Neonatal circumcision is neither medically necessary nor ethically permissible: A response to Clark et al.

Comment to:

Mandatory neonatal circumcision in sub-Saharan Africa: Medical and ethical analysis Peter Clark, Justin Eisenman, Stephen Szapor Med Sci Monit 2007; 13(12): RA205-13

In their review article, Clark et al. claim, "Neonatal circumcision is medically necessary and ethically imperative" [1]. This represents a double contradiction of, among others, the positions of the American Academy of Pediatrics [2], the British Medical Association [3], the Canadian Paediatric Society [4], and the Royal Australasian College of Physicians [5].

To justify such a dramatic conclusion, the authors need to make a strong case. This is all the more true given the authors' far-reaching intent to examine the medical evidence, give an ethical analysis, and develop guidelines to implement mandatory neonatal circumcision in sub-Saharan Africa. Unfortunately the authors stumble so badly on the first two steps that the third step becomes irrelevant. We will evaluate the accuracy and quality of the "medical evidence" Clark et al. use in their analysis by parsing the facts from the fantasy, providing an overview of the risk-benefit analyses of circumcision, evaluating the authors' ethical justification of infant circumcision, and providing our own modest proposal.

Medical Evidence

When discussing the medical evidence surrounding circumcision it is important to first separate facts from fantasy, facts from speculations, and then to determine the strength of the evidence.

Facts and fantasy

Several of the statements made by Clark et al. have no factual basis or are factually inaccurate.

- Without providing citations, the authors refer to studies that the foreskin has greater susceptibility to traumatic epithelial disruptions during intercourse. To our knowledge, such studies do not exist. To the contrary, the only study we are aware of found a non-significant trend that penile abrasions are more common in circumcised men [6].
- 2. While Clark et al. suggest, again without citation, that the frenulum is "particular susceptible to injury during

intercourse," to our knowledge no studies substantiate such a claim.

- 3. The authors suggest, again without citation, that the micro-environment in the preputial sac "may be conducive to viral survival." We are not aware of any studies to support this claim. To the contrary, the two sexually transmitted virus, herpes simplex type 2 and human papillomavirus, occur with equal frequency in circumcised and normal men [7-10]. The authors further state that this micro-environment "favors microorganism survival and replication." Again, we are aware of no studies to support this claim. What is known is that the flora on the normal glans and the circumcised glans differ. The former have many gram-negative organisms, which are the bacteria most commonly found in the colon, while the later have more gram-positive organisms, which are most commonly found on the skin. This difference in flora may explain why circumcised newborn males are 12 times more susceptible to community-acquired methicillin-resistant Staphylococcus aureus infections [11].
- 4. Clark and co-authors suggest that the pain of circumcision can be "minimized" by local anesthesia. While local anesthesia can reduce the pain of circumcision, studies indicate the procedure is still stressful and painful [12]. The pain of circumcision is minimized by general anesthesia and/or a caudal block.
- 5. The authors suggest that circumcision protects against the development of phimosis, paraphimosis, cervical cancer, herpes simplex type 2 infections, and other sexually transmitted infections. The medical literature tells another story. There is not a single comparative study that demonstrates that phimosis or paraphimosis is significantly more common in normal males than in circumcised males. Similarly, of the sixteen studies known to us that evaluated the impact of circumcision status of the male partner on cervical cancer risk in females, only one found a significant association, which is what would be expected by chance alone. For sexually transmitted diseases, syphilis and genito-ulcerative disease are more common in normal males in Africa, while genital discharge syndrome is more common in circumcised males [7,13]. The other sexually transmitted diseases have been shown not to differ with circumcision status; however, a meta-analysis of the risk of contracting any sexually transmitted disease as opposed to not being infected shows the risk is greater in circumcised men.[Van Howe, unpublished data]
- 6. Clark et al. suggest several times that neonatal circumcision minimizes the phenomenon of risk compensation. In making this claim, they cite an opinion piece by Rennie et al., [14] which makes this claim without any reference. Once again no reference to research

supporting this claim is given because, to our knowledge, no reference exists. Evidence to the contrary does exist. Laumann et al. found that circumcised men in the United States exhibit higher risk behaviors than normal men [15]. The authors' concern about risk compensation is understandable because the impact on HIV infection rates of large increases in the circumcision rate can be undone with small decreases in the rate of condom use. If a man feels his circumcision is protecting him, he will be less likely to use condoms. Consequently, he is actually putting himself at a greater risk than if he had not been circumcised and used condoms more frequently.

