



A Practical Approach to Ethics in Adolescent Research



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Overview



DESMOND TUTU
HIV FOUNDATION

- Adolescents and why they are important in research
- Overview of some Adolescent projects at DTHC/F
- Basic Ethical Principles
- Recruiting and retaining
- Consent
- Confidentiality
- Social, ethical considerations
- Logistical challenges with adolescent research

Who are adolescents?



2.3.1 Minors: *Children and adolescents*: A minor for the purposes of these guidelines is defined as a person under 21 years of age, ie. Majority begins at 21 years of age¹⁵. Minors should participate in research only where their participation is indispensable to the research. Where research involving minors is proposed, a research ethics committee should determine where the research might be equally informative if carried out with consenting adults. If so, the research ethics committee should require strong justification for the inclusion of minors. The research should investigate a problem of relevance to children. Note that all types of clinical research on minors should be scrutinized carefully.

SA GCP, 2006

Why use adolescents in clinical trials?



Lets Use HIV as an example:

- **Globally** young women aged 15-24 years account for **19% of new infections**
- **Young women and adolescent girls** account for **80% of new HIV infections in sub-Saharan Africa.**
- **“YOUTH BULGE”**



Why use adolescents in clinical trials?



- 2017, around 290 000 [160 000–390 000] new HIV infections occurred among young people aged **15–24 years**.
- Two out of three of those new HIV infections occurred among young women aged 15–24 years.



Why use adolescents in clinical trials?



- Behaviors, features, structural factors increase risk of HIV
 - E.g. early sexual debut, sensation-seeking, access to services (that are adolescent and youth friendly)
- Adolescents are a key population for intervention
- **Adolescents are not mini adults**
 - Extrapolation from adult studies is difficult; it will *be necessary* to establish feasibility, acceptability, adherence

Adolescents is a critical life & Development transition



- The biological and psycho-social changes that take place during this period affect every aspect of adolescents' lives
- Increase with age in sexual and reproductive health problems
- Psychosocial and emotional changes
- Greater Risk Taking
- Poor knowledge and application of knowledge
- Lack of abstract thought
- Disregard for rules and establishment
- Poor health seeking behaviors
- Prejudicial and inadequate health services
- The meaning assigned to this transition is different in different cultures and contexts, but everywhere it signifies the move from childhood to adulthood.

Adolescents are NOT mini adults



- Adolescents need **explicit attention**.
- Adolescents are **not all the same**.
- Adolescent development has **implications for adolescent health**.
- Adolescent development has **health implications throughout life**.
- The **changes** during adolescence affect how adolescents **think and act**.
- To contribute positively, **adults** need to understand the processes taking place during adolescence.



2018

DESMOND TUTU HIV FOUNDATION YOUTH CENTRE & RESEARCH OFFICE - MASIPHUMELELE

CHAMPS

- Prevention menu for adolescents
- PrEP administration "Uchoose"
- (PrEP) "Plus Pills"
- Male circumcision "Macho"



HVTN 705

- Evaluate effect of Ad26.Mos4 and Clade C gp140 vaccines
- 2600 healthy, HIV uninfected women
- 18 – 35



3P

- Enumerate the demand for PrEP.
- Characteristics of PrEP uptake and initiation.
- Social marketing campaign.



Youth Centre

- Assist adolescents in discovering their potential
- Youth Clinic
- Internship and Reward Programme
- Active Programmes



The Zimele Programme



- A multi-pronged **prevention social and health intervention** programme for $\approx 20\,000$ adolescents: **predominantly adolescent girls and young women** aged 10-24 years, both in and out of school.



Primary Objectives:

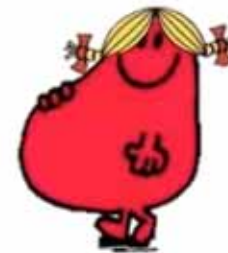
Reduce New HIV Infections
in girls and young women



Keep girls in school
until graduation



Decrease teenage
pregnancy incidence



The Zimele Programme



In Addition: Child Protection Services & HOP (Soul Buddyz Parents)



In Addition: Rise Clubs, Teen Parenting & PrEP



In Addition: Rise Clubs & Community dialogues with men



Adolescent-tailored health services

**Soul Buddyz Clubs:
In School**

**Keeping Girls in School:
Health Education in
School**

**Women of Worth:
Incentive & Care
Programme**

Age

10 years

14 years

19 years

24 years

**Impact evaluation
Service utilisation**



Different Approaches depending on the type of Clinical Trial/Research



- Uptake and adherence of daily oral PrEP as a primary prevention strategy for young African women: A vanguard study
 - *16-25 YEARS*
- Crossover Trial Evaluating the Safety of and Adherence to a Vaginal Matrix Ring Containing Dapivirine and Oral Emtricitabine/Tenofovir Disoproxil Fumarate in an Adolescent Female Population
 - *16-21YEARS*

Ethical Principles



- Beneficence
- Autonomy
- Non-maleficence
- Confidentiality and Privacy
- Retention?
- Referral?
- Being "youth friendly"

Recruiting & Retaining Adolescents



- Community Involvement is Key
 - *ESPECIALLY when asking for parental consent Waiver*
- Youth CAB
- Adolescent Friendly, Centered and Driven Services
 - *AND STAFF*
- Need creative ideas to keep them engaged
 - *Creating good relationships and a friendly environment*
 - *Support Clubs*
- Support for adherence to product/visits

KNOW YOUR COMMUNITY & YOUR POPULATION

Informed Consent



- 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 consent approach (DoH 2004; DoH 2015 national guidelines)
- Guidelines – consent from parent or guardian for clinical trials with children unless 'exceptional circumstances'
 - 'E.g. emergencies' (DoH 2006 clinical trial guidelines)
- Independent consent to HIV testing, male circumcision, contraceptives, termination of pregnancy (*Childrens Act No. 38 of 2005, Choice of Termination of Pregnancy Act No. 92, 2007*)

