June 29, 2020

Ambassador Deborah L. Birx, M.D.
U.S. Global AIDS Coordinator & U.S. Special Representative for Global Health
The United States President’s Emergency Plan for AIDS Relief
U.S. Department of State
2201 C St., NW
Washington, DC 20520

Re: World Health Organization, HIV, PEPFAR, and male circumcision

Dear Ambassador Birx:

Doctors Opposing Circumcision is a non-profit educational organization with expertise in all aspects of male circumcision.

As we are certain you know, President Trump has severed the relationship of the United States with the World Health Organization, purportedly because of corruption and malefacing at WHO. In this light, we think that it is time for a re-assessment of the effectiveness of the voluntary medical male circumcision program (VMMC), sponsored by WHO and supported by PEPFAR, that has caused the non-therapeutic circumcision of more than 22 million African men.

Here is our respectful request, supported by the discussion to follow below:

That the provision of non-therapeutic male circumcision be suspended until such time as the following conditions are satisfied:

- The COVID-19 pandemic ends.
- Male circumcision is shown to be cost-effective in preventing HIV infection.
- The value of the health benefits is shown to exceed the maleficial effects of the loss of the foreskin including the iatrogenic spread of HIV by non-medically-trained ‘operators.’

And that all funding currently assigned to male circumcision be reassigned to provision of anti-retroviral therapy (ART) and condom usage.
We submit the following discussion for your consideration:

**The conception**

The notion that male circumcision could prevent HIV infection was conceived and promoted by Drs. Valiere Alcena, M.D. and circumcision advocate Aaron J. Fink, M.D., who without any medical evidence, wrote a letter to the *New England Journal of Medicine* to promote his speculation.  

**Effect of circumcision on physicians and medical literature**

Circumcision is a traumatic procedure. Van der Kolk (1989) reports that traumatized persons tend to repeat the trauma on themselves or others, resulting in harm to others, harm to self, or being re-victimized. Goldman (1999), in discussing the effects of circumcision on physicians, comments:

One reason that flawed studies are published is that science is affected by cultural values. A principal method of preserving cultural values is to disguise them as truths that are based on scientific research. This 'research' can then be used to support questionable and harmful cultural values such as circumcision. This explains the claimed medical 'benefits' of circumcision.

As a result, the medical literature regarding male circumcision is a battleground between evidence-based papers and emotion-based papers.

**Immunological qualities of the foreskin**

Nature put the foreskin there for numerous physiological purposes. Fleiss, Hodges & Van Howe (1997) reviewed the immunological functions of the human foreskin. They reported:

- The gliding action of the foreskin reduces abrasions of the penis of the male partner and the vagina of the female partner making infection less likely.
- The inner prepuce contains apocrine glands, which secrete cathepsin B, lysozyme, chymotrypsin, neutrophil elastase, cytokine (a non-antibody protein that generates an immune response on contact

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1 Alcena V. AIDS in third world countries. *NY State J Med.* 2006; 8: 446
2 Fink AJ. A possible explanation for heterosexual male infection with AIDS. *NEJM.* 2006; 315(18):1167.
with specific antigens), and pheromones such as androsterone. Lysozyme, which is also found in tears, human milk, and other body fluids destroy bacterial cell walls.

- The prepuce is also richly vascular. The most vascular parts of the body are those least vulnerable to infection.
- Men with a prepuce are less likely to engage in risky sexual activities.
- The prepuce contains Langerhans cells in its epithelium. Langerhans cells are part of the immune system.

Carael et al. (1988) studied HIV transmission among heterosexual couples in Central Africa. No difference was found between couples in which the male was circumcised and those in which the male was intact.  

Lee-Huang et al. (1999) report that lysozyme is active against HIV-1.  

De Witte et al. (2007) report that the Langerhans cells in the prepuce express a substance called Langerin that blocks the uptake of HIV. The authors concluded:

Here we show that in stark contrast to DC-SIGN, Langerin prevents HIV-1 transmission by LCs. HIV-1 captured by Langerin was internalized into Birbeck granules and degraded. Langerin inhibited LC infection and this mechanism kept LCs refractory to HIV-1 transmission; inhibition of Langerin allowed LC infection and subsequent HIV-1 transmission. Notably, LCs also inhibited T-cell infection by viral clearance through Langerin. Thus Langerin is a natural barrier to HIV-1 infection, and strategies to combat infection must enhance, preserve or, at the very least, not interfere with Langerin expression and function.

Excision of a clearly immunological structure to prevent infection is counterintuitive.

Early research

Early studies of the effectiveness of circumcision in preventing HIV infection on balance did not make a case for using circumcision to prevent HIV infection. De Vincenzi & Mertens (1994) carried out an editorial review of 36 studies of various types. They concluded:

As the safety, expected benefits, feasibility and acceptability of mass circumcision are all questionable, neither public-health interventions nor intervention studies appear to be defensible options before there is stronger evidence from observational studies in different settings that show lack of male circumcision may be a genuinely independent risk factor for the transmission of HIV.  

Van Howe (1999) conducted a review of the literature and meta-analysis of 29 published articles. He reported a consistent relationship between the presence of genital ulcer disease (GUD) and HIV infection, but not between the presence of the foreskin and HIV infection. Van Howe concluded, “[b]ased on the

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studies published to date, recommending routine circumcision as a prophylactic measure to prevent HIV infection in Africa, or elsewhere, is scientifically unfounded.\textsuperscript{12}\\n\textsuperscript{12} Van Howe RS. Circumcision and HIV infection: review of the literature and meta-analysis. \textit{Int J STD AIDS}. 1999; 10: 8-16.
\textsuperscript{15} WHO | WHO and UNAIDS announce recommendations from expert consultation on male circumcision for HIV prevention.
Thomas \textit{et al.} (2004) carried out a case-control study of male HIV-infected U.S. military personnel with controls of non-infected personnel. They found male circumcision is \textit{not} associated with HIV or STI prevention in this U.S. military population.\textsuperscript{13}

\textbf{The randomized controlled trials}

Pro-circumcision doctors were not satisfied with the lack of evidence to support male circumcision to prevent HIV infection. It was decided:

- Bertand Auvert would work at Orange Farm, near Johannesburg in South Africa.
- Ronald H. Gray and Godfrey Kigozi would work in the Rakai district, Uganda
- Robert Bailey and Stephen Moses would work at Kisumu, Kenya.

The French National Institute of Health and Medical Research (INSERM) funded the Orange Farm study\textsuperscript{14} while Anthony Fauci of the U. S. National Institute of Allergy and Infectious Diseases approved funding by the National Institutes of Health (NIH) to fund the Gray and Kigozi work in the Rakai District and the Bailey and Moses work at Kisumu, Kenya.\textsuperscript{15}

Auvert published his report in 2005.\textsuperscript{16} Gray & Kigozi and Bailey & Moses coordinated the publication of their reports together in the February 24, 2007 issue of \textit{The Lancet}.\textsuperscript{17} \textsuperscript{18}

\textbf{The response of the WHO and UNAIDS}

There was at that time an intense political demand for something — anything — that would help with the epidemic of HIV/AIDS and the focus was on circumcision. According to Dowsett & Couch (2007):

"Indeed, the clamour for circumcision silenced many questions, overrode any misgivings and swept sceptics to the sidelines."\textsuperscript{19}

The World Health Organization (WHO) and UNAIDS had already scheduled a major international consultation on Male Circumcision and HIV Prevention: Research Implications for Policy and Programming.
at Montreux, Switzerland on 6-8 March 2007, only 12 days after the publication of the two papers in *The Lancet*.20

**Critical commentary**

Although there clearly was insufficient time to properly consider the new reports, Dowsett & Couch report:

> The meeting formulated draft recommendations to the world from WHO/UNAIDS and the rest of the UN system on adopting male circumcision as one additional approach to enhancing prevention efforts in high HIV prevalence, generalised epidemics where HIV transmission between women and men is the major route of infection. A WHO/UNAIDS *Statement on the Conclusions and Recommendations* of that meeting was released on 28 March 2007.21 22

After an extensive discussion, Dowsett & Couch concluded:

> At the moment, the enthusiasm for male circumcision is proferred to displace the disappointment of previous “silver” or “magic” bullets that have not worked as well as we had hoped. It is a dreadful pandemic, to be sure; but that does not mean we should lose sight of the fact that care, judgement, experience and knowledge are required before action. Evidence is but one form of this, and the determination not to harm others through haste or expedience must prevail.23

Green *et al.* (2008) reviewed the RCTs, pointed out many unsolved issues, and concluded:

> The world community must cautiously review and carefully consider the long-term consequences of mass circumcision campaigns, from the risk of increasing deaths and infections to human rights violations. In the rush to save lives, many may instead be lost and human rights trampled in the stampede. Circumcision is not the panacea the world has been waiting for in the battle to stem the HIV crisis.24

The *South African Medical Journal* published three articles about HIV and male circumcision in its October 2008 issue. The authors of all three articles opposed the introduction of male circumcision to prevent HIV infection.

