INTRODUCTION

The HIV AIDS Vaccines Ethics Group (HAVEG) at the University of KwaZulu-Natal (UKZN) was funded through the European and Developing Countries Clinical Trials Partnership (EDCTP) to develop resources on the ethical-legal framework for researchers and research ethics committees (RECs) working with adolescent HIV prevention trials. This memo was originally designed to assist and guide researchers working on the South African Studies on HIV in Adolescents (SASHA) project. The aim of the SASHA study was to build stakeholder capacity for adolescent prevention trials. The memo has been revised, updated and adapted to assist other protocol developers and protocol reviewers by identifying key ethical-legal issues in adolescent HIV prevention trials and describing the legal obligations relating thereto. Current funding to update this resource is received from the National Institutes of Health via the Desmond Tutu HIV Foundation (DTHF).

Key legal complexities in HIV prevention research with adolescents include:

1. Who consents for trial enrolment? Who consents to the health-related interventions in the trial?
2. What components of the trial should adolescents enjoy confidentiality for?
3. What disclosures are likely to trigger reporting obligations?
4. What should researchers do to intervene to assist adolescents when key problems are picked up?

Based on the current ethical-legal framework, this memo has identified nine key norms which should apply to adolescent HIV prevention trials. These are:

1. A parent or legal guardian (LG) should provide consent for adolescents to take part in prevention trials;
2. Adolescents should consent independently to key trial components, even though their parents/ LGs will provide consent to enrolment in the trial;
3. Adolescents should enjoy confidentiality for key trial components;
4. Adolescents’ right to confidentiality can be limited and adolescents could be asked to disclose to otherwise confidential information to a trusted adult in certain instances;
5. Parents/ LGs and adolescent should understand what information will or will not be made available to parents/ LGs;
6. If adolescents are being abused, neglected or maltreated, this should be reported to authorities and adolescents should be assisted;
7. If adolescents are engaged in underage sexual relationships that are consensual but exploitative, this should be reported to the authorities and the adolescents should be assisted;
8. There is no legal obligation to report other offences but adolescents should be assisted; and
9. Parents/ LGs and adolescents should consent to confidentiality limits posed by reporting to authorities.

These are each discussed in more detail below:
1: A parent or legal guardian (LG) must provide consent for adolescents to take part in prevention trials

1. The first norm is that a parent or LG must provide consent for trial enrolment.

2. How was this established? The Department of Health’s GCP (2006) guidelines\(^1\) provide that children cannot consent on their own to clinical trials and that consent must be obtained from a parent or a LG. The National Health Research Ethics Council guidelines (2004)\(^2\) allow that adolescents can only consent unassisted to minimal risk research (where research risks are approximate to those of the child’s everyday life). Clinical trials are generally held to present a higher standard of risk than this, therefore, consent from a parent or LG must be secured.

3. Parents or LGs must consent to adolescent enrolment only when they understand the implications for their children and themselves. Some of the norms relating to the manner in which the trial will be run (described in more detail below) may be unacceptable to a parent, for example, the protocol may provide that parents will not necessarily be told that their child is pregnant or that their child elected to have the pregnancy terminated. Therefore, in such situations parents or LGs may refuse to enrol their child in the trial. Adolescents themselves must provide assent to participation. Some norms may be also unacceptable to an adolescent, for example, the obligation to disclose HIV status to a trusted adult if they test positive. Therefore, adolescents may also refuse to enrol in the study.

4. Section 71 of the National Health Act\(^3\) has now been implemented which requires parental/legal guardian consent for all health research. This requirement has been criticized as being overly restrictive for some forms of child research. However, for clinical trial enrolment parental consent is reasonable.

2: Adolescents should consent independently to key trial components, even though their parents or LGs will provide consent to trial enrolment

1. The second norm is that even where a parent or LG provides consent for enrolment, adolescents should consent independently to certain trial components.

