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MINORS, HEALTH CARE RESEARCH AND HIV/AIDS

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Introduction

In terms of national legislation¹ and international ethics guidelines,² all health care research to be conducted in South Africa must undergo ethical review to ensure that individual participants in research are protected from exploitation and abuse as well as to ensure that the society in which the research is conducted is protected from exploitation. The remit of a South African university research ethics committee (hereafter REC) is thus two-fold: to protect individual interests of participants, on the one hand, and to ensure that the public interest will be served by the research to be conducted, on the other.³

Available statistics⁴ of the incidence and prevalence of HIV point to the urgency of finding ways to prevent the further spread of the virus as well to cope with the large numbers of existing infections. In particular, the statistics indicate that young people between the ages of 15 and 24 years are especially vulnerable

¹ The National Health Act 61 of 2003 s 73(1) Every institution, health agency and health establishment at which health research is conducted, must establish or have access to a health research ethics committee, which is registered with the National Health Research Ethics Council. (2) A health research ethics committee must-

(a) review research proposals and protocols in order to ensure that research conducted by the relevant institution, agency or establishment will promote health, contribute to the prevention of communicable or non-communicable diseases or disability or result in cures for communicable or non-communicable diseases; and

(b) grant approval for research by the relevant institution, agency or establishment in instances where research proposals and protocol (sic) meet the ethical standards of that health research ethics committee.

² Guidelines include Medical Research Council of SA (MRC) *Guidelines on Ethics for Medical Research* 4th ed (currently under revision); International Conference on Harmonisation (ICH) and South African Department of Health clinical trial guidelines (the latter are currently under revision); Council for International Organizations of Medical Sciences (CIOMS) *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (2002); Declaration of Helsinki (World Medical Association) (2000).

³ See s 73(2)(a) of the National Health Act 61 of 2003.

⁴ See eg 'Deaths soar as Aids drug rollout falters' in *The Sunday Independent* February 20 2005 quoting Statistics South Africa's recent 'Mortality and Causes of Death in South Africa' report; 'Quarter of young women are HIV-positive, new survey reveals' in *Cape Argus* Wednesday April 7 2004; T Barnett & A Whiteside (2002) *Aids in the Twenty-First Century: Disease and Globalