Ethical and social implications of proposed HIV cure research: stakeholder perspectives from South Africa

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South Africa

Population +/- 52 million

GDP $350 billion

(US) 19.3%------9.1% on health (SA)

2019 Target: 1.5% on research
GINI COEFFICIENT
0.77
HIV BURDEN OF DISEASE - 2015

6.8 million HIV positive

340 000 new infections

200 000 deaths

42% on ARVs
“Why would a person with HIV, who is doing well on ARVs, be willing to jeopardise his health by enrolling on such a trial?”

Bromwich & Millum, JME, 2016
Qualitative research

• Phase 1:
  • 15 in-depth interviews

• Phase 2:
  • 14 HIV experts

• Phase 3:
  • 28 stakeholders & 2 FGDs
Methodology

- Purposive sampling of 42 HIV clinicians, HIV researchers, HIV activists, researchers, psychologists, policymakers, HIV positive patients, medical students, community members, pharmaceutical companies in Cape Town, Johannesburg, Pretoria and Durban

- Informed consent was obtained prior to interviews

- 42 in-depth interviews and 2 Focus Group Discussions (FGDs)

- Contextualised thematic approach.
The meaning of “cure”

• Some patients on antiretroviral treatment with a suppressed viral load perceive themselves to be “cured” and are becoming excited “about the virus being undetectable….and they are spreading the wrong message…you take your treatment…you adhere to your treatment, you can be cured” (Ethics committee member)

• The terms “cure” and remission must be clarified: “I’ve heard people with cancer talk about their remission as a cure; and yet I would say strictly speaking doctors would say ‘in remission’ means we cannot guarantee that it won’t come back.” (HIV clinician)
The meaning of “cure”

- Activists were concerned about the duration of a future cure “Will the cure be something that is once off...when people think cure they think you go in, you’re cured and you are done, that’s it....you don’t have to bother about HIV, you don’t have to take another medication for the rest of your life” (Activist)
Risk-benefit ratio of treatment interruption

- Will be perceived as a significant risk
  - For those doing well on ARVs
  - For treatment naïve patients if the “cure” fails
  - May encourage treatment interruption to try illegitimate “cures”
Risk-benefit ratio of treatment interruption

- Can it be justified by poor adherence?

“One cohort that we have been studying in the Eastern Cape...1000 adolescents...only 1/3 of them are adherent” (HIV Policymaker)
How informed will the consent process be?

- Complex Science: Reservoirs, latent infection, gene editing, off target effects

“There’s a significant body of evidence questioning (a) patients’ understanding and (b) patients’ recollection of what they were informed of” (Academic)
New approaches to consent necessary

• “There needs to be a lot more dialogue than normally would happen” (Private clinician)

• What is needed is “quite an extensive psychological evaluation on potential candidates…a psychologist would have to determine…if the patient is in a stable position where he would happily make this decision and cope with the consequences” (Medical students)

• “This kind of informed consent…it’s just not a process of informing and educating…it’s actually….a counselling process” (HIV activist)
Role of regulatory framework

• RECs will need to be trained and capacitated to review cure protocols

• Policy & guidance must be developed for cure research

“We have legislation which is robust in some areas and incredibly wanting in others…current policy environment addresses different degrees of depth issues around experimental forms of treatment; the requirements of informed consent, peer review, registration with the Medicines Control Council…there’s policy that deals with stem cells but nothing that deals with gene therapy” (HIV Researcher)
Conclusion

• Early engagement is necessary

• Could early engagement undermine treatment & prevention?

• Science translation & informed consent
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