

**Male circumcision as a
(compulsory) component of a
HIV prevention package in a
HIV vaccine trial:
analysis in terms of a
public health ethics framework**

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Questions

- When are researchers obligated to add a new HIV prevention to the prevention package for a *planned* trial?
- When are researchers obligated to add a new HIV prevention to the prevention package for an *ongoing* trial?
- Are researchers obliged to provide all HIV prevention tools to trial participants?

Childress et al

- **Effectiveness:** It is essential to show that infringing one or more general moral considerations (such as convincing communities about the probable effectiveness of male circumcision in the face of cultural norms and practice) *will probably protect public health*. A new proposed intervention (such as circumcision) that infringes one or more general moral considerations in the name of public health but has little chance of realizing its goal is ethically unjustified.
- It will be essential to show that the proposed intervention will, on a balance of probability (based on existing scientific evidence and taking into account possible confounding factors), will be effective in realizing the goal of reducing HIV infection amongst male study participants.

- **Proportionality**: It is essential to show that the probable public health benefits of compulsory male circumcision outweigh the infringed general moral considerations. For instance, will the men who opt not to be circumcised face undesirable consequences such as stigma or ostracism? Does this factor outweigh possible benefits of having the procedure done? All of the positive features and benefits must be balanced against the negative features and effects.

- **Necessity**: Not all effective and proportionate policies are necessary to realize the public health goal that is sought. The fact that a policy (such as inclusion of circumcision as compulsory HIV prevention package) will infringe a general moral consideration provides a *strong moral reason to seek an alternative strategy that is less morally troubling*.
- Proponents of circumcision have the burden of moral proof. This means that they must have a good faith belief, for which they can give supportable reasons, that a relatively extreme measure such as obligatory circumcision as a condition of trial enrolment, is necessary.

- **Least infringement**: Even when a proposed policy satisfies the first three justificatory conditions — that is, it is effective, proportionate, and essential in realizing the goal of public health — proponents of male circumcision should seek to minimize the infringement of general moral considerations (such as cultural ostracism).
- Are there less restrictive measures that can be adopted that may achieve the same goal without infringing on moral considerations (for example, even greater promotion and provision of male and female condoms, post-exposure prophylaxis)? A proposed extreme intervention (such as obligatory male circumcision) must be necessary in degree as well as in kind.

- **Public justification:** When public health agents or investigators believe that one of their proposed actions (provision of compulsory male circumcision as a HIV prevention strategy), infringes one or more general moral considerations, they also have a *responsibility to explain and justify that infringement to the relevant parties, including those affected by the infringement.*
- This could equate to meaningful community engagement and public engagement prior to the intervention's introduction, taking into account sensitive cultural norms and personal preferences. This transparency stems in part from the requirement to treat citizens as equals and with respect by offering moral reasons, which in principle they could find acceptable, for policies that infringe general moral considerations. Transparency is also essential to creating and maintaining public trust; and it is crucial to establishing accountability.

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- **What are the public health goals of the proposed HIV prevention package?**

A research study should have as its ultimate goal (or the ultimate goal of a larger trajectory of which it is a part) that findings of study, if positive, will be implemented with the target population and improve its health status.

- **How effective is the intervention in achieving its stated goals?**

The greater the burdens posed by a policy — in the context of HIV vaccine trial, compulsory male circumcision, the burdens may be described as considerable — the stronger the evidence must be to demonstrate that the program will achieve its goals.

- **What are the known or potential burdens of the proposed intervention?**

What are the known or potential burdens / disadvantages of compulsory male circumcision as a precondition to enrolment in a trial? What are the advantages of having a foreskin? There must be frank consideration of these issues and a full consideration of the disadvantages of having a circumcision.

- **Can burdens be minimized? Are there alternative approaches?**

How can / should the burden of possible social ostracism and possible reduced sexual sensitivity be minimized? How should investigators ensure this? There should be a frank consideration of alternate approaches to male circumcision. Should there be more promotion of condom use, which offers far greater efficacy than male circumcision?

- **Is the program implemented fairly?**

Must be fair distribution of benefits and burdens. Are the benefits and risks of obligatory circumcision being adequately explained? Are the benefits and risk of *not* being circumcised being adequately explained? Will the engagement exercise create stereotypes or stigmatise uncircumcised men or men who ultimately decide to remain uncircumcised?

In multi-site studies, where sites differ regarding acceptance of circumcision or there is differential access to safe provision of circumcision services, the unequal distributions of provision of circumcision must be justified with data. Moreover, the social consequences must be considered if a community is allotted resources unequally, and these consequences must be balanced against the benefits to that community or others.

- **How can the benefits and burdens of a program be fairly balanced?**

If it is determined that a proposed public health intervention, policy, or program is likely to achieve its stated goals, if its potential burdens are recognized and minimized, and if the program is expected to be implemented in a nondiscriminatory way, a decision must be reached about whether the expected benefits justify the identified burdens. Recognizing, of course, that public policy is based on multiple considerations in addition to ethics, the question must still be asked whether, *from an ethics perspective, the program should go forward.*

- Solutions to these inevitable disagreements must be reached through a system of fair procedures. Procedural justice requires investigators to engage in a democratic process to determine which public health functions it wants its government to maintain. There should be open discussion of what the study community and society gains from compulsory circumcision and why such benefits often cannot be obtained through more liberty-preserving methods.