- 7. The authors state that circumcision is more effective in preventing HIV infection if it is performed earlier in life. There is conflicting evidence regarding the impact on HIV risk of the age of circumcision. The studies used age cutoffs of 12 and 15 years and did not break out those circumcised neonatally as opposed to those circumcised later [16,17].
- 8. The authors suggest that the majority of Muslims are circumcised at birth, when this is clearly not the case [18]. How did such an egregious statement escape the scrutiny of reviewers and editors? Clark et al. also suggest that 30% of males in the world are circumcised, but fail to include the important qualification that outside of the North America, Australia, and those of the Jewish faith, very few of these procedures are done on newborns.
- 9. Clark and collaborators erroneously suggest that HIV infection trends are "stable" and "increasing." The HIV infection rates in Africa peaked in the late 1990s and are declining [19].
- 10. The authors suggest that methods of HIV prevention that are less invasive and more effective than circumcision may be discovered between when a newborn is circumcised and when he reaches sexual maturity. Clark et al. thus obscure the fact that less invasive, more effective, less expensive methods already exist, in the forms of condoms and abstinence.
- 11. Clark et al. state that circumcision will reduce the risk of women becoming infected with HIV. Recently it has been reported that following circumcision the female partner of a HIV infected man is not protected and may be at greater risk of infection immediately following the circumcision [20–22].
- 12. Without supplying a reference, the authors claim that neonatal circumcision is less expensive than circumcision later in life. Since most of the estimates of the cost of circumcising Africa are based on using local anesthetic and most of the difference in the cost of circumcision in developed nations is the cost of general anesthesia, it is hard to know where the difference in cost is coming from. The surgeon's time, the local anesthetic, etc. would be similar for both procedures. The only difference is that it is easier to hold an infant down.
- 13. Clark and co-authors claim that neonatal circumcision has fewer complications than later circumcisions. Again, no references are provided. Most of the comparisons have been between studies that used different criteria for what constituted a complication. Only two studies have done a direct comparison, in a single setting, using parallel definitions, of complication rates from neonatal circumcisions and complication rates from post-neonatal circumcisions. One found no difference in the com-

plication rates, while the second found more complications in the neonatal circumcisions [23,24].

The authors provide an incomplete discussion of the complication rates of circumcision and ignore studies that fail to support their premise. For example, one ignored study of circumcisions performed mostly on newborns in a medical facility in Ibadan, Nigeria found a 20.2% complication rate with 3.1% of the circumcisions resulting in part of the glans being amputated [25]. Expounding on the benefits of the allegedly low complication rate associated with circumcision, while ignoring the realities of performing the procedure in developing nations, is negligence that borders on recklessness and academic dishonesty.

Facts and speculation

- 1. The authors erroneously suggest that the "outer shaft of the penis is protected by a barrier of keratinized stratified squamous epithelium, much like the structure of skin found throughout the outer surfaces of the body. In these tissues, keratin provides a tough structural matrix that resist friction and fluids. The inner mucosa of the foreskin, however, is made up of non-keratinized squamous tissue and thus does not offer the same level of protection." To the contrary, it has never been demonstrated that there is any difference in protection provided by keratinized and non-keratinized squamous tissue. Mucosal immunity works much differently than skin immunity, and so far there have been no studies that provide a comparison.
- 2. The authors provide a description on how Langerhans cells are believed to be involved in HIV infection. To date, this is speculation and has not been proven in vivo. Langerhans cells are effective at preventing HIV infection, as reflected by a low infection rate per unprotected sexual contact. It is only when the Langerhans cells are overwhelmed with a high viral load that the HIV virus gets into the system [26]. This may explain why antiretrovirals, by lowering the viral load, help reduce HIV transmission. Currently, the Swiss have stated that for HIV-positive individuals on antiretroviral therapy with low viral loads and no active sexually transmitted infections, there is no risk of HIV transmission [27]. The Langerhans cells also fight against other sexually transmitted diseases, which may explain why circumcised men have a greater overall risk for sexually transmitted diseases. [Van Howe, unpublished data]
- 3. The authors express the hope that "mandating neonatal male circumcision could open up discussions about HIV prevention and would allow time for the children to be educated on subjects such as condom use, testing for HIV, mutual monogamy, and partner reduction as they get closer to the age of sexual activity. This education, along with the preventative effects of the circumcision, would cause a major decrease in the spread of the HIV virus." It is hard to understand how a procedure performed on infants would open up discussion about HIV prevention. Any discussion with an infant would likely be forgotten. Education and discussion would be most effective just prior to or around the age when sexual activity is initiated. It is hard to picture how this could be linked to infant circumcision, unless the parents are the objects of the discussion. For them, the opportunity for meaningful, effective discussion may have already passed. Further,