Informed Consent to Sexual/ Reproductive Health Services



Table 1. The sexual- and reproductive-health rights of adolescents

Interventions	Age of consent (yr)	Capacity requirement, if any	Public policy requirement, if any
Contraceptives	12	Not specified	None
HIV testing	12	None, unless the child is under 12, when they must show 'sufficient maturity and the mental capacity to understand the benefits, risks, social and other implications of the test'	Testing must be in the 'best interests' of the child Pre- and post-test counselling must be provided
Medical treatment	12	'Sufficient maturity and the mental capacity to understand the benefits, risks, social and other implications of the treatment'	None

Strode, Essack, SAMJ 2017

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

Informed Consent to Sexual/ Reproductive Health Services



Prescribed drugs	14 (to change to 12 when amendments to the Act are brought into operation in the future)	None	None
Male circumcision	16	None	Circumcision must be preceded by 'proper counselling'
Virginity testing	16	No	Only after 'proper counselling'
Sterilisations	18	No	None
Termination of pregnancy	No specified age	No	The medical practitioner/ midwife to advise the child to consult with her parents, guardian, family members or friends before the pregnancy is terminated

Confidentiality Considerations



- Even where parent/ guardian consents to enrolment, adolescents should enjoy **confidentiality**
 - Especially for SRH interventions they consent to independently
 - Adolescents 12 years and older should receive results
 - Receive confidentiality for sexual behaviour data

Slack C, Strode A, HAVEG 2016

Researcher's willingness to respect an adolescent participant's autonomy and right to confidentiality will likely determine that adolescent individual's willingness to participate in research.

- Singh *et al* 2006

Confidentiality Considerations



- **HIV infection** --> adolescent should disclose to a 'trusted adult' in 'reasonable' time-frame. Responsibility of staff to facilitate and assist
- Parent may want to be informed of their child's HIV status - breach confidentiality
- Sexual offence against a child is reportable offense.
 - Consent to sexual activity if close in age 12-15 y/o with 16/17 y/o (2 year age gap)
 - Reportable if age difference exceeds two years and if younger party is 12-15y/o and partner is an adult

Social & Ethical Considerations



Adolescents' best interests will be served by their autonomous participation.

- **Obstacle to Parental Consent**
 - Absent Parents/ Guardians
 - Living in a child-headed household
 - Surrogate Caregivers not formally appointed as legal guardians (grannies/aunts/sisters)
- **Waiving parental consent**
 - Some studies involve investigation of adolescents' beliefs and behaviour regarding sexuality or use of recreational drugs
 - When parental knowledge of the subject matter may place adolescents at some risk of questioning/intimidation by their parents/guardians
- Make sure you are in line with ethico-legal frameworks

GCP on Community



2.4 COMMUNICATION AND COMMUNITY INVOLVEMENT

Research to be carried out a community level (e.g. vaccine trials) should ideally ensure **adequate consultation** with civil organisations that may exist within affected communities at all phases of the trial. Sponsors are encouraged to establish **Community Advisory Groups (CAGs)**. A CAG can be viewed as a community representing body that may **advocate for human rights and promote ethical conduct in clinical research**; contribute to **addressing and resolving grievances about the research process**; give **advice on accrual and retention of trial participants** and voice concerns around the development, implementation and outcomes of specific clinical and related studies. Researchers are encouraged to ensure that: **information flow mechanisms are developed between investigators and participating communities**; and that **communities are educated** on the aspects of research **before** recruitment begins.

Youth CAB Involvement



- Information flow between investigators and community
- Community education
- Strategy for recruitment/Recruitment messaging
- Retention strategies
- Ongoing community consultation
- Getting trial results back to community
- Contribute to human rights compliance and ethical conduct

Benefits: Providing the best care to our adolescents



- Youth friendly
- Adequate expertise, Non-judgemental Staff
- Free/Accessible Care with Built-in SRH services
- Standard of care/prevention met
- Adequate referral, e.g. psycho-social, welfare specialist

Combining services during the conduct of a trial



- Incorporated into the service we provide adolescents
- Adolescents don't have time to attend a research centre AND go to the clinic for contraception AND attend school
- **One Stop Shop**
- Contraception provision, STI testing and/treatment, referrals for pregnancies

Adolescent Friendly Healthy Services



- Implementation of the AYFS programme in targeted areas – with a dedicated Peer Navigator at each facility
 - 9 x Provincial health facilities
 - 15 x City of CT clinics
- Roll-out of health services in Secondary Schools
- Mobile services (TT) in place offering HCT and SRHS



Referral Networks

- Engaging in adolescent research requires appropriate referral networks
- Partner with community youth organisations
 - Retention
 - Facilitate better referrals and close the loop



Logistical Challenges in Adolescent Research



- School going- after hours clinic visits
- Transport/transport money
- Working parents/guardians
 - scheduling appointments for consent
- Absent parents/guardians
- Unpredictable/changeable futures
 - Retention
- Strong fertility drive- pregnancy rates



LGB, 2017

Conclusion



- Research in adolescents is NEEDED
 - Can't extrapolate data from adult studies
 - Unique key population
 - By improving the available adolescent (10–14 and 15–19 years) data, countries will be better able to plan, monitor and improve health outcomes
- Consent, confidentiality, social and ethical issues to be carefully considered
- Thorough community engagement non-negotiable
 - including adolescents
- Consider risk/benefit
- Pre-trial engagement with local expertise is important to understand ethico-legal framework

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