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)

Procedures/ components in HIV prevention research

- 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,

http://www.nhrec.org.za

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

4c Limits of confidentiality? (2)

- 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)

4c 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

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