and voluntary HIV testing offered to the participants were effective (Bailey et al., 2007). It was also found that circumcised men partook in slightly riskier behaviour, however, they attributed this discrepancy to increases in safer sexual practices in the control group rather than to riskier behaviour patterns in the circumcision group (Bailey et al., 2007). The conclusion the authors drew is that we do not need to worry about risk compensation. But isn't the real message here rather that counselling and voluntary HIV testing are effective? And if their efficacy has been demonstrated in the RCT, doesn't this then negate the need for circumcision?

UNAIDS (2009, [online]) issued a position statement in 2009 stating that "the male latex condom is the single, most efficient, available technology to reduce the sexual transmission of HIV and other sexually transmitted infections". Van Howe and Storms (2011, p.e4) argue "It is not hard to see that circumcision is either inadequate (otherwise there would be no need for the continued use of

condoms) or redundant (as condoms provide nearly complete protection)". This puts medical practitioners in a difficult position to explain what is actually contributing to HIV prevention: medical male circumcision or the condom when the two prevention methods are used concurrently, as they should be (Gwandure, 2011). Lay people can be forgiven for starting to wonder if the introduction of medical male circumcision is an admission that condoms have failed to prevent HIV infection or that they are unreliable (Gwandure, 2011).

Many impoverished South Africans are reliant on free condoms supplied by government clinics and it has been suggested that, should circumcision come to be regarded as an alternative to condom use, this population will be at greatest risk, especially as they may not see the need to buy condoms if the clinic is out of stock or travel long distances to the clinic to collect condoms if they have been circumcised (Gwandure, 2011).

Furthermore, when circumcision proponents make statements such as "One of the beauties of circumcision is that it is a one-off operation which takes 16–20 minutes but then has a profound effect on the rest of a man's life. Whereas to promote condom use or microbicides, repeated long-term promotion is needed" (Wise, 2006, p.509), it creates the impression that circumcision has replaced the need for ongoing HIV prevention strategies. This could not be further from the truth. Whether a man is circumcised or not, ongoing long term HIV prevention strategies are needed.

4.1.5 Age of circumcision

While the promotion of male circumcision at all ages simultaneously is possible in principle, the limitations in human and material resources in developing countries necessitate a more practical approach (Rennie *et al.*, 2007). The age at which circumcision should be performed for HIV prevention is one that has not received much attention, particularly in public debate and policy making. Quite apart from the issues surrounding circumcision of neonates and boys younger than 16 years (which I shall consider separately later), the age at which adult men are circumcised also has an effect on the protective effects conferred by circumcision. It is thought that circumcision before sexual debut will confer the greatest lifetime protection (Easton & Kalichman, 2009). In the South African RCT, more than 90% of participants were sexually active prior to undergoing circumcision (Auvert *et al.*, 2005) and a survey of men in South Africa in non-trial conditions found that 40% were circumcised after sexual debut (Connolly *et al.*, 2008).

Rennie *et al.* (2007) have considered the ethical, medical and public health perspectives on male circumcision at three logical points: soon after birth, just before sexual debut and at some point after sexual debut (sexual adulthood). Their findings are summarised in the following table (Rennie *et al.*, 2007, p358):

Ethical issue	Age group targeted for male circumcision		
	Infants	Pre-adolescent	Adult
Consent	Parental (proxy) consent only	Assent and parental consent	Informed consent for competent adults
Feasibility	High: integration in existing reproductive care	Low: possible difficulties in reaching target population	Low: infrequent use of health services by male adults
Risk compensation	Not significant	Significant	Significant
Epidemiological impact	Distal: 15–20 years	Potentially immediate	Potentially immediate, but lost opportunities for prevention among sexually active adults
HIV testing	Not applicable	Potential stigma, inadvertent disclosure Appropriateness of circumcision when the adult of parental status is HIV positive	
Burden on health services	Lowest: integration into existing reproductive care	High: demand may require substantic investment and involvement of traditional healers	alHigh: demand may require substantial investment and involvement of traditional heale

4.2 Community considerations

4.2.1 Cultural considerations

Circumcision is certainly not new to Africa or, indeed, South Africa where it is traditionally practised by the Xhosa and South Sotho, as well as the Ndebele, Pedi, Venda, Muslim and Jewish communities (Connolly *et al.*, 2008).

Traditional circumcision is associated with ethnic marks, virility, masculinity, agricultural produce abundance, a rite of passage or to promote a cultural sense of manhood and sexual enhancement (Gwandure, 2011). However, male circumcision is not a universal cultural practice, and Auvert *et al.* (2005, p.1121) noted that "cultural practices can be barriers in policy considerations". These barriers include the perceived replacement of traditional authority and values by the medicalicalisation male circumcision resulting in community resistance, community defensiveness for the freedom to practise religious beliefs or the right to seek alternative medical care (Gwandure, 2011).

We need to distinguish between medical circumcision and traditional circumcision. Circumcision is in itself an ambiguous term as in traditional settings, it can mean different things to different cultures. Some cultural groups (such as the Xhosa) practice full circumcision whereas others perform only partial circumcision (such as the Zulu practice of *ukugweda* which entails cutting a band of tissue beneath the glans penis but leaving the foreskin intact) (Sithole *et al.*, 2009). A survey done in Lesotho found that 41% of men who reported being traditionally circumcised were intact (Thomas *et al.*, 2011).

There is another layer of complexity beyond the procedure itself. Traditional male circumcision is more than just the cutting of the foreskin, it is a social institution which includes traditional figures held in high esteem by the community whose role is passing along teachings regarding sexual practices, a man's role in the community and cultural values, not merely HIV testing and counselling as occurs in VMMC (Gwandure, 2011). By advocating medical circumcision even in cultures that were not traditionally circumcising, some possible negative consequences may include a negative influence on the cultural identity of those traditionally non-circumcising cultural groups, a lost opportunity to impart these cultural values, compromise of the position of traditional circumcisers as leaders in their community and a change in a man's status in communities where women prefer or seek out non-circumcised men or men circumcised in the traditional way (Gwandure, 2011). Easton and Kalichman (2009, p.7) warn "it is indeed unwise to ignore the cultural meaning of circumcision and its relationship to perceptions of masculinity, social roles, tribal identities, parenting practices, rites of passage, and religious covenants when constructing VMMC programs" and "VMMC for HIV prevention will require careful attention to the socio-cultural context of circumcision".

Despite the various cultural values surrounding circumcision, a South African study showed that 59% of uncircumcised men were open to circumcision if it reduced their chance of being infected with HIV and sexually transmitted infections, which shows that despite traditions regarding circumcision, it is generally highly acceptable (Lagarde *et al.*, 2003).

The MRC's Cochrane Review of the three RTCs advised, based on the significantly higher complication rate following traditional circumcision, that medical procedures could potentially be included into traditional customs (Siegfried *et al.*, 2011). Plans along those lines have been announced by Department of Health officials, motivated in part by the shortage of doctors to perform VMMC (Theunissen, 2013). It is questionable whether this is the right way to go, as traditional circumcision carries a well-known history of devastating complications and unacceptably high mortality rates (Peltzer *et al.*, 2008).

Another cultural perspective that we would do well to take into consideration is that of the West, which also largely informs cultural norms in certain South African populations, particularly whites, but is growingly steadily more influential across all cultural groups as the global community grows smaller with telecommunications. As discussed previously, the popularity of circumcision in the West is largely due to Victorian influence and routine neonatal circumcision is still widely practiced in the United States, from which South Africa receives the majority of its international media, which also contributes to the establishment of cultural norms.

4.2.2 Justice: the gender divide and female subjugation

Girls and women are vulnerable in our society both because of their biological vulnerability as well as gender norms, roles and practices and this puts them at particularly high risk of HIV infection. It is possible that male circumcision could worsen the unequal power dynamic between men and women with regards to

negotiation for safer sex, especially in cases where the woman is financially dependent on the man, as she might no longer have the power to ask for condoms after VMMC (Gwandure, 2011). If condoms are already viewed negatively among men and women, then VMMC will make men even less likely to use barrier protection correctly and consistently (Gwandure, 2011).

One of the offshoots of risk compensation is that there is also the risk that if circumcised men believe that they are somehow protected from HIV infection and subsequently become infected, they might assign the blame to women, rather than their own unsafe sexual practices. This could create a stigma of women as the "spreaders" of HIV infection and worsen the gender divide.

In the South African RCT, Auvert *et al.* (2005) contentiously assumed that women and therefore children would be indirectly protected from HIV infection on the basis that if men are less susceptible to HIV infection, women will be less exposed to HIV infected partners. The same argument is presented by Venter (2012). However, the MRC's Cochrane Review did not demonstrate that VMMC had any direct HIV benefits to women and, in fact, potentially increased the risk of transmission with early assumption of sex after the procedure (Siegfried *et al.*, 2011). Model simulations based on Auvert's South African RCT found that VMMC will increase the proportion of infected people who are women from about 52% to 58% (Williams *et al.*, 2006). A study by Wawer *et al.* (2009) in Rakai, Uganda of the effect of male circumcision on HIV transmission to female partners was stopped early due to futility. It was found that circumcision of HIV-infected men did not reduce HIV transmission to

female partners over 24 months and condom use after VMMC remains essential for prevention of HIV infection of female partners in sero-discordant couples (Wawer *et al.*, 2009).

In fact, there have been some reports that suggest that a woman's risk of HIV infection may be *heightened* following VMMC, if sexual relations are commenced before the wound has properly healed (Differding, 2007) and that women's chances of contracting HIV are increased by as much as 60% over the period of 24 months following circumcision if their partner is HIV positive (Sidler, *et al.*, 2008). Whatever the hypothesized benefit of male circumcision on the female partner, in this case the medical evidence has disproved it.

It should also be borne in mind that efforts to address gender inequality on a community and national level will go a long way to toward resolving one of the most powerful drivers of HIV transmission (Sawires *et al.*, 2007).

4.2.3 Distributive justice

VMMC also raises ethical concerns regarding distributive justice. It is well known that South Africa's public healthcare system is overburdened and funds for HIV/AIDS prevention programs are already stretched thin. Due to VMMC's recent popularity and international attention, there has been a shift in funding from other HIV prevention strategies to VMMC. This is particularly worrisome, in the light of the fact that VMMC only shows a benefit on female to male transmission of HIV and increasing proportions of funds are being shifted away

from the more vulnerable group, females, and allocated to an intervention that is only benefitting men, more specifically HIV negative men. This shift in focus and resources is highly questionable in South Africa with its high rates of HIV infection in women, vertical transmission of HIV and gender inequality.

Women are not the only group that stands nothing to gain from VMMC. HIV positive men, men who have sex with men (either penetrative or receptive partners) and heterosexual couples that engage in anal sex also gain no protection from VMMC (Easton & Kalichman, 2009). It should be guarded against that in the midst of VMMC euphoria and under the pressure of international agencies, we do not neglect these groups in HIV/AIDS prevention strategies.

4.2.4 Social stigmatisation as a result of VMMC

VMMC in HIV positive men is not recommended by the WHO/UNAIDS (2007) as it has been found that it does not reduce HIV transmission to HIV negative female partners and during the wound healing phase, risk of HIV transmission to female partners is actually increased. However, this recommendation is problematic because if all HIV positive men were to be excluded from VMMC rollout, stigma could quickly arise around circumcision status, with all circumcised men assumed to be negative and all uncircumcised men assumed to be positive. And yet, if we offer circumcision to all men regardless of HIV status (as is currently done in South Africa), we are exposing HIV positive men to a medically futile procedure that will have no benefits for either partner, wasting resources in an already over-stretched health care setting and

exposing immunocompromised men to increased risk complications if their immunity is low.

There are also changing cultural perceptions in light of the media attention VMMC has received, with some studies demonstrating that women now express a preference for circumcised men (Layer *et al.*, 2013). This is referred to as "circum-sorting". This in turn will influence men's preferences, as they might be influenced to accept VMMC against their autonomous will in order to increase their sexual desirability. VMMC may influence social norms in traditionally circumcising cultures, where women might prefer men who have been traditionally circumcised over those who are medically circumcised and also in non-circumcising cultures, where medically circumcised men might be rejected or fail to find a partner because they no longer fit in with cultural expectations (Gwandure, 2011). The danger of stigmatisation and the influence of cultural norms remind us that circumcision is about more than just the foreskin, it has far reaching effects on complex social, behavioural and societal interactions and that we may be unable to fully anticipate the repercussions of a "little snip".

4.3 National considerations

4.3.1 Adverse events and complications on a macro level

I have considered the adverse events and complications of VMMC on an individual level as part of my discussion on non-maleficence, but it is also important to take a step back and consider adverse events from a macro level as well.

In the three landmark RCTs, it was found that the adverse event rate in the South African study was 3.6% versus 1.5% in the Kenyan study (Bailey *et al.*, 2007). The difference in rates was attributed to multiple factors: all procedures in Kisumu, Kenya were performed at the study clinic by highly trained and experienced practitioners, they had regular surgical case conferences to review outcomes, participants received clear written postoperative instructions and frequent follow-up visits at 3, 8, and 30 days after the procedure as opposed to the Orange Farm, South Africa trial where experienced local private practitioners performed the surgeries in their own offices with no scheduled follow-up as participants were only seen again if they presented with a complication (Bailey *et al.*, 2007). Bailey *et al.* (2007, p.653) reached the recommendation that "extensive training, proper instrumentation, clear postoperative instructions, and continuing quality assurance and control are helpful to assure optimum outcomes".

A prospective observational study done in Kenya in 2004 found the actual, real world complication rate of medical circumcisions to be 17.7%, a more than 10 fold increase compared to trial conditions, due to a lack of training of medical personnel as well as proper equipment and medical supplies (Crabb, 2010). For instance, only half of the public health centres and one-fifth of the private facilities had working autoclaves while there was no suture material available at almost half of both private and public facilities (Crabb, 2010).

The circumcisions that were performed in the RTCs that demonstrated the significant reduction in HIV infection were performed under optimal conditions, which differ wildly from the actual scenario we are faced with in South African public hospitals. In our setting, circumcisions are often performed by inexperienced clinical associates and junior doctors like interns and community service doctors with little or no supervision, or supervision provided by medical officers and general practitioners, not specialists. In the unfortunate event of complications, there may be a delay in recognising complications due to inexperience, inappropriate responses to recognised complications, limited access to emergency equipment and delay in transfer of patients to referral centres or, in the worst case scenario, no transfer facilities. The constraints are even more exaggerated when VMMC campaigns are held in non-medical settings, like mobile units and "camps" that are set up in rural regions. These challenges severely limit the generalisability of the RCT results to our setting. Should the Department of Health proceed with its plan to use technicians rather than medically trained personnel for VMMC, I fear this would amplify these challenges even further. It should also be borne in mind that if VMMC is performed under poor hygienic conditions, this can lead to

infection, bleeding, permanent injury, HIV infection from non-sterilized instruments and death if complications are not recognised and treated (Auvert *et al.*, 2005).

