Ethical-legal norms for adolescent HIV prevention trials in South Africa

Catherine Slack (MA, PhD) & Ann Strode (LLM, PhD)
HIV AIDS Vaccines Ethics Group, UKZN, South Africa
http://www.saavi.org.za/haveg/

MTN Oct 2016
Overview of Talk

• Four issues
  • Who should consent to enrolment?
  • Who should give permission for other aspects (contraceptives, testing)?
  • What should researchers do about mandatory reporting for abuse?
  • What should researchers do about mandatory reporting for sexual offenses?

• Guidance in the SA ethical-legal framework

• Recommendations for researchers – navigating tensions
Ethical-legal frameworks for (child) research

- Omissions, ambiguities, contradictions, scattered (UNAIDS 2012) – “imperfect”
- Might not strike right balance between ‘access’ to research & protection
- Challenging for researchers and reviewers so pre-trial ‘audit’ can help
  (Slack 2007; UNAIDS 2007; UNAIDS 2012)
- Child = minor = person under 18 in South Africa
1 Consent for Enrolment?

- **LAW:** Consent from parent/ guardian for child research \((571\, NHA\, 2003\, implemented\, in\, March\, 2012)\)
  - Undermines discretion of RECs to approve other consent approaches
  - Subject of law reform proposal (according to public NHREC-REC meeting)

- **ETHICAL GUIDELINES:** Consent from parent/ guardian for child research generally:
  a. Unless other factors e.g. risks are ‘minimal’, research is ‘sensitive’, child is older, community support; then self-consent allowable \((DoH\, 2015)\)
  b. Unless orphan research, then alternative proxies are allowable \((DoH\, 2015)\)
  c. Unless ‘exceptional circumstances’ ‘e.g emergencies’; then care-giver consent allowable \((DoH\, GCP\, 2006)\)

- Tension between law \((571,\, NHA)\) and guidelines \((DoH\, 2015)\) re. allowable consent approach

- **Recommendation** – Secure consent from parent/ LG for trials unless waiver conditions met
2 Consent for Components (& Privacy)?

- **LAW:** Various statutes - adolescents can self-consent to health-related interventions, e.g.
  - **Contraceptives from 12** (s 134, Children’s Act, No. 38 of 2010)
  - **HIV testing from 12** (s 130, Children’s Act, No. 38 of 2010)
  - **Medical treatment from 12, incl. STI / HIV treatment** (s 129, Children’s Act No. 38 of 2010)

- **ETHICAL GUIDELINES:** Child research must take into account ‘privacy interests’ (DoH 2015)

- **Recommendation – even if parent/ LG consents for enrolment:**
  - Secure self-consent from adolescents for various components
  - Ensure they enjoy confidentiality for these components
  - Ask adolescents who acquire HIV to disclose to trusted adult in reasonable time-frame
  - Set this out in consent materials (‘no surprises’)
  - Allow that some persons may object/ refuse enrolment on these grounds
3 Mandatory Reporting of Abuse?

- LAW: Abuse and neglect must be reported
  - Broad range of persons (medical practitioners, psychologists, others) must report any child that has been sexually abused, neglected or physically abused (s110 of the Children’s Act (2010))
  - To child-protection organizations, social development department, police

- ETHICAL GUIDELINES:
  - Be familiar with obligations (DoH 2015)
  - Ensure abuse and neglect are reported (DoH 2015)

- Recommendation:
  - Partner with professional organizations for assessment and referrals
  - Set out limits of confidentiality in consent materials (‘deal-breaker’)
  - Allow that some persons may object/ refuse enrolment when approach is understood
4 Mandatory Reporting of Sexual Offenses?