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24 Green LW, McAllister RG, Peterson KW, Travis JW. Male circumcision is not the HIV ‘vaccine’ we have been waiting for! *Future HIV Therapy* 2008;2(3):193-9. doi:10.2217/17469600.2.3.193
Sidler, Smith & Rode (2008) said in the conclusion of their article;

Male non-therapeutic infant circumcision is neither medically nor ethically justified as an HIV prevention tool. Circumcision is not equivalent to successful immunisation, is being practised with decreasing frequency in English-speaking countries, and is becoming illegal in South Africa under the new Children’s Act. There are far more effective prevention tools costing considerably less and offering better HIV reduction outcomes than circumcision.

Finally, the WHO and UNAIDS appear to be basing these multi-million-dollar prevention programmes on limited and in some instances biased information. In order to prevent confusion and parents making misguided decisions on behalf of their infants, and to offer effective help in alleviating the suffering that is being created by HIV/AIDS, a much broader review process would be called for. Such a process would involve more objective scientific opinion, and the involvement of a representative panel of African experts, such as paediatric surgeons and neonatologists.  

Myers & Myers (2008) expressed concern over the heterogeneity of the effect of male circumcision in various countries. They concluded:

Despite a strong pro-circumcision lobby driven by enthusiasts who have been promoting MC as an (HIV) intervention for many years, and impatience expressed by protagonists about the long delay after the 2006 - 2007 RCT results and the UNAIDS/WHO policy recommendations of March 2007, few mass campaigns have been launched in African countries.

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.  

Connally et al. (2008) reported the results of a study in a group of 3,025 men of the effectiveness of male circumcision in preventing HIV infection that was carried out in 2002. They reported:

Circumcision had no protective effect in the prevention of HIV transmission. This is a concern, and has implications for the possible adoption of the mass male circumcision strategy both as a public health policy and an HIV prevention strategy.  

Van Howe & Storms (2011) criticized the three RCTs, saying:

The trials were nearly identical in their methodology and in the number of men in each arm of the trial who became infected. The trials shared the same biases, which led to nearly identical results. All had expectation bias (both researcher and participant), selection bias, lead-time bias, attrition bias, duration bias, and early termination that favored the treatment

effect the investigators were hoping for. All three studies were overpowered such that the biases alone could have provided a statistically significant difference.

Van Howe & Storms found male circumcision wasteful and distracting. Instead they recommended reliance on proven methods such as condoms, treatment of STIs, and antiretroviral therapy (ART). 28

Boyle & Hill (2011) reviewed the three RCTs and found a plethora of issues that cast doubt on the validity of the findings. 29

- Lack of equipoise. The principal investigators were long-time proponents of male circumcision and lacked neutrality.
- Another RCT had found that male circumcision increases the male to female transmission of HIV infection by 61 percent.
- Lack of blinding. It is impossible to conceal the fact of male circumcision.
- Experimenter bias. The experimenters already had made up their minds in favor of male circumcision.
- Supportive bias. Circumcised men received counseling on safe sex, but the non-circumcised control group did not.
- Participant expectation bias.
- Attrition. There were 673 drop-outs. Were these drop-outs circumcised or intact? HIV+ or HIV-? No one knows.
- Time-out discrepancy. The circumcised group were required to abstain from sex during their period of healing, but the intact group had no similar period of abstention. This meant that the intact group had more opportunity for infection than the circumcised group.
- Statistical artifice. The reported relative decrease in HIV infection was reported to be 55 and 60 percent, but the not-reported absolute decrease in HIV infection was only a non-significant 1.3 percent.
- Early termination. The studies were terminated early which increased the apparent effectiveness of male circumcision in preventing HIV infection.
- Coordination. The authors reported strong evidence of coordination between the studies, perhaps to produce similarity in results.
- Failure to control for confounding factors. HIV infection may be transmitted by medical procedures or by same-sex relationships. No consideration was given to these factors.