2. How was this norm established? According to various statutes, adolescents can consent independently to a number of health-related interventions, such as:

a. **Terminations of Pregnancy** at any age (s 5, Choice of Termination of Pregnancy Act, No. 92 of 1996)\(^4\). However the Act requires providers to advise adolescents to “consult with their parents, guardian, family members or friends” before the termination (s 5, Choice of Termination of Pregnancy Act)\(^5\)

b. **HIV testing** from the age of 12 (s 130, Children’s Act, No. 38 of 2010)\(^6\) and even children below 12 can consent independently to such testing if they have “sufficient capacity”

c. **Medical treatment** from the age of 12, including STI and HIV treatment provided the child has “sufficient maturity”. In other words the child should be 12 and have the mental capacity to understand the benefits, risks, social and other implications of the treatment; and (s 129, Children’s Act No. 38 of 2010)\(^7\)

d. **Contraceptives** and contraceptive advice, including emergency contraceptives from the age of 12 (s 134, Children’s Act, No. 38 of 2010)\(^8\)

e. **Circumcision** at the age of 16\(^9\). If boys are below the age of 16, then consent must be obtained from their parent or legal guardian. The Act also requires that boys below 16 can only be circumcised for ‘religious’ or ‘medical reasons on the recommendation of a medical practitioner’ whereas those above 16 may undergo circumcision for any reason. Boys over 16 must receive counselling prior to the circumcision, and they have the right to refuse circumcision. (s12 (8) and s12(9-10) of the Children’s Act No. 38 of 2005)

f. **Surgical operations** at the age of 12 provided he/she (i) has ‘sufficient maturity and has the mental capacity to understand the benefits, risks, social and other implications of the surgical operation’, and (ii) is assisted by a parent or guardian. (See section 129(3) of the Children’s Act No. 38 of 2005).
3. Another factor that is relevant to consent by adolescents within HIV prevention trials is the age at which they can lawfully engage in sex. This is set at 16 in the Sexual Offences Act (s 15, Criminal Law (Sexual Offences and Related Matters) Amendment Act, No, 32 of 2007). See section 7 for more detail.

4. Currently in prevention trials this means that:
   a. Adolescents, who need to be tested for pregnancy regularly as part of a prevention trial, can give their own consent for pregnancy tests from the age of 12 and could receive a TOP at any age with their own consent, provided they have the capacity to consent;
   b. Adolescents, who need to be tested for HIV regularly as part of a prevention trial, can give their own consent for these HIV tests from 12;
   c. Adolescents, who need to be tested regularly for STIs, can give consent on their own from 12 for STI testing and treatment, if required, provided they meet the capacity requirements (which could vary according the medical condition or procedure); and
   d. Adolescents wanting access to male or female condoms or other forms of contraceptives or contraceptive advice could receive these on their own from the age of 12.

3: Adolescents should enjoy confidentiality for key trial components

1. The third norm is that adolescents should enjoy confidentiality for key trial components. How was this norm established?

2. Firstly, adolescents have the right to confidentiality for the range of health-related interventions to which they have consented independently. That is:
   a. Adolescent TPs of 12 years and older (and not their parents) should receive HIV test results;
   b. Adolescents of 12 (who have capacity) and older (and not their parents) should get the results of STI tests;
   c. Adolescent TPs of 12 years and older should enjoy confidentiality for access to contraceptives;
   d. Adolescent TPs (and not their parents) should get results of pregnancy tests and/or enjoy confidentiality for TOPs.

3. Secondly, adolescents have a right to privacy if there is an expectation of privacy that society regards as reasonable. Where the law is silent on whether a right to privacy exists, one can use the “legitimate expectation test” to establish if something should be kept private.

   a. It can be argued that adolescents who are 16 years and older have the right to confidentiality regarding their sexual risk data. That is, older adolescents (and not their parents) should get the results of sexual risk assessments. This is on the grounds that older adolescents would have an expectation of privacy (which most would hold as reasonable) because adolescents can lawfully consent to sex at 16. For adolescents who are between the age of 12 and 15 given that consensual sex with their peer group is no longer a sexual offence it is argued that the same principles would apply.