a false sense of assurance obtained from an assertedly, but not in fact, effective HIV prevention measure such as circumcision could result in the stifling of further dialog regarding HIV prevention, as the matter would incorrectly seem to have been adequately resolved.

4. The authors state that neonatal circumcision will prevent HIV infections and save lives. This suggestion represents fantasy based on speculation. The speculation is that data from circumcision performed in randomized clinical trials in self-selected, well-paid, motivated, high-risk adults can be extrapolated to infants. The observational data from populations that perform primarily infant circumcisions indicate that it cannot. For example, the largest studies of heterosexual men in the United States have failed to find such an association. The first was a systematic population survey in the 1990s. It found that nine men out of 2567 interviewed were HIV positive and no significant association was found between HIV infection and circumcision status [15]. The second was a study of patients of a sexually transmitted disease clinic in San Francisco from 1996 through 2005. Among the 52,143 heterosexual men, those who had been circumcised were at slightly greater risk for HIV infection, although the trend was not statistically significant (OR=1.07, 95%CI=0.95-1.21).[28] While studies based in sexually transmitted clinics are susceptible to various forms of bias, it is extremely unlikely these forms of bias would erase the 50% to 60% protective effect the authors believe should result from neonatal circumcision. What is more likely is that infant circumcision performed on the general population has no impact on the risk of HIV infection.

Strength of the evidence

Much has been made of the results of the randomized clinical trials in Africa. [29-31] Although these trials were randomized, they still have a number of sources of bias, some of which were unavoidable and some of which were avoidable. These include selection bias, lead-time bias, expectation bias (both on the part of the participants and the researchers), attrition bias (700 men were lost to follow-up, while only 205 became HIV infected), length bias, improper randomization (Auvert study[29]), and early termination, which amplified the lead-time bias. Each of these forms of bias contributes positively to the treatment effect the investigators were hoping for. While the small absolute risk reductions found in these studies appear to be statistically significant due to the large number of subjects, their clinical importance has not been fully vetted.

The participants in the randomized clinical trials were men who wanted to be circumcised and were mostly unemployed. For participating, they received a free circumcision (thereby saving themselves the equivalent of about two months of wages), cash (also equivalent to about two months of wages), cash bonuses for recruiting additional subjects, and up to two years of free health care. It is not clear whether subjects were given full disclosure regarding the negative consequences of circumcision. Although these studies were approved by various investigational review boards, a case could be made that these men's participation in the studies was financially coerced and informed consent was inadequate.

When interviewed by *Nature*, Helen Weiss, a statistical epidemiologist at the London School of Public Hygiene & Tropical Medicine, stated that given the results of the observational studies and randomized clinic trials, this is "as convincing evidence as one ever gets in public health" [32]. A faculty member of a school of public health ought to know better. The findings of a randomized clinical trial do not necessarily result in public health benefits. To test and demonstrate the practical applicability of their findings, randomized clinical trials should be followed by translational studies. Quite often the patients included in a clinical trial are those individuals most likely to respond the intervention. When application of the intervention is expanded to a more general population, who are often less likely to respond, the positive response is often attenuated or can disappear completely. Compared to the populations in the clinical trials, the general population will be not be self-selected, will be less motivated, will be at lower risk for infection, and will not be paid to undergo the procedure. Likewise, the general population will not have similar access to care for the complications of the procedure and may not have same quality of care delivered at the time of the procedure. Consequently, there are many reasons why the results in the research setting may not translate into a public health success.

