Adolescent HIV prevention research in South Africa: Researching complexities and engaging reviewers

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Overview

• Background

• Key complexities in adolescent enrolment in HPTs

• Concluding remarks
Adolescent vulnerability to HIV infection

- Behaviours, features, structural factors increase risk of HIV
  - E.g. early sexual debut, sensation-seeking, access to services

- Adolescents are key population for intervention, incl. biomedical approaches

- Extrapolation from adult studies is difficult; even where possible some studies may be necessary to establish safety, feasibility, acceptability, adherence

- Regulatory approval/ licensure requires data from this group

(Hosek 2010; Rudy 2010; Kapogiannis 2010; Wilson 2010)
Shift towards protecting children from unsafe, ineffective interventions through data from rigorous studies and away from protecting children from research participation per se

(Nelson 2010)
Adolescent vulnerability in research

• Research enrolment is critical (Pomfret 2010; MacQueen 2007)

• Yet adolescent features may heighten risk of trial-related harm
  – E.g. sensitivity to peer evaluation may heighten experiences of stigma (Hosek 2010)

• Yet adolescent features may undermine consent
  – E.g. deficiencies in reasoning may compromise understanding (MacQueen 2007)

• Ensuring adolescents ‘adequately represented and protected’ (Nelson 2010)
HPTs - invasive procedures, ‘sensitive’ data, stakeholder concern

E.g. participants may undergo:
- Assessment of sexual risk
- Assessment of pregnancy & contraceptive compliance
- Assessment of STIs, HIV status
- Administration of study product

Other components...
- Ensure access to HIV prevention modalities
- Ensure access to SRH care
Ethical-legal frameworks for child research

• Ambiguous, in-flux, contradictory, or absent norms (UNAIDS 2012)

• Striking the right balance between ‘protection’ and ‘access’?

• Challenge for researchers and reviewers

• Pre-trial ‘audit’ (Slack 2007; UNAIDS 2007; UNAIDS 2012)
‘perfect storm’

At-risk group deserving of prevention products with specific vulnerabilities that may raise research risks or may compromise consent facing invasive procedures yielding sensitive information within complex ethical-legal contexts and intense stakeholder scrutiny
Research Ethics Committees

- Charged with ‘arms-length’ independent review (Emanuel 2004)

- Required by regs/guidelines to ensure closer scrutiny of child research

- Ideally –well reasoned judgments with efficient processes (Abbot 2011)

- Challenge of poorly justified responses, or unjustified variations (ibid)

- Pre-review discussions, awareness-raising, between-REC networking,
Ethics in Health Research

Principles, Processes and Structures

Second Edition

Department of Health
Republic of South Africa

2015
Resource development in South Africa

• Complex questions face RECs and researchers for HVTs
  – Consent to enrolment?
  – Consent for components of study? (e.g. STI/HIV tests)
  – Confidentiality? (e.g. limits for abuse, under-age sex)

• Opportunity to reflect on norms and strengthen responses
  – EDCTP-funded SASHA study
  – NIH-funded CHAMPS studies

• HAVEG developed a resource to inform protocol development; consent materials; SOPs at sites; and to accompany protocol as appendix
1  Consent to enrolment?

- Law - consent from a parent or guardian for child research (s71 NHA 2003)
  - Critiqued as restrictive/conflicting with other legal and ethical norms
  - According to public NHREC/REC meetings subject of law reform proposal

- Guidelines – consent from a parent or guardian for child research unless certain circumstances prevail:
  - When the risks are minimal, the child is older, and where there is community support for this approach (DoH 2004; DoH 2015)

- Guidelines – consent from parent or guardian for clinical trials with children unless ‘exceptional circumstances’
  - ‘E.g. emergencies’ (DoH 2006)

- Taken together, parent/ LG should give consent *(unless exception met)* (?)


2 Consent to key components?

• Various statutes - adolescents can self-consent to health-related interventions

  – **Medical treatment** from 12, including STI and HIV treatment (‘sufficient maturity’)  
    (s 129, Children’s Act No. 38 of 2010)
  – **HIV testing** from 12  
    (s 130, Children’s Act, No. 38 of 2010)
  – **Contraceptives** and contraceptive advice, incl. emergency contraceptives from 12  
    (s 134, Children’s Act, No. 38 of 2010)
  – **Terminations of Pregnancy** at any age  
    (s 5, Choice of Termination of Pregnancy Act, No. 92 of 1996)
  – **Circumcision** at 16 with counselling (under-16 with consent from parent/guardian)  
    (s12 (8) and s12(9-10), Children’s Act No. 38 of 2005)

• Even where parent/guardian consents for enrolment, adolescents of 12y/o should self-consent to various components
3 Confidentiality?

- Even where parent/guardian consents to enrolment, adolescents should enjoy confidentiality -
  - For health-related interventions to which they have consented independently
    - Adolescents of 12 years and older should receive results, not the parent/guardian
  - For components where expectation of privacy that society would regard as reasonable
    - Adolescents should have confidentiality for sexual behaviour data

- Parents can agree not to receive information, given safeguards
4b Limits of confidentiality? (1)

- HIV infection should disclose to a ‘trusted adult’ in ‘reasonable’ time-frame

- Abuse and neglect should 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 organisations, social development department, police

- Partner with professional organisations for assessment and referrals

- Set out limits of confidentiality in consent materials

- Declare approach for REC
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)

However sex still remains 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 (over 18)
Limit of confidentiality? (2) cont’d

• Reporting challenges
  – May drag adolescent participants into criminal justice system
  – May encourage adolescent participants to censor disclosures

• Adolescent participants who report sex/activity that is sexual offence should
  – Have ‘exploitation assessment’ (no easy formula)
  – Made by a multi-disciplinary team (incl. professional organisations)
  – Consider duress, coercion; age differential
  – Partner

• Ensure limits of confidentiality are understood

• Declare approach for REC- cautioned against ‘thoughtless reporting’ (DoH 2015)
Conclusions

• Critique norms and prepare approach well in advance of submission

• Provide assurance to RECs of careful planning
  – And to site-staff who may experience anxieties (Gilbert 2015)

• Note RECs may still not agree that approach corresponds best with norms

• Note REC concerns re. sufficient adult data to justify enrolment (Philpott 2011)

• Acknowledge that impact of resource-document not ‘researched’
  – For time-frame; consistency/substance of judgments; REC-researcher relations
Recommendations

• Assess ‘barriers’ to enrolment (legal framework? parental consent?)
  – For adolescents, parents, RECs, p/community representatives

• More record-keeping of ‘critical ethico-legal events’
  – Frequency, impact, resolution

• More sharing of approaches
  – Consent material, protocol descriptions, SOPs

• More advocacy to strengthen the framework
Key references

Key references


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