4: Adolescents’ right to confidentiality can be limited and adolescents could be asked to disclose otherwise confidential information to a trusted adult in certain instances

1. The fourth norm is that even though adolescents have rights to confidentiality, these rights can be limited.

2. How was this norm established? In law, a child’s right to confidentiality regarding their health status can be limited where this is in their “best interests” (s 13(1)(d), Children’s Act). In ethics, respect for emerging autonomy can be balanced by the need to minimize harms and promote welfare. In law, South African courts have generally held that the best interests of children require a wide range of factors to be considered in decision-making, including those which promote a child’s physical, moral, emotional and spiritual welfare. This means decision-makers must evaluate, weigh and balance these competing factors. They must also take into account the child’s wishes.
3. In prevention trials, adolescents, who acquire conditions or a health status with long-term complications that need on-going support, should be asked to disclose to a trusted adult (which may constitute their parent should they so wish) within a reasonable time-frame, because this is in their best interests. For example, maintaining confidentiality regarding a child’s HIV status or their pregnancy may not be in their best interests as these are chronic, long-term conditions that require specialist treatment and emotional support.

5: Parents/ LGs and adolescents should understand what information will or will not be made available to parents/ LGs

1. The fifth norm is that both parties must understand what information will be kept confidential and what will be disclosed to another party.

2. How was this norm established? In law, consent is valid only if it is based on a full appreciation of information that most people would consider very important to know. In ethics, consent is only meaningful if it is based on a full understanding of the personal implications of research participation. In prevention trials, it is possible that the parent/guardian may refuse enrolment when they understand these matters, or the child may refuse to take part.

6: If adolescents are being abused or neglected, this should be reported to authorities and adolescents should be assisted

1. The sixth norm is that adolescents’ right to confidentiality is expressly limited where they are being abused or neglected, or are identified as being in need of care and protection.

2. How was this norm established? In terms of s 110 of the Children’s Act (2010) there is a broad range of persons who must report any child that has been sexually abused, deliberately neglected or abused in a manner causing physical injury.

3. The category of persons who must report such abuses includes medical practitioners, nurses, psychologists, social service professionals, social workers and members of staff or volunteer workers at a drop-in centres or child and youth care centres.

4. Reports must be made to designated child protection organisations, the provincial department of social development or police officials. While all research staff are not expressly included in this list, some members of the team will fall into these designated categories and are obliged to report.

5. Even if staff do not fall within a designated category obliging them to report, the Act also states that any person who, on reasonable grounds, believes that a child is in need of care and protection may report that belief to the provincial department of social development, a designated child protection organisation or a police official.

6. In addition, researchers should assist children by referring them for various kinds of support. Assistance could involve encouraging adolescents to reach out for all forms of adult support, including their reaching out to their parents, where this seems helpful.

7. Trial sites could partner with professional organisations to assist them to make determinations of abuse or neglect.

7: If adolescents are engaged in underage sexual relationships that are consensual but exploitative, this should be reported to the authorities and the adolescents should be assisted

1. The seventh norm is that adolescents’ right to confidentiality may be expressly limited in certain circumstances, such as when certain sexual offences are being committed.
2. How was this norm established? In ethics, respect for emerging autonomy can be balanced by the need to minimize harms and promote welfare. In law, the Criminal Law [Sexual Offences and Related Matters] Amendment Act, No. 32 of 2007 requires any person who is aware of a sexual offence having been committed against a child to report this to the South African Police Service (SAPS).

3. This memo recommends that all instances the sexual offences of rape and commercial sex work should be reported to SAPS. In terms of rape, it is important to note that all sex (even if it is 'consensual') with persons under the age of 12 is rape in terms of the Sexual Offences Act. Therefore, even if a child participant discloses 'consensual' sex under 12, this will have to be reported as statutory rape.

4. According to the Sexual Offences Act (§ 15, Criminal Law [Sexual Offences and Related Matters] Amendment Act, No. 32 of 2007) it is a sexual offence for an adult (older than 18 years) to have consensual sex/sexual activity with a child between the ages of 12 – 15 years. This is still the case.