Circumcision as a "vaccine" and other hyperbole

Resorting as often as they do to hyperbolic statements, the authors make themselves look foolish. Statements like, "Innocent lives are being lost daily," have no place in a serious discussion of this issue. If circumcision was such a great intervention, why do the authors need to resort to hyperbole to convince others?

The authors repeatedly emphasize that WHO and UNAIDS have "recommended" circumcision. (UNAIDS as a non-scientific organization could more accurately be described as advocating for circumcision.) Before it can be recommended, circumcision as a preventive for HIV infection needs to be compared to the alternative interventions. As discussed below, the ABC (abstinence, be faithful, condoms) approach is more effective, less expensive, has fewer side effects, is less invasive, and is more readily available. The ABC approach also has the additional benefits of protecting against sexually transmitted diseases and unwanted pregnancies. The only unsettled component is compliance. Compliance can depend on social pressures and on how persuasively health care workers promote condoms.

To recommend an intervention when more effective, less expensive, less harmful, and less invasive alternatives exist is unethical. Based on this comparison, it is unethical to *recommend* circumcision over the ABC approach. At best circumcision can be offered as an alternative while making it clear that it is less effective, more invasive, more expensive, and has more side effects than the ABC approach.

The authors equate the impact of adult circumcision in a self-selected, well-paid, motivated, high-risk population with that of a vaccine. By doing so they are hoping to play on the impression that most people have of vaccines: minimal negative impact, protection rate of 85%, cost-effective, low rate of complications, non-interference with daily activities, and the best alternative available. Protection of 40% to 50% in a selected population that may not translate to the general population is pathetic compared to what most people wo-

uld consider the "vaccine-level protection" of 85% or more provided by the vaccines currently in use [33]. Circumcision also has a much higher rate of complications that what would be expected from a vaccine. Early complication rates in developed countries are 2% to 6% [34,35]. In developing countries, they are as high as 20% [25]. Later complications, such as meatal stenosis requiring meatotomy, can occur in 5% to 8% of cases [36]. Serious complications, such as amputation of the glans and death, do occur. These rates are much greater than would be expected from vaccines. Moreover, issues result from tissue amputation that are not associated with vaccines. Circumcision removes nearly all of the fine-touch neuroreceptors and the most sensitive portion of the penis [37,38], decreases the sensitivity of the glans [38,39], and results in problems with erectile dysfunction, loss of sexual pleasure, premature ejaculation, difficulty with insertion, and loss of sensitivity [40-43]. Such a disruption in daily function from a vaccine would not be tolerated. Vaccines are used because they are effective, have an acceptable rate of side effects, and are the best available option. Circumcision of infants has not even been proven to be effective and is far from the best available option. For the illnesses that circumcision proponents believe to be impacted by neonatal circumcision, other less invasive, more effective interventions are available. If a vaccine were released that only offered 50% protection for HIV, but reduced condom usage, it would be rejected.

Risk benefit analysis

The authors make multiple references to the balance of risks and benefits and how the benefits allegedly outweigh the risks without actually performing a risk-benefit analysis. Several analyses of the costs of neonatal circumcision have been published [44-48]. None has found neonatal circumcision to be cost-effective. The most recently published cost-utility analysis, which incorporated into the analysis an assumption that circumcision would reduce the rate of HIV by half, found that neonatal circumcision resulted in more costs and poorer health than for those not circumcising [47]. Even a cost-analysis published by one of circumcision's most prominent proponents found that circumcision was more costly than not circumcising [48]. So based on the information in the medical literature and no further analysis in their article, it is not evident that neonatal circumcision has benefits that outweigh the risks.

The conclusion that neonatal circumcision has fewer risks than benefits may come from a cultural bias rather than medical information. It has been well documented that in cultures that have high neonatal circumcision rates, the pain, harm, and risks of the procedures are either ignored or minimized, while the benefits are exaggerated and promoted [49,50]. Because of the cultural blinders and multipliers associated with this issue, purely rational discussions of neonatal circumcision have become nearly impossible [50].