Boyle & Hill also reported a fourth RCT, 30 one that studied male to female transmission of HIV in discordant couples. Most disturbingly, a 61 percent increase in transmission when the male partner is circumcised was reported.

The findings of Boyle & Hill suggest that the three RCTs are grossly inaccurate. The WHO’s 2007 recommendations are based entirely on these dubious reports. 31

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Results in actual practice of male circumcision to prevent HIV infection

Garenne (2008) investigated the effects of male circumcision on the HIV epidemic in sub-Saharan Africa. He found a pattern of heterogeneity with “no evidence of an overall protective effect of male circumcision”.  

Van Howe (2015) reviewed the data on the effectiveness of male circumcision in preventing HIV infection. He reported:

> No consistent association between presence of HIV infection and circumcision status of adult males in general populations was found. When adjusted for other factors, having a foreskin was not a significant risk factor. This undermines the justification for using circumcision as a primary preventive for HIV infection.  

Garenne & Matthews (2019) studied HIV/AIDS situation in Zambia six years after the onset of mass campaigns of Voluntary Medical Male Circumcision (VMMC). They found:

> In a multivariate analysis, based on the 2013 DHS survey, circumcised men were found to have the same level of infection as uncircumcised men, after controlling for age, sexual behaviour and socioeconomic status. Lastly, circumcised men tended to have somewhat riskier sexual behaviour than uncircumcised men.

Garenne & Matthews questioned the value of male circumcision to prevent HIV infection.  

World Health Organization

The World Health Organization (WHO) adopted its present policy hastily in 2007, after publication of RCTs produced by biased circumcision advocates. The effectiveness of circumcision at reducing HIV infection cannot be shown in practice. However, the WHO shows no intention of reforming its thirteen-year-old circumcision policy.

President Donald Trump has severed the connection of the United States with WHO. PEPFAR is now free to independently determine its own course of action.

COVID-19

The world is now trying to cope with COVID-19. Healthcare systems in every nation are struggling to provide care to the large numbers of COVID-19 patients. Healthcare workers are at grave danger of contracting the highly infectious disease.

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Male circumcision to reduce the risk of infection with HIV actually is a non-therapeutic and non-essential surgery. It is now customary to defer such procedures so as to free health care resources to treat COVID-19 patients. PEPFAR’s policy of paying healthcare workers to perform these non-therapeutic circumcisions (for which efficacy cannot be shown) is likely to divert healthcare workers from caring for COVID-19 patients and puts healthcare workers as well as circumcision patients at risk of contracting COVID-19 due to lack of social distancing. Provision of non-therapeutic circumcision seems inappropriate when health care systems are so burdened with COVID-19 patients.

**Conclusion and recommendation**

Male circumcision is not a benign surgical operation.\(^{35}\) It excises a functional body part with protective, immunological, sensory, and sexual functions, and leaves the patient in a harmed and degraded condition.\(^{36,37}\) Furthermore, male circumcision causes sexual and psychological injury.\(^{38}\)

Van Howe & Storms (2011) reported that male circumcision is expensive and ineffective, while anti-retroviral therapy (ART) and the provision of condoms is less expensive and more effective with discordant couples.\(^ {39}\)

Doctors Opposing Circumcision formally makes this recommendation to PEPFAR:

**That the provision of non-therapeutic male circumcision be suspended until such time as the following conditions are satisfied:**

- The COVID-19 pandemic ends.
- Male circumcision is shown to be cost-effective in preventing HIV infection.
- The value of the health benefits is shown to exceed the maleficent effects of the loss of the foreskin.

**That all funding currently assigned to male circumcision be reassigned to provision of ART and condoms.**

Very truly yours,

George C. Denniston, M. D., M. P. H.
President, Doctors Opposing Circumcision

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\(^{37}\) Cold CJ, Taylor JR. The prepuce. *BJU Int.* 1999;83 Suppl. 1:34-44.


On behalf of the Board Members of Doctors Opposing Circumcision and our medical advisors:

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cc: President Donald J. Trump