5. Recently, the High Court declared certain sections of the Sexual Offences Act - which criminalized consensual sex between children (12 - 15 years) - to be unconstitutional. Resultantly it is no longer a sexual offence if both parties to the consensual sex/sexual activity are between 12-15 years. In addition, the court held that it is no longer a sexual offence if children between 16 - 17 years have sex with children between 12-15 years if there is a two year age gap or less between the older and younger child. This means that certain instances of consensual sex/sexual activity are no longer illegal. The Sexual Offences Act has thus (to some degree) become more aligned with the principles articulated in the Children’s Act (2005) which expressly allows sexually active children under the age of 16 years to access services such as contraceptive advice and methods, HIV testing, and medical treatment.

6. This also means that where there is a large age gap between those in the sexual relationship or where one party is an adult (over 18), the older person is committing a sexual offence and the law requires that reporting to the police take place.

7. However, we have proposed a more nuanced approach:
   i. When adolescent participants (12-15) report that they are sexually involved with persons 18 years and older, site staff should be aware that this is a reportable offence. However, the partner, if known, should not be reported unless that sex/activity is clearly exploitative. This is because adolescent participants themselves (between the ages of 12 and 15) are not committing a crime by having under-age, consensual sex and because reporting – where relationships are not exploitative - is not in their best interests as it will drag young persons into the criminal justice system requiring them to give evidence in court against their partner, and causing them to face possible negative consequences from their partner who faces a criminal record and being entered onto the Sexual Offences Register. In some instances, reports may trigger reporting because they fall under the definition of abuse (see earlier sections of this memo).
   ii. When younger adolescent participants (12 -15) report being sexually involved with older adolescent partners (with more than a 2 year-age gap) site staff should be aware that this is a reportable offence. However, the partner, if known should not be reported unless the sex/activity is clearly exploitative; after an assessment by the trial site team.
   iii. When older adolescent participants (16/17) report that they are sexually involved with younger children (with more than a 2 year age gap) site staff should be aware that this is a reportable offence. However, the adolescent participant should not be reported unless the sex/activity is clearly exploitative, in other words, after an assessment by the trial site team.
   iv. The determination of whether the sex/sexual activity is exploitative should be made by a multi-disciplinary team who consider whether the ability of the adolescent to consent to the sexual activity has been compromised by factors such as coercion, violence or a lack of power.

8. This approach can also be defended on ethical grounds that harmful activities (such as non-consensual or exploitative sex) are reported, but that non-harmful activities (consensual and non-exploitative sex) are not reported because this is unlikely to protect children, may erode trust in adult or authority figures and may
decrease the veracity of disclosures children make to research staff – impeding the ability to steer them to appropriate services.

9. This approach requires trial sites to undertake an assessment of exploitation. Site staff should consider the age differential as well as other aspects of the relationship such as where one party assumes an unfair level of benefit relative to another party. There is no easy formula for this assessment.

10. This approach should be discussed with Research Ethics Committees involved in oversight of the prevention trial.

11. Sites may wish to partner with professional organisations to assist them to make such determinations.

12. If adolescents are aware that certain categories of sexual activity, including 'exploitative' sex, may be reported to authorities, they may elect not to disclose this to site staff.

8: There is no legal obligation to report other offences but adolescents should be assisted

1. The eighth norm is that where adolescents are acting in a way that contravenes other laws, there may be no legal obligation to report this, but there is an ethical responsibility to assist. Again, such assistance could involve encouraging adolescents to reach out for forms of adult support, including their reaching out to their parents where this seems helpful.

2. How was this norm established? The South African Schools Act (1996)\textsuperscript{12} requires all children between the ages of 7 – 15 to attend school. The Basic Conditions of Employment Act (1997)\textsuperscript{13} asserts that it is illegal for children under the age of 15 to work, or those between the ages of 15 and 18 to perform unsuitable work (work that places their well-being, education, physical or mental health, or spiritual, moral or social development at risk).