The authors make much of the studies that extrapolate the findings from the shortened randomized clinical trials to the rest of Africa. Extrapolation from a small non-representative population over a short period of time to the rest of Africa over a lifetime is fraught with danger. These models may give a very rough estimate of the costs and benefits, but like most models the GIGO (garbage in, garbage

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out) principle applies. What is missing from the discussion of risk and benefits of those promoting circumcision as a preventive for HIV infection is a comparison of circumcision to other interventions. The authors state that circumcision of the neonate is "relatively inexpensive" without providing a comparison. For example, a study using aggressive surveillance and treatment of sexually transmitted infections found that one HIV infection could be averted for each \$217.62 (1993 USD) spent [51]. A recent estimate places this in the \$321 to \$1665 range [52]. Gray et al. have estimated, based on their results in a research setting, that using circumcision, it would cost \$1269 to \$3911 to avoid one HIV infection [53]. This assumed that similar treatment effects and complication rates could be obtained outside of a research setting, which is not a very safe assumption. Treating sexually transmitted infections has the additional benefit of reducing the number of HIV infections. By contrast, the randomized clinical trials found that circumcision had no significant impact on gonorrhea, syphilis, or herpes type 2 seroconversion [54].

Once the infrastructure to deliver care is established, condoms cost approximately 2¢ each. For the price of one circumcision in Africa, one could purchase 3500 condoms, enough to provide a condom a day for nearly ten years. Condoms, if used consistently, can provide 99% to complete protection. In a cost comparison, relying on circumcision cost 95 times more to have the same impact as condom use [55]. Of course the infrastructure needed to provide circumcision under sterile conditions would much more costly than that needed to distribute condoms. So for primary prevention, condoms and abstinence are the most effective, least expensive, least invasive interventions. With complete protection available through condoms at very low cost, what value does circumcision add? It is either ineffective or redundant. Noting that the authors are part of a Catholic institution, there may be some reluctance to discuss condoms, but the authors may want to present a follow-up article on the ethics of interfering with condom distribution.

Regarding the medical evidence, one can only conclude that it is not known whether infant circumcision will reduce the rate of HIV infection. Evidence from the United States indicates that it does not.

Ethical analysis

All medications have effects. Some we like, some we don't. The latter we call side effects. Sometime a medication is used for its "side effects," depends on the illness.

The authors rely on an ethical analysis of dual effects. To prove their case, they must fulfill four conditions and three criteria associated with the fourth condition [56,57]. The authors try to demonstrate that the criteria are met. We find their arguments unconvincing.

The first condition requires proof that neonatal circumcision is in and of itself good. The authors state that this condition has been met because neonatal circumcision "can effectively reduce male heterosexual HIV infection by 60%." As noted above, this has not been demonstrated and there is ample evidence to the contrary. Until this can be proven, this condition is not met. The second condition is that the good effect is not produced by means of the evil effect. The authors state this condition is met because circumcision "provides a degree of protection against acquiring HIV infection not only for the individual but for others in society." Neither of these has been proven, so this condition is not met. One of the problems with circumcision is that the evil effects can produce more evil effects. For example, circumcision removes the most sensitive portion of the penis (an evil effect) [38]. The foreskin is functional genital tissue that serves important protective, immunological, and erogenous functions (an evil effect). Moreover, the loss of tissue can lead to behaviors that are associated with an increased risk of HIV infection (another evil effect), such as less frequent condom use, an increase in the number of sexual partners, a greater likelihood to engage in anal sex [15], and greater likelihood to be gay or bisexual [28].

The third condition is that the evil effect is not intended, but merely tolerated. The authors state this condition is met because "the direct intention of mandating neonatal circumcision is to provide a degree of protection to the individual against HIV infection and to offer a degree of protection for society as a whole." Once again, neither of these desires the authors have for circumcision has been demonstrated. Throughout history, the intended effects of circumcision have been less than beneficial. In most cultures and religions that practice circumcision, it is used as way of controlling sexuality in contrast to having the full pleasure of the penis and having the freedom to choose what to do with it [58–63]. It may come down to which is evil: societal control or personal freedom?

The fourth condition is that a proportionate reason exists for performing the action, in spite of its evil consequence. This condition has three criteria.

The first criterion is that the means used will not cause more harm than necessary to achieve the value. If it is not clear that neonatal circumcision can achieve the goal, this criterion is not satisfied. As discussed above, condoms are less invasive, more effective, and less expensive than circumcision. Even if neonatal circumcision provided 60% protection, using circumcision causes more harm than necessary to achieve the goal of reducing HIV infection.