It is also important to note that in the healing period following circumcision, sexually active men are at a *higher* risk of HIV infection (Auvert *et al.*, 2005). As certain circumcision proponents argue for VMMC because they claim abstinence is ineffective, it follows then that it is inconsistent to expect men who have been circumcised to abstain for 6 weeks following the procedure. If the abstinence part of the ABC campaign is really such an impossible ideal, then they should, for the sake of consistency, realise that they are putting these men in danger by *increasing* their chances of HIV infection if they have sexual intercourse during the healing period following circumcision.

4.3.2 Cost saving and unforeseen expenditure of VMMC

As mentioned previously, proponents of VMMC often cite cost saving as one of the motivations for the scale-up and rollout of mass VMMC campaigns. However, this ties in with the challenges I have described above with regards to VMMC in our setting, where it is mostly performed by the most junior medical staff, often in rural communities with poor support from senior staff and specialists and difficulties in referral in the case of complications. This leads to much higher complication rates and increased adverse outcomes than anticipated, which will in turn lead to much higher costs than originally anticipated. A case in point, in June 2013, the Kwazulu Natal Department of Health were ordered to pay R2.2 million as well as legal costs to the family of a

boy who suffered complications following a circumcision in 2009 (Regchand, 2013). Expert witness in the court was quoted as saying that "the standard of practice and aftercare at the hospital (a rural Kwazulu Natal district hospital) constituted gross negligence by staff who had failed to follow the most basic principles of surgery" (Regchand, 2013 [online]). While proponents of VMMC frequently cite the cost-saving measures of male circumcision, cases like this one highlight the fact that unless the VMMC campaign can be carried out under optimal conditions such as those in the clinical trial, there is the danger that it might actually cost far more money than it might save.

Just as someone suffering a complication of a surgical procedure might be in a position to claim compensation, it is also conceivable that men who undergo circumcision for the sake of HIV prevention and subsequently become infected with HIV after being circumcised might consider this failure of the procedure and demand compensation. At the moment there is no written policy from our government or international non-profit organisations funding VMMC regarding medical injury compensation following VMMC (Gwandure, 2011). If this was the case, the possible financial implication on an already under-resourced, over-burdened public health care system in South Africa could be disastrous.

4.3.3 The implications of international funding for VMMC

There have been many international agencies involved in funding VMMC in South Africa, including USAID, U.S. President's Emergency Plan for AIDS Relief and the Global Fund to Fight AIDS, Malaria and Tuberculosis (Bennett, 2011). As Dan Ncayiyana (2011, p.776) has put forth, "it is curious and indeed even

worrisome that the campaign to circumcise African men seems to be driven by donor funding and researchers from the North". As an example, in Zambia and Swaziland, the Bill and Melinda Gates foundation has partnered with local authorities and donated \$50 million to circumcise 642 000 adolescent boys and men over 5 years (Ncayiyana, 2011). This occurrence brings to the fore the ethical dilemma surrounding medical hegemony of wealthy first world agencies.

It should be highlighted that the force behind the drive towards VMMC campaigns in developing countries has come predominantly from traditionally circumcising countries, such as the United States of America and Israel.

Johnson (2010) suggests that it may not be appropriate for individuals who have themselves been circumcised in a country where this is the social norm, to make decisions regarding whether circumcision is in the best interests of anyone else, particularly anyone else in a different country, in a different cultural group with completely different social norms and values regarding circumcision.

It is also interesting to note that developed countries have not followed suit with circumcision promotion as a means of preventing HIV infection. The Australian Federation of AIDS Organisations has rejected circumcision for Australia, reiterating that "correct and consistent condom use, not circumcision, is the most effective means of reducing female-to-male transmission, and vice-versa. Circumcision does not prevent HIV — in high prevalence areas it reduces the risk of female-to-male transmission. HIV

acquisition rates were nevertheless high in both the circumcised and the non-circumcised groups involved in the trials" (Australia, 2007, p.2). This may create the perception of an ethical double standard if VMMC is targeted exclusively at resource poor countries (Rennie *et al.*, 2007). Van Howe *et al.* (2005) have even gone so far as to call this phenomenon "veiled colonialism".

Another possible pitfall of international funding is that it introduces what Gwandure (2011, p.92) calls "double agency" by which he means that a conflict of interest may be created between the physician serving the patient and financial gain. Doctors working for these organisations might be caught between reporting adverse events and promoting the project for financial gain, where whistle-blowing might result in the loss of international funding leading to retrenchment (Gwandure, 2011).

4.3.4 The public health ethics of VMMC

It has been proposed that, based on the 60% reduction rate in HIV infection in circumcised men and 2005 conditions in Gauteng province, VMMC would be cost effective, saving \$2.4 million over 20 years per 1000 circumcisions (Kahn, Marseille & Auvert, 2006). The national Department of Health has committed large budgets to VMMC rollout (Venter, 2012). However, it is vitally important to keep in mind that every cent out of the health budget that is put towards VMMC, is being taken away from voluntary counselling and testing (VCT), antiretroviral therapies (ART) and prevention of mother to child transmission (PMTCT) programs – all of which have a proven impact on prevention (Ncayiyana, 2011).

When it comes to funding, it would seem that there are unanswered ethical questions whether funds are acquired from within our own Department of Health, in which case they are diverted from proven interventions and vulnerable populations, or from without, where the motivations and double standards of international agencies are questionable. Perhaps the issue then is not so much, where is the funding coming from? But rather, why are we allocating such a large proportion of funds to an intervention that is questionable in itself? Given the widespread controversy within the medical community and the medical uncertainty surrounding VMMC as well as the limited resources of our healthcare system, it does not seem wise that such expensive VMMC program has been implemented.

4.3.5 Risks of "de-medicalisation" of a surgical procedure

Venter, a prominent South African circumcision advocate, has suggested that "there is no need for doctors to do it [VMMC]. It is a simple procedure that trained technicians could carry out" (Wise, 2006, p.511). The idea of technicians performing a surgical procedure, one with very serious and potentially fatal complications, is to my mind unprecedented, especially given the scale on which VMMC is envisioned in South Africa.

In the face of the well-known shortage of doctors and clinical associates available to perform circumcisions compared to the government's ambitious target of 4 million circumcisions by 2016, they are now entertaining non-traditional methods of circumcision. In a session at the 2013 South African

AIDS Conference in Durban, Loykissoonlal, Deputy Director at National Department of Health, stated that future plans include task shifting to nurses, the involvement of general practitioners and involving traditional circumcision practitioners to integrate medical and traditional practice (Theunissen, 2013). Worryingly, trials are also shortly due to commence for a circumcision device that will not even require a medically qualified operator (Mapumulo, 2013). While it is too soon to judge what the results of these trials might be, it is certainly a move in a very disturbing direction.

All of these efforts represent a move even further away from the environment of the clinical trials, making the HIV prevention effect even more questionable. Given the scale of the rollout of VMMC and the terribly ambitious targets that the Department of Health has set, we are in serious danger of sacrificing quality for quantity of circumcisions.

4.3.6 The ever present danger of corruption

It is an uncomfortable truth that the South African medical system has a history of corruption and misuse of government funds. Even with local VMMC campaigns being launched as recently as 2010, already reports of corruption have surfaced. The Mpumalanga health department was recently called upon by Minister of Health Aaron Motsoaledi to explain how a R182 million contract to circumcise hundreds of thousands of boys and men in the province was awarded without going to tender (Bailey, 2013). What's more, the doctor that this contract was awarded to is linked to an allegedly botched circumcision on

a four-year old Mpumalanga boy five years ago which is currently the subject of a R10 million legal suit in the Pretoria High Court (Bailey, 2013).

