



# Ethico-legal challenges in conducting HIV prevention trial research with adolescents: a South African case study of tool development

Melissa Wallace<sup>1</sup>, Ann Strode<sup>2</sup>, Cathy Slack<sup>2</sup>,  
Agnes Ronan<sup>1</sup> and Linda-Gail Bekker<sup>1</sup>  
[melissa.wallace@hiv-research.org.za](mailto:melissa.wallace@hiv-research.org.za)

<sup>1</sup> Desmond Tutu HIV Centre, University of Cape Town, South Africa

<sup>2</sup> HIV/AIDS Vaccine Ethics Group (HAVEG), University of Kwa-Zulu Natal



# Background



- Conducting HIV vaccine trials with adolescents poses particular ethical-legal challenges including:
  - Establishing what adolescents can provide consent for within the research framework
  - The degree of privacy adolescents can enjoy within research
  - Establishing when reports must be made to authorities



# Objectives



- As part of an EDCTP funded multi-site project building capacity for HIV vaccine trials in South Africa, objectives include:
  - Building ethico-legal capacity of research staff to work through complex and unprecedented ethico-legal issues
  - Developing a tool to assist research staff in making complex ethico-legal decisions



# Methods



- A partnership was formed with an ethico-legal group, the HIV/AIDS Vaccine Ethics Group (HAVEG)
- Tools were developed through consultation between HAVEG, research staff, clinicians and Research Ethics Committees (RECs)
  - A preliminary meeting with REC members was held prior to protocol submission
  - Ethico-legal issues were discussed and concerns raised regarding what information would remain private, what would be disclosed to parents and what would be reported to authorities
  - As a result, specific recommendations were made in relation to consent, privacy, mandatory reporting and ethics review, in the form of an ethical-legal memo



# Methods (2)



Example of consent issue addressed in memo:

- In South African research framework, adolescents under the age of 18 are legal minors and it is argued that they do not have the capacity to consent to trial enrolment independently. They do however have the capacity to consent to some components eg. HIV testing from the age of 12 (s 130, Children's Act, No. 38 of 2005).
- Applied to study: Under-18's will require consent from a parent or legal guardian to enter the study; but they will have the capacity to consent independently to HIV testing within the study. **Note**: Even if adolescents consent independently to testing, it does not automatically follow that they will enjoy privacy for these results and they may be asked to disclose results.
- **Recommendation 1** *It is recommended that a parent or legal guardian must provide consent for under-18s to participate in this trial. This means that a parents or legal guardian will consent to:*
  - *Screening of the adolescents eligibility to enroll in the trial*
  - *Enrolment in the trial.*
- **Recommendation 2** *It is recommended that under-18s should consent independently to HIV testing in the trial*
- This approach is made clear during consent process



# Methods (3)



- Training was implemented using tools developed, to ensure staff recognise and apply legal obligations when conducting research with adolescents
- Through feedback from clinical staff receiving training, the tools were amended and updated



# Results



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- The ethical-legal memo developed through this process was integrated into the protocol and submitted along with it for ethical review
- This was approved by five South African RECs
- The memo was found to be helpful in facilitating protocol review by several of the RECs



## Results (2)



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- A legal directory was updated and finalised, providing a comprehensive overview of all laws in South Africa affecting child research
- Protocol development, consent form development, and standard operating procedures were influenced by the directory and the ethico-legal memo recommendations
- These tools provide the basis for the management of ethical-legal issues arising during the conduct of the adolescent HIV vaccine trial capacity-building project



# Discussion & Conclusions



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- Ethical-legal requirements are a legitimate and often neglected area of inquiry
- Clinical trial groups are recommended to form strategic partnerships with ethico-legal experts
- Such research tools can contribute to national norm-setting around minimum standards for adolescent research



# Future perspectives



- Ethical-legal issues arising in the project will be documented and the value of the tools developed in managing such issues evaluated, with amendments made to the tools if necessary
- Plans are afoot to use these tools in conducting other adolescent prevention trial research and for their versatility and relevance for other adolescent research contexts to be evaluated