- **LAW:** Any person aware of a sexual offence against a child must report to police (Criminal Law [Sexual Offences and Related Matters] Amendment Act, No. 32 of 2007)

- No longer a reportable offense when adolescents who are peers or ‘close-in-age’ (2y age gap) engage in sex/sexual activity
  - 12-15yo children with 12-15yo children
  - 12-15yo children with 16-17yo children (if 2year-gap) (Criminal Law (Sexual Offences and Related Matters) Amendment Act Amendment Bill B18B-2014)

- Still a reportable offense when
  - Younger party is 12-15yo and the older party is 16-17 yo (+ age difference exceeds 2y)
  - Younger party is 12-15yo and partner is an adult (18 and over)
  - Older party commits the ‘offense’

- Change in law has relaxed requirements....
• ETHICAL GUIDELINES:
  • Caution against ‘thoughtless reporting’ (DoH 2015)

• Recommendation:
  • Recognize that reporting may cause censorship (undermine prevention services)
  • And may drag participants into the CJS (cause social harms)
  • Adopt nuanced approach
  • Assess carefully - consider coercion, harm
  • Partner with experts
  • Report only clearly exploitative activity
  • Ensure limits understood in consent
  • Allow that some persons may object/ refuse enrolment when approach is understood
UNAIDS AVAC GPP (2011)

Global Stakeholders

National Stakeholders

Broader Stakeholders

Community Stakeholders

Examples

national NGOs • parliamentarians • ministries of health • media • regulatory bodies • ethical review committees • international organisations • international foundations • funders

international NGOs • trial sponsors and networks • WHO/UNAIDS • local health service providers • local media • medical professionals • community advisory boards • peers • trial site staff • trial site staff

NGOs • local policymakers • local religious institutions • traditional leaders

CBOs • participant's family • friends • schools • colleagues

Trial Participant
Recommendations For Adolescent Researchers

1. Think of the REC as a stakeholder to be engaged

2. Prepare approach carefully - using justifiable norms (see existing resources)

3. Use and cite the most up-to-date ethical guidelines (DoH 2015)

4. Set out the approach for the REC to assess (NIH-CHAMPS studies e.g. PlusPills & EDCTP HPV study)

5. Develop Standard Operating Procedures/ training for site-staff (EDCTP-funded HPV study)

6. Report to REC ‘critical ethico-legal events’ (frequency, impact, resolution)
Shift towards protecting children from unsafe, ineffective interventions through data from rigorous studies and shift away from protecting children from research participation per se

(Nelson 2010)

Building the case for including adolescents in ethically sound studies
Acknowledgments

The work was in part made possible by funding from the National Institutes of Health CHAMPS (Choices for Adolescent Methods of Prevention in South Africa) (1RO1 A1094586, PI: Prof L-G Bekker). Opinions expressed herein are the views of the authors and do not represent any position or policy of the NIH, nor any council or committee with which the authors are affiliated. Funding for earlier versions was made possible by EDCTP.
Useful Resources

Useful Resources


Ethics Review

• LAW:
  • RECs must review ‘health research’ incl. with children – as per s73 of NHA (implemented 2005); regulations (gazetted Sep 2014)
  • RECs must register with NHREC - as per s73 of the NHA

• ETHICAL GUIDELINES:
  • RECs must review ‘health research’ incl. with children (exemptions allowed) (DoH 2015)
  • RECs must have child expertise (DoH 2015)
Ministerial Consent For NT Child Research

• LAW:
  • MoH required to ‘consent’ to NTR with children – as per s71(3)(a)(ii) of the National Health Act (NHA)
  • MoH delegated authority to RECs fully registered with NHREC – as per s 92(a) (implemented Oct 2014)

• NHREC OPERATIONAL GUIDELINES:
  • Recommend researchers use Form A in Regulations with Human Participants (published Sep 2014) to show how criteria for ministerial consent are met
  • Recommends RECs review Form A in their ethics reviews
  • [Website Link]

• ETHICAL GUIDELINES: - recognizes RECs may have been delegated authority and recommends deliberations recorded

• Offsets overly broad wording of Act requiring all NT child research *regardless of risk level* to be reviewed by MoH