4.4 Global considerations

4.4.1 Female genital mutilation

Female circumcision, more generally referred to as female genital mutilation, is strongly discouraged almost universally. Female genital mutilation and nontherapeutic male circumcision are generally considered two separate practices which need to be evaluated differently where female genital mutilation is generally seen as a serious violation of the rights of the child but nontherapeutic male circumcision is something which the parents may decide on for themselves (Royal Dutch Medical Association, 2010). However, some authors argue that it is discriminating to categorically reject circumcision in girls (even in a non-mutilating form) but permit it in boys and that there is no reason why female genital mutilation and non-therapeutic circumcision should be judged differently in moral or legal terms (Karim & Hage, 2008 cited in Royal Dutch Medical Association, 2010, p10). Rennie et al. (2007) have raised the concern that confusion could be created between policies advocating male circumcision but forbidding female genital mutilation. Similarly, promoters of female circumcision could use the growing widespread promotion of male circumcision to defend female circumcision as well (Auvert et al., 2005).

Coherence would suggest that we apply the same reasoning that we use against female genital mutilation to "mutilation" of the male genitalia, especially in those younger than 16 years who are not able to consent to the procedure.

4.4.2 Non-sexual HIV transmission

The driver of HIV transmission in the developing world is undeniably heterosexual transmission, however, non-sexual transmission of HIV does occur and has received relatively little attention.

In their criticism of the 3 landmark RCTs, Van Howe and Storms (2011) point out that of the 205 HIV seroconversions that occurred in participants during all 3 trials, only 89 (43.1%) occurred in men who admitted to unprotected sexual contact. While there are myriad complex factors affecting someone's willingness to disclose details about something as private and value-laden as sexual practices, if we are to take these men at their word, this is a disturbing statistic. Where then are these other infections coming from? Not only have these non-sexual HIV transmissions been ignored in the statistical models of the RCTs, no attempts were made to find them to find the cause.

In another troubling statistic, a South African study found that 4.8% of HIV-positive children had HIV-negative mothers in a health district in the Free State where major lapses in infection control in public hospitals and clinics were found (Reid *et al.*, 2010). These lapses included syringe reuse, needle reuse, multi-dose vial reuse after reconstitution with a used syringe or other unsafe procedures, including poor use of sterilisation equipment or use of equipment still visibly stained with blood (Reid *et al.*, 2010). Another study of non-vertical HIV transmission in children found 69 000 iatrogenic infections in the 2 to 4 year-old age group nationwide in 2005 (Reid *et al.*, 2010).

With such glaring lapses in our public health care system and iatrogenic HIV infection being an undeniable reality in our over-burdened, under-resourced setting, the scale-up of roll-out of VMMC is exposing even more healthy boys and men to the risk of iatrogenic HIV infection, ironically, in an effort to prevent HIV infection. While it might be argued that the number of infections averted would greatly outweigh the small number of iatrogenic infections, even a single HIV-negative child that contracted the virus following a prophylactic measure such as VMMC is unjustifiable.

4.4.3 A dangerous shift in focus

The emphasis on VMMC is shifting the focus of HIV prevention strategies from education and empowerment to change high-risk behaviour to a surgical intervention. This follows the mentality that it is easier to change someone's foreskin than change their mind-set. This type of reasoning that has informed the mass rollout of VMMC to date is problematic in itself.

Van Niekerk (2012, p.5) asks "Why, incidentally, is it so easily accepted that Africans or people living in the developing world are not prone to respond positively to good advice and practice safe sex? What assumptions about African people underlie the idea that such a paternalistic intervention as that planned by the WHO and UNAIDs is warranted?" We need to be aware of creating a stereotype of African men as disease vectors, unconcerned about their female partners and children, spreading disease and violence, and neglecting families which can lead to an erroneous perception of moral depravity of African men (Sawires *et al.*, 2007).

Given the success that campaigns aimed at behaviour change have achieved elsewhere in the world (Cassell *et al.*, 2006) as well as the behavioural changes that were found in non-circumcised men in the RCTs, it would seem that not only is this shift in focus dangerous, it is also unfounded.

4.5 Other considerations

4.5.1 A statistical perspective on VMMC

If we assume a 50-60% reduction in HIV infection as the three RCTs would suggest, the fact is that the remaining 40-50% is still a worryingly high risk. Gwandure (2011, p.91) points out that "quantification in percentages does not count much in protecting the individual from HIV infection- it is only a statistical probability and there is no percentage of HIV infection that can be regarded as safer or any exposure to HIV infection risk that can be considered to be safer in HIV prevention". Men who are undergoing circumcision should be made to understand that at each unprotected sexual encounter, they will either be infected or not infected, even if they have been circumcised (Gwandure, 2011). At each encounter, the chance of infection, with or without circumcision, remains 1 or 0. If the men and boys undergoing circumcision really did understand this concept, it is very difficult to see why they would still wish to proceed with a painful, irreversible surgical intervention.

It is also important to make a clear distinction between *clinical efficacy* (the effect of an intervention found in clinical trials) and *population effectiveness* (the impact of the intervention on a large scale). The challenge is to communicate in layman's terms that VMMC is very promising for reducing HIV infections on a societal level, but on an individual, personal level VMMC alone is not reliable for HIV prevention (Easton & Kalichman, 2009). Garenne (2012) explains that when an intervention has a large (>90%) or very large (99%) clinical efficacy, then results on a population level tend to be similar to those

found in clinical trials. However, a 50% reduction in HIV risk with VMMC as demonstrated in the RCTs, is statistically considered a small efficacy and this is the reason why results found in demographic data diverge from those in the clinical trials. The reason for this can be explained by repeated exposure. When a man is repeatedly exposed to HIV, he will contract HIV eventually, whether circumcised or not, because there is no real protection, only a reduced risk at each exposure (Garenne, 2012).

In general, public health interventions with such a low level of efficacy of 50% are not recommended either on an individual level (for example, rhythm method of contraception) or population level (for example, a vaccine with 50% efficacy). In the presence of proven methods of HIV prevention with almost 99% efficacy, that being the male latex condom, it is a wonder why this same rationale has not applied to VMMC (Garenne, 2012).

4.5.2 Circumcision technique

The surgical technique in which a circumcision is performed represents a source of variation in the protective effect of male circumcision in HIV prevention as the amount of foreskin tissue remaining after circumcision is operator dependant and this in turn affects healing time (Bailey *et al.*, 2007). In the RTCs, urologists performed the circumcisions, whereas in our setting, circumcisions are mostly performed by junior doctors, including general practitioners, community service doctors and intern doctors. As stated previously, the amount of foreskin that remains is thought to be determinant in the risk of HIV infection, and yet there have not thus far been any attempts

at standardisation of the circumcision technique used in South Africa. The WHO (2009) has issued guidelines for the technique of circumcision, but in South Africa, no such guidelines have been adopted and currently the method and results of circumcision remains entirely operator dependant.

A study done in Lesotho found that even in men who reported having been medically circumcised, physical examination revealed only 73% were completely circumcised (Thomas *et al.*, 2011). Their recommendation was that countries scaling up VMMC should obtain male circumcision data based on physical examination by trained professionals to guide service delivery and cost estimates (Thomas *et al.*, 2011) but this has not been implemented in South Africa thus far.