3. Currently, in HIV prevention trials:
   a. A researcher is not under a legal obligation to report truancy from school to any authority. However given that parents are required to ensure that children under 15 attend school and they may be unaware that their child is not attending, researchers may wish to inform parents of under 15 year-olds of truancy, so that parents can act to fulfil their duty. Children should also get assistance, advice and appropriate referrals. Trial attendance should not interfere with the school attendance.
   b. A researcher is not under a legal obligation to report child labour or inappropriate work. There may however be an ethical obligation to act in the best interests of the child by providing assistance, advice and appropriate referrals.
   c. A researcher is not under a legal obligation to report information regarding a child participant who has committed, or is committing, crimes (e.g. abusing substances, committing theft). However, where a child, involved in a criminal offence, is being exploited, this should be reported to the police or other relevant authorities because this amounts to ill-treatment (e.g. where a child is being forced to sell drugs by an adult). However, in the instance of criminal activity, researchers should intervene through advice and appropriate referrals.
   d. A researcher is not under a legal obligation to take further steps when a research participant informs the researcher of a third party, who has been the “victim” of a crime or has “committed” a crime. However, they may be under an ethical duty if a child is in clear and imminent danger, for example from a violent and abusive parent. In such a case they should assist the child research participant to report this information to the local police or social workers for further investigation.
9: Parents/ LGs and adolescents should consent to confidentiality limits posed by reporting to authorities

1. The last norm is that both parties (parent and adolescent) must understand what information will be kept confidential and what will be disclosed to authorities.

2. How was this norm established? In law, consent is valid only if it based on a full appreciation of information most people would consider very important to know. In ethics discourse, consent is only meaningful if it is based on a full understanding of the personal implications of research participation.

3. In prevention trials, it should be explained to parents that the researchers are not necessarily required by law to tell parents if a report is made to authorities. However, each case will be approached on an individual basis with the best interests of the child being the basis for deciding whether parents should be informed by researchers.

4. In all instances, the adolescent will receive assistance, support and appropriate referrals.

5. It is possible that the parent/guardian may refuse enrolment when they understand these matters, or the child may refuse to take part.

CONCLUSION

1. Ethical-legal norms for adolescent HIV prevention trials should be understood by, and acceptable to, key stakeholders such as participating communities. Where high levels of objection to trials are anticipated, it may not be feasible to run such trials. It may be helpful to research the acceptability of such norms among participating communities.

2. It may also be helpful for researchers implementing such norms in prevention trials to monitor “events” such as mandatory reports to authorities and direct disclosures to parents to estimate frequency and impact.

3. In the long run, success of adolescent prevention trials will, in part, involve identifying and partnering with range of adolescent service organisations around sites, to assist researchers to implement their responsibilities.

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Acknowledgements & disclaimer: This memo was originally made possible by funding from the European and Developing Countries Clinical Trials Partnership (EDCTP) to the HIV AIDS Vaccines Ethics Group (HAVEG). Subsequent funding to update and revise the resource was supported by award number 1RO1 A1094586 from the National Institutes of Health entitled CHAMPS (Choices for Adolescent Methods of Prevention in South Africa). The content is solely the responsibility of the authors and does not necessarily represent the official views of EDCTP nor the NIH.

Thanks to Jacintha Toohey for research and editing, and to Jennifer Koen for edits to the document, as well as to Melissa Wallace and Agnes Ronan.
REFERENCES

3 Section 71 of the National Health Act No. 61 of 2003
4 Section 5 of the Choice on Termination of Pregnancy Act No. 92 of 1996
5 Section 130 of the Children’s Act No. 38 of 2005
6 Section 129 of the Children’s Act No. 38 of 2005
7 Section 134 of the Children’s Act No. 38 of 2005
8 Section 12(8) and section 12(9-10) of the Children’s Act No. 38 of 2005
9 Section 110 of the Children’s Act No. 38 of 2010
10 Section 15 of the Criminal Law (Sexual Offences and Related Matters) Amendment Act No. 32 of 2007
11 South African Schools Act No. 84 of 1996
12 The Basic Conditions of Employment Act No.75 of 1997

HAVEG CHILD RESOURCES http://www.saavi.org.za/haveg.htm