The second criterion requires that no less harmful way exist to protect the value. Again condoms are more effective and less harmful.

The third criterion mandates that the means to achieve the value will not undermine it. To meet this criterion the authors state that "mandatory neonatal male circumcision does not undermine the value of human life." The authors talk about the loss of autonomy as a counter argument, but fail to address it. The authors fail to recognize that the infant has the right to bodily integrity as guaranteed by a number of international human rights declarations [64–66]. An indepth study of consent in children concluded that a preference for performing a procedure on infants rather than waiting until the child can assent is associated with a disrespect for the value of the infant as a person [67]. Circumcision is also performed for cultural reasons that benefit the society instead of the child [68,69]. The foreskin is conside-

red community property. This approach treats the child as a means instead of as an end to himself, thereby diminishing his worth as a human in a manner that may make Kantians squirm [70]. A consistent thread in the articles that support newborn circumcision from an ethical perspective is the lack for respect for the newborn as a person [71].

More on point, circumcision undermines itself by leading to a lower usage of condoms and an increase in other highrisk behaviors.

The ethical argument thus fails to meet any of the criteria and conditions. However, employing the types of arguments used by the authors, and in homage to Jonathan Swift, we offer a "modest proposal." Using similar arguments as those put forth by the authors, we believe one could argue that neonatal penectomy is "medically necessary and ethically imperative."

The first condition would be met because penectomy would virtually eliminate all sexually transmitted HIV in both heterosexuals and homosexuals. It would also have the added benefit of eliminated nearly all sexually transmitted infections. It would also have a beneficial impact on overpopulation and unwanted pregnancies and an indirect positive impact on poverty. It could be predicted to also have a positive impact on the subjugation of women.

The second condition is likewise met because the good effect of neonatal penectomy does not come from its evil effect (that is if there is an evil effect).

The third condition is met because the direct goal of neonatal penectomy is to reduce HIV infections, which it would accomplish, along with the positive effects listed above.

The fourth condition depends on three criteria. The first criterion would be met using the authors' standards because the value of HIV prevention trumps any harms. The second criterion is met using the authors' standards because neonatal penectomy offers vaccine level protection. It is probably more effective than any of the vaccines currently under development could hope for. The third criterion is met because neonatal penectomy does not undermine the value of human life any more than circumcision does and protects women and the rest of society.

So using the authors' logic, neonatal penectomy would be preferable to neonatal circumcision because it is more effective in preventing HIV and has many additional benefits. The *reductio ad absurdum* that the authors' arguments produces speaks for itself.

Other issues

Clark et al. manage to avoid discussion of broader issues that might provide a more nuanced perspective less consistent with their antipathy to the foreskin. There are two camps in the fight against HIV infection. There are those who feel there is a quick-fix biological cure [72]. Alternatively, there are those who realize that the HIV pandemic is driven by high-risk behaviors and that the pandemic will continue until the behaviors are addressed [19,73]. While the quick-fixers, such as the authors, point out the difficulties of getting people to adopt healthier sexual behaviors, the effectiveness of the ABC program in Uganda indicates that significant improvement is possible and that behavior can change and these changes can have a large impact on infection rates.

The second issue that the authors breeze past is whether efforts should be focused on primary or secondary prevention. Advocating newborn circumcision for all Africans is primary prevention. The problem with primary prevention is that you may have to circumcise hundreds or thousands of infants to have a net benefit in one individual twenty years later. That approach expends a lot of resources that could be utilized elsewhere or while we are waiting. By contrast, secondary prevention (condoms or antiretroviral therapy) has been shown to be nearly completely protective, and focuses resources to where they will have the most positive impact. In his recent book, The AIDS Pandemic, James Chin expresses the opinion that primary prevention of AIDS is a waste of resources better focused on secondary prevention [19]. Circumcision may have a mild benefit for self-selective, well-paid, motivated, high-risk adult males in Africa, while its impact in other populations remains to be seen. Even so, the high costs, potential for complications, and disregard for individual autonomy make it difficult to justify a mandate for circumcision in high-risk adults. Doing so will squander resources that could be better applied to interventions that would have a much more positive impact. Extrapolating the weak protective effect in a selective adult population to infant circumcision without any data to support can best be described as silly.

Sincerely,

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