4.5.3 Lack of ethical awareness

In their discussion of ethical, medical and public health trade-offs of VMMC in low-income countries, Rennie *et al.* (2007) proposed the following basic ethical conditions that must be met for rollout of a mass VMMC campaign:

- "Sufficient material and human resources to perform circumcisions safely
- 2. Careful monitoring of the quality of follow-up care
- International and national commitments to low-cost circumcisions to facilitate equitable access
- 4. Flexible policies informed by concerns of local communities regarding if, when, where and how circumcisions should be performed

- 5. Careful attention to the consent process and sustained condom promotion to minimise the risk of behavioural disinhibition
- 6. Monitoring of circumcision promotion messages to ensure that prospective clients are aware of potential benefits and limits
- 7. Education of women and girls about male circumcision initiatives to combat potentially tragic misconceptions
- 8. Conformity of circumcision policies with international norms (such as the Siracusa principles) limiting the extent to which individual rights can be infringed to promote the public good."

If we consider the body of research that I have been referring to throughout this thesis, I think it could not be more obvious that certain of these basic ethical conditions are not being met with the current VMMC campaign as it stands in South Africa today. This is not to say that there is no place for VMMC as part of a holistic HIV/AIDS prevention program, but what is currently happening is not defensible.

The first call in South Africa raising the ethical concerns of using medical male circumcision in HIV prevention in South Africa was published in the *South African Journal of Bioethics and Law* by Gwandure in 2011. And yet, two years later and three years after the rollout of circumcision in South Africa, these concerns remain unaddressed. Gwandure's (2011, p.89) call that "rolling out medical male circumcision to the larger community without adequately addressing the ethical concerns could weaken programme initiation,

implementation and evaluation in sub-Saharan Africa" seems to have gone unnoticed.

4.5.4 Dealing with medical uncertainty

When we review the literature, it is clear that there are very strong VMMC proponents (Auvert *et al.*, 2005; Gray *et al.*, 2007; Bailey *et al.*, 2007; Wamai *et al.*, 2012) and detractors (Van Howe & Storms, 2011; Boyle & Hill, 2011) internationally. Locally, debate as also raged between those supporting circumcision (Kesinger & Millard, 2012; Venter *et al.*, 2012) and those advocating against it (Myers & Myers, 2008; Sidler *et al.*, 2008; Ncayiyana, 2011). This leaves one in a vacuum of scientific certainty. If medical professionals and experts in their fields cannot reach a consensus on what the evidence means, is it right that South Africa went ahead and implanted the recommendations of the WHO for mass scale up of VMMC? Given the scale of the rollout proposed and the fact that this intervention is irreversible, surely it would have been better to wait until a consensus is reached and more robust scientific evidence has become available to silence the debate once and for all. How can we be sure that this intervention is, as intended, beneficent?

Rennie *et al.* (2007, p.357) have succinctly summarised this issue, saying: "Disagreements persist about the justification of promoting male circumcision as a part of the HIV prevention policy, on the basis of current scientific evidence. These disagreements hinge on whether a similarly high degree of protective effect can be replicated, over the long term, outside the context of a carefully controlled clinical trial. Some argue that health policies always involve

risk, and HIV/AIDS is an urgent public health emergency, warranting and even demanding bold measures. However, the long term and/or absolute reduction in HIV transmission risk via male circumcision remains uncertain and partly depends on population prevalence. There is room for discussion about the justification of implementing male circumcision for HIV prevention before its overall health impact has been fully quantified".

Furthermore, if such strong conflicts exist in the medical community, how are we to communicate these concerns in a way that does not confuse people, especially when a large majority of people in sub-Saharan Africa come from lower socioeconomic circumstances and have low education levels? While there is no easy answer to this question, it is clear that, at the very least, the one-sided promotion of the benefits of VMMC is doing a grave disservic.

While I believe that any one of the ethical considerations I have explored would be enough to cast doubt on the moral status of VMMC, the scientific uncertainty at the very heart of the matter, the questionability of the premise on which the entire campaign is based, is what renders the VMMC campaign unethical.

Chapter 5: Neonatal circumcision

Neonatal circumcision is, in and of itself, a contentious issue. Neonatal circumcision for the purpose of HIV prevention later in life even more so! It would probably have been possible to write an entire thesis on neonatal circumcision, so I will try to briefly highlight some aspects of this topic. I have considered it separately from the ethical considerations surrounding VMMC as neonatal circumcision has no place in VMMC campaigns.

At this point it is salient to consider the anatomy and function of the male prepuce, in order to fully appreciate the impact of circumcision on a male neonate. Gairdner (1949) found that in 96% of male neonates, the mucosa of the glans penis is fused to the inner lining of the prepuce, which prevents complete retraction of the foreskin. In the past, this state was misidentified as "infantile phimosis", but it is now understood to be the natural state (Darby, 2005). Separation occurs spontaneously and gradually and is usually complete in a 17 year old male, though the mechanism remains poorly understood (Cold &Taylor, 1999). Neonatal circumcision occurs before this natural separation has taken place thus involves tearing the common penile and prepucial mucosa apart which runs the risk of glandular excoriation and injury. It results in permanent distortion of the penile anatomy, with a significant proportion of erogenous tissue as well as penile musculature removed, altering the physiological response of the circumcised penis to temperature changes (Cold &Taylor, 1999). The effect of circumcision on male sexual function remains highly controversial. The foreskin also serves an immunological function

through the action of Langerhans cells (which is one of the proposed, but as yet unproven, mechanisms of HIV prevention through circumcision) however Weiss *et al.* (1993) were not able to demonstrate any Langerhans cells in the neonatal glans, which implies that neonatal circumcision also has deleterious effects on immune function in relation to the penis.

In the landmark Uganda RCT, Gray *et al.* (2007, p.665) boldly conclude that "in the long term, neonatal circumcision or circumcision of younger boys will provide a simpler, safer, cheaper option than adult circumcision, although HIV benefits will be delayed until these boys reach sexual maturity". This is a contentious and unfounded claim at best. The Uganda RCT was confined to adult males between the ages of 15 to 49 years and there has been no RCT done on the neonatal population to date. Locally, Venter *et al.* (2012) argue for neonatal circumcision based on the fact that neonatal circumcision happens already for cultural religious and health reasons. Furthermore, they claim that it is biologically implausible that circumcision would not confer the same effects as in adults and that it would take too long (i.e. more than 20 years) to obtain sound evidence (Venter *et al.*, 2012).

Internationally, there have been varied positions taken on neonatal circumcision. American Academy of Paediatrics' policy statement is that "the health benefits of newborn male circumcision outweigh the risks and that the procedure's benefits justify access to this procedure for families who choose it. Specific benefits identified included prevention of urinary tract infections, penile cancer, and transmission of some sexually transmitted infections,

including HIV" (Blank et al., 2012, p.585). The Royal Dutch Medical Association (KNMG) supports a policy of powerful deterrence and aims to minimise nontherapeutic circumcision of male minors (Royal Dutch Medical Association, 2010). Reasons for this position include an increasing emphasis on children's rights, that children should not be subjected to medical procedures that have no therapeutic or preventative value, growing concern over complications, both serious and minor and a discrepancy between the firm stance against female genital mutilation and lack of a stance with regard to non-therapeutic circumcision of male minors, as the two are very similar (Royal Dutch Medical Association, 2010). The Royal Australasian College of Physicians holds the position that "After reviewing the currently available evidence, the RACP believes that the frequency of diseases modifiable by circumcision, the level of protection offered by circumcision and the complication rates of circumcision do not warrant routine infant circumcision in Australia and New Zealand" (Royal Australasian College of Physicians, 2010). However, UNAIDS/WHO (2011), the driver behind VMMC worldwide, has included the recommendation that circumcision should be integrated into early infant care in its Joint Strategic Action Framework 2012-2016.

The position of the American medical fraternity with regards to neonatal circumcision is unique in that no other surgical procedure that involves the removal of healthy tissue from a minor is tolerated, as this goes against one of the underlying principles of Western biomedical ethics, *primum non nocere* (first, do no harm) (Dristas, 2001). As I have stated previously, Hutson's (2004) fundamental principle of surgery is that "no operation should be done if there is no disease, as it cannot be justified if the risk of the procedure is not

balanced by the risk of a disease". Herein lies the problem for routine neonatal circumcision: since there is no disease, no complication whatsoever can be tolerated, since the risks of the procedure are not being balanced against the risks of any present disease (Hutson, 2004). Complications are potentially devastating, including accidental amputation of the end of the penis, excessive removal of penile shaft skin leading to secondary deformity, diathermy burns leading to complete necrosis of the penis, even accidental amputation, in extreme cases leading to gender reassignment to female because of the loss of the penis (Hutson, 2004). Proponents of circumcision frequently make optimistic claims about the low rate of complications but there is little evidence to support these claims, whereas anecdotal evidence suggests that urologists in the United States see as many as one complication per week (Darby, 2005). Hutson (2004, p.239) concludes "this cost benefit analysis approach exposes routine circumcision as an unnecessary social operation, rather than one justified by medical indications".

Locally, Sidler *et al.* (2008, p.764) have taken a firm stance against neonatal circumcision, arguing, "Parents should not be misled into thinking that the results of studies performed on adult African males could be extrapolated to health policy for newborns. It is unprecedented and unethical for a prophylactic surgery to be offered as a 'health benefit' to parents of newborns to reduce the risk of a disease acquired in adulthood for which there are safer, less invasive, less expensive, and proven prevention methods available.

Newborns are not sexually active and not at risk of sexually contracted diseases. Furthermore, by the time today's newborns are sexually active, a vaccine or other methods of treating the disease may be available. They may

prefer to retain their foreskin and as adults choose vaccination and safe sex practices, including using condoms".

The ethics of neonatal circumcision is one aspect of VMMC that has received more attention than the rest, but despite strong feelings on all sides, no consensus has yet been reached. A Treatment Action Campaign Briefing asks if it is ethical to carry out circumcisions on children who might regret being circumcised at some point in their lives? (Geffen & Heywood, 2007) It states: "Parents and guardians have a duty to provide essential medical care, such as vaccinations, to their children. However, in contrast to vaccination, circumcision causes physical distress and permanently and significantly changes a boy's physical appearance" (Geffen & Heywood, 2007 [online]). Sidler *et al.* (2008, p.764) answer that "male non-therapeutic infant circumcision is neither medically nor ethically justified as an HIV prevention tool".

Yet others have reached completely opposite conclusions, with Clark *et al.* (2007, p.RA205) arguing that "neonatal male circumcision is medically necessary and ethically imperative" as "mandatory neonatal male circumcision is an effective therapy that has minimal risks, is cost efficient and will save human lives" and "to deny individuals access to this effective therapy is to deny them the dignity and respect all persons deserve". The mandatory neonatal male circumcision advocated by Clark has come under scathing criticism by van Howe and Svoboda (2007) who call this suggestion fantasy based on speculation, questioning their medical evidence, providing risk-

benefits analyses that reach the opposite conclusion and dismissing their ethical analysis as unconvincing.

Furthermore, South African law is quite clear. The Constitution states that children have the right to basic healthcare services and to be protected from maltreatment, neglect, abuse or degradation and it also provides that "the child's best interests are of paramount importance in every matter concerning the child" (Republic of South Africa, 1996). Neonatal circumcision is prohibited according to section 12 of the Children's Act No. 38 of 2005 (Republic of South Africa, 2005) which states:

- 1. Every child has the right not to be subjected to social, cultural and religious practices which are detrimental to his or her well-being.
- 3. Genital mutilation or the circumcision of female children is prohibited.
- 8. Circumcision of male children under the age of 16 is prohibited, except when-
 - a. circumcision is performed for religious purposes in accordance with the practices of the religion concerned and in the manner prescribed; or
 - b. circumcision is performed for medical reasons on the recommendation of a medical practitioner.
- 9. Circumcision of male children older than 16 may only be performed-
 - a. if the child has given consent to the circumcision in the prescribed manner;
 - b. after proper counselling of the child; and
 - c. in the manner prescribed.

10. Taking into consideration the child's age, maturity and stage of development, every male child has the right to refuse circumcision.

The questions that then arise when we consider these legal implications are as follows:

- 1. Is neonatal circumcision, specifically for the purpose of HIV prevention, a basic healthcare service?
- 2. Would circumcision of those boys younger than 16 years be considered maltreatment or abuse? Conversely, would failure to circumcise constitute neglect or maltreatment?
- 3. Is it in the child's best interests?
- 4. Can circumcision for the purpose of HIV prevention, especially in traditionally non-circumcising communities, be considered a religious practice?
- 5. Can HIV prevention in a pre-pubescent, non-sexually active individual be considered a medical reason?
- 6. Is it recommended by medical practitioners?

The answers to these questions are far from apparent. There have been no good quality RCTs done in the neonatal population to date to provide the answers to questions 1, 2 and 5. However, observational evidence would suggest that neonatal circumcision does not reduce the prevalence of HIV infection in adulthood, if we consider that in the USA two-thirds of young males have been circumcised and yet USA has one of the highest rates of HIV infection in the developed world (Darby, 2005; Sidler *et al.*, 2008). The answer

to question 6 depends on which medical practitioners one asks, with myriad opinions from strongly supporting to strong discouraging. Benatar and Benatar (2003), in a discussion of these conflicting views, have concluded that non-therapeutic neonatal circumcision should be left at parents' discretion.

In answer to question 3, the United South African Neonatal Association (USANA) has issued a statement that non-therapeutic prophylactic neonatal male circumcision to prevent future HIV acquisition does not fulfil the "in the best interest" of the newborn criteria (Smith *et al.*, 2011 [online]):

- i. "The condition for which it is advocated is not a condition/disease which the infant currently has and is not likely to develop
- ii. The procedure is not without risks
- iii. The institution of routine male neonatal circumcision is not based on any scientific evidence it is based on the extrapolation of scientific data obtained from three studies performed in adult males
- iv. There is no immediate or short-term net benefit and only hypothetical future benefit to the patient because it is not known who will and who will not be exposed to the possibility of acquiring HIV through heterosexual contact in the distant future."

USANA also argues that "children, especially infants, are uniquely vulnerable as a result of inability to provide informed consent. Routine neonatal male circumcision to prevent later-in-life acquisition of HIV is reasoned to be unethical. It takes advantage of the infant's inability to refuse and submits him to a medically unnecessary surgical procedure that a competent adult might refuse. The sexual transmission of HIV depends on adult lifestyle choices that

cannot be determined in the neonatal period. The infant is unable to provide informed consent and proxy consent is invalid because of the lack of medical necessity" (Smith *et al.*, 2011 [online]).

Despite the above, USANA has reached the same conclusion as Benatar and Benatar (2007), that "the decision to act in the child's 'best interest' may lie with the parents in this regard and should therefore be left with them, following counselling about risks and benefits of such a procedure" (Smith *et al.*, 2011 [online]). This equivocal position, which reflects the American Academy of Pediatrics' policy, places neonatal circumcision in a unique category wherein it is the only widely practiced surgical procedure that is indicated by parents' wishes rather than medical necessity (Dristas, 2001).

The answer to question 4 is complex. In the Zulu community in Kwazulu-Natal, where traditional circumcision has not been practiced since the 19th century, King Goodwill Zwelithini has now attempted to change this by issuing a call to restore the tradition of circumcision (Dugger, 2010). McQuoid-Mason (2013, p.284) argues that "It is trite that cultural circumcision ceremonies are 'rites of passage' whereby boys are initiated into manhood and instructed in the ways of their culture. The circumcision of neonates clearly does not fulfil this function. Even if circumcision were a revived cultural practice for Zulu males, parents would have to wait until their sons are 16 years of age and able to consent to this cultural practice before encouraging them to be circumcised". When faced with Zulu parents who request that their neonate or boy under the age of 16 years be circumcised for cultural reasons to comply with the

King's edict, McQuoid-Mason (2013) advises that doctors should inform parents that it would be illegal for them, as well as traditional healers, to comply with such a request as this would be against the Children's Act.

Yet, seemingly despite the clear legal prohibition, Kwazulu-Natal MEC Dr Sibongiseni Dhlomo announced in a speech on 4 November 2010, "By January 2011 we will be commencing with the neonatal male medical circumcision. We are currently embarking on an awareness campaign for pregnant mothers to understand the importance of having their babies circumcised at birth" (Dhlomo, 2010 [online]). In the same framework in which the WHO called for neonatal circumcision, it also called for country-specific operational plans (WHO/UNAIDS, 2011). This is the point at which the South African Department of Health has gone awry. It has attempted to follow an international directive that is in conflict with South African law by implementing a strategy before considering its appropriateness in our South African context. The result is an institutionalised practice that is in direct contravention of South African law and the Constitution.

The current state of affairs leaves doctors in Kwazulu-Natal in an ethical dilemma between complying with the directive supplied by provincial Department of Health and performing a procedure that has not been proven beneficial and may even be harmful to babies and is prohibited in terms of South African law. McQuoid-Mason (2013) warns us that doctors who are currently performing these neonatal circumcisions are breaching the Constitution and the Children's Act and risk being prosecuted criminally by the

state, sued civilly for damages by the person circumcised, and disciplined by the HPCSA.

Despite the absence of medical evidence, against the advice of eminent paediatric surgeons, urologists and neonatologists, in contravention of the majority of international standards and in direct contravention of South African law, neonatal circumcision for HIV prevention is being practiced in South Africa today. Not only practiced, but encouraged in certain provinces! From the preceding discussion, I think it could not be more obvious that neonatal circumcision and the circumcision of young boys for the purpose of HIV prevention is not only illegal, but unethical. For this reason, it has no place in HIV prevention strategies.

Chapter 6: An anecdote

As a junior doctor in South Africa, I have been involved with the VMMC rollout campaign personally (and involuntarily as the HPCSA has now specified that junior doctors need to personally carry out a certain numbers of circumcisions as part of the requirement of the internship training program) and it was this first-hand experience that brought many of the issues that I have discussed in this thesis to my attention. I would like to share just a single anecdote from my personal experience, that I believe demonstrates the need for ethical awareness surrounding VMMC and the urgent need to address these issues.

I came across this case in a paediatric HIV "wellness" clinic that I work in as part of my community service. The patient was a 12 year old HIV positive boy that came to collect anti-retrovirals (ARVs) on a routine, elective appointment. To provide some context, both of his parents had passed away as a result of HIV and he's living with an elderly, infirm grandmother and occasionally visited by an uncle. It was this uncle that brought him to the hospital for his routine visit and recounted this incident.

One Sunday morning, the boy wasn't at home and neither his grandmother nor uncle knew where he was. When he came home that afternoon, his pants were covered in blood and he had a slip of paper in his pocket stating that he had been circumcised at the local regional hospital along with some post-operative instructions. The boy said that the school principal had loaded about 14 boys into a school bus and taken them all to be circumcised! No consent

was taken from the parents or caregivers of these boys. In fact, they were not even informed and no HIV counselling and testing was done as part of the circumcision. Worse even, the child in question is immunosuppressed because he's failing treatment on ARVs, so his potential for complications is much higher. One hopes that the strictest sterile conditions were adhered to as any cross-contamination of instruments or equipment would result in the other children being exposed to his multi drug-resistant strain of HIV.

Cases like this one occur every day. There are very many ethical issues in this case alone. Deeply unethical practices surrounding VMMC are happening, in South Africa, every day. In this case, the uncle had an attitude of "what's done is done". Most likely, as long as there are no complications, none of the parents of any of these boys will take any action against the hospital or doctors or nurses or the principal involved. Partly because it will not change what has been done, partly because they may have some idea that VMMC may be beneficial thanks to advertising campaigns, but mostly because the boys come from an impoverished peri-urban community and parents and caregivers are most likely not aware of their rights or that there are any lanes of recourse open to them.

In a case such as this one, the school principal, nurses and doctors involved have all escaped any legal or moral repercussions. Most likely, cases such as this one will continue to occur daily as public hospitals strive to reach the ambitious goals set by the Department of Health and work towards circumcising as many men and boys as possible to gain financial incentives. Far

be it for me to suggest that the whole VMMC program is wrong or that there are no benefits at all to be gained from it. But the presence of even a single case such as this one, the fact that the rights of even one child have been violated on so many levels, is unacceptable and is a call for all of us to sit up and react to what is happening.

Chapter 7: Conclusion

In this thesis, I have explored a wide range of ethical considerations surrounding VMMC in South Africa on every level, from individual to cultural to national to global. The reality is that every single day, men and boys are having their foreskins amputated whilst these questions remain unanswered.

In the introduction, I quoted Rennie *et al.* (2007) in saying that the serious study of the ethical considerations surrounding VMMC requires finding a rational path between the two extremes of a flat dismissal of VMMC on the basis of a rejection of male circumcision as a form of genital mutilation and an overly optimistic interpretation of the three RCTs that downplays the scientific and social uncertainties and assumes that translating circumcision research into policy and practice will be straightforward and risk free. From all of the research that I have presented (a considerable proportion of which was done in South Africa) and all of the unresolved ethical considerations that I have discussed, I think it should be clear that the South African Department of Health has, to date, tended towards the extreme of optimism. What has started out as an ambitious HIV/AIDS prevention strategy that was supposed to save millions of lives is, at the moment, of deeply questionable morality.

When the WHO (2011) made its recommendation for the scale-up of VMMC for HIV prevention, it also clarified certain underlying principles of the VMMC campaign:

- 1. Country leadership and ownership
- 2. Human rights: that VMMC needs to be voluntary, based on informed consent, non-coercive and carried out under safe conditions.
- 3. Gender dimensions: The effects of VMMC on women need to be considered, including education, behaviour change communication, greater gender equality through changing gender norms, improved reproductive health and promotion of respect for sexual partners and communication between partners
- 4. A comprehensive package of services for HIV prevention
- 5. Combination of dedicated and integrated approaches to maximize public health benefits
- 6. Strategic, co-ordinated action

Sadly, while South Africa has succeeded in cutting off thousands of foreskins to date, most of these underlying principles have been violated.

When the MRC's Cochrane Review advised circumcision should be included into HIV prevention programs, it also specified that "further research [is] required to assess feasibility, desirability and cost-effectiveness in local contexts" (Siegfried *et al.*, 2011, p.2). While some efforts were made to determine these in a South African context and circumcision was included in HIV/AIDS prevention campaigns, all of the ethical dilemmas that have been created reveal that clearly, the campaign does not fit our local context.

There is, undeniably, a pressing need for HIV/AIDS prevention strategies in South Africa and other developing countries. But the role of circumcision has

been overemphasised to the detriment of more holistic approaches. VMMC is not a magic bullet and none of the literature ever tried to suggest that it was. The need for behavioural modification like the ABC approach is as relevant now as it ever was. Possibly even more so, with the spectre of behavioural disinhibition lurking that threatens to negate any positive effects gained from VMMC. Furthermore, there is no place for neonatal circumcision in HIV/AIDS prevention strategies.

Every day that the VMMC campaign continues, every day that babies, boys and men are losing their foreskins, every day that we – as doctors and leaders, as ethicists, as South Africans, as fellow human beings – sit by, idle and let it continue, every day that we do not speak out against VMMC, we are becoming more and more morally responsible for the harm that is being done, or even the possibility that harm is being done, in the name of beneficence. Each of us has a role to play in protecting the interests of those too young to refuse, those who hold false beliefs, those who have been misinformed by the media, those who are coerced by community pressure and the other vulnerable groups I have mentioned in this thesis.

I don't have any answers to the ethical considerations that I have presented throughout this thesis. I don't believe that there *are* any easy or straightforward answers to these complex ethical, social, cultural and personal dilemmas. To answer these questions will require input from all groups of people – HIV infected, HIV negative, men, women, doctors, traditional healers, ethicists, politicians, cultural leaders, policy makers, etc. – and all levels –

individual, cultural, societal, medical, political, etc. My goal with this thesis was to raise awareness that there are serious ethical concerns surrounding VMMC. So serious, I believe, that the program as it stands in South Africa today is not morally defensible. The need for a revision of the current application of VMMC policies and the cessation of neonatal circumcision is urgent.

Where we go from here, I cannot say. But the road we are headed down at the moment should be avoided at all costs.

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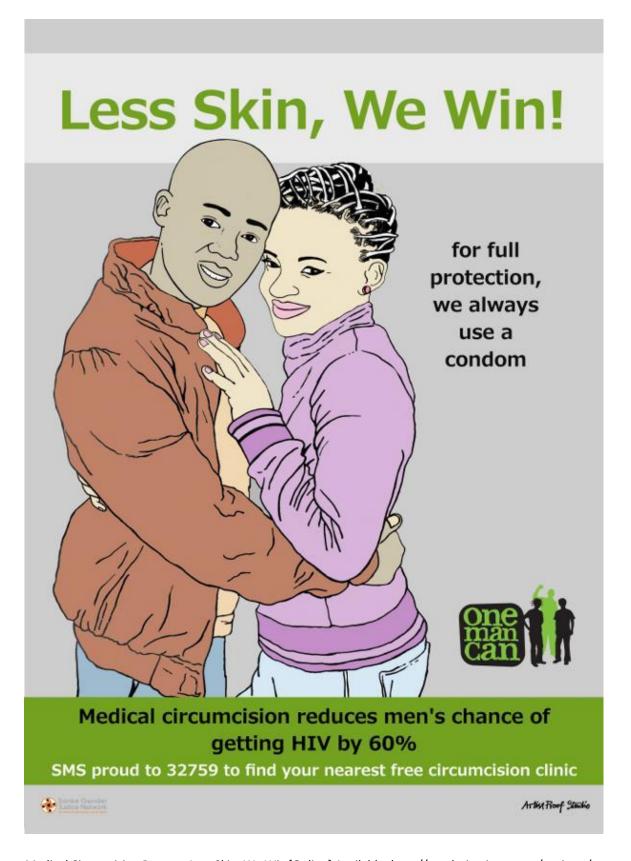
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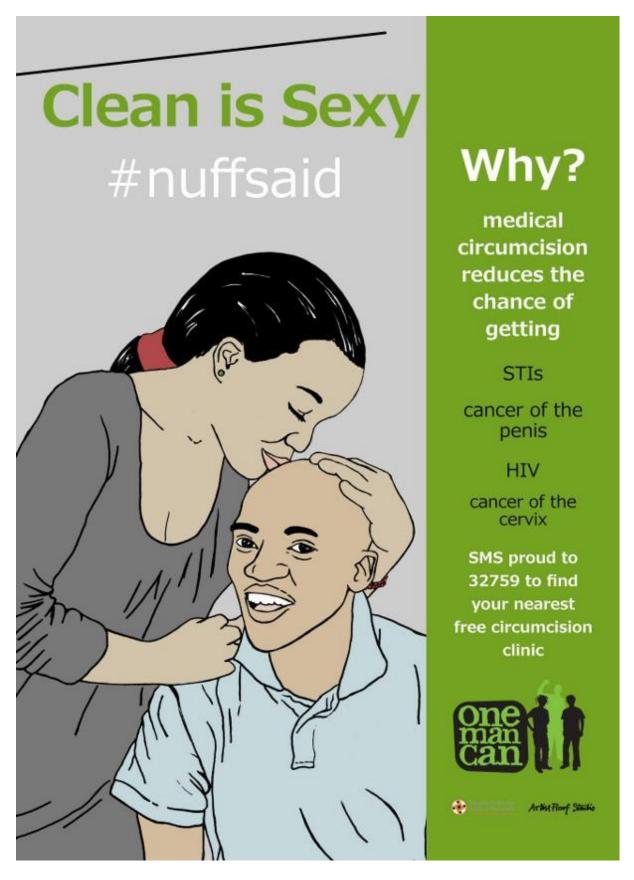
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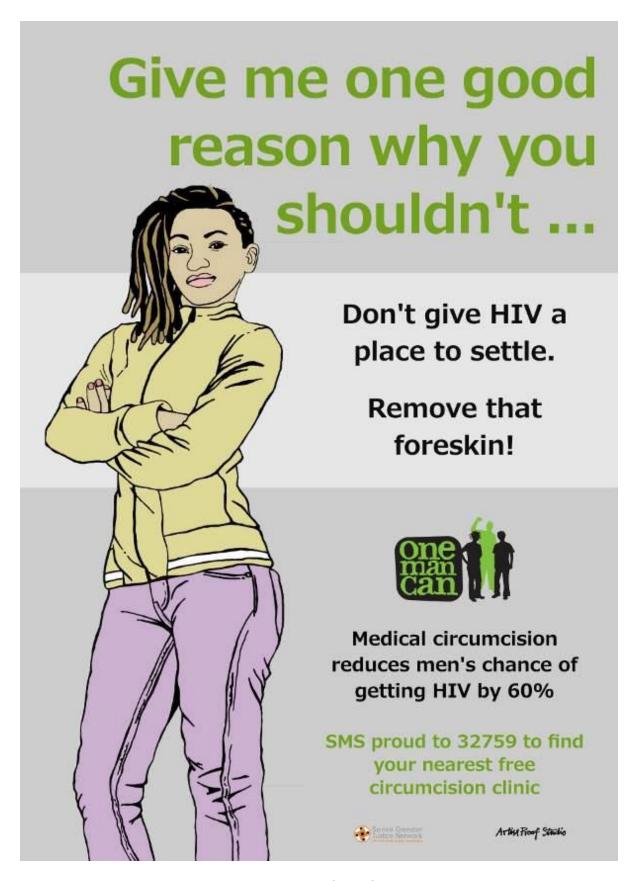
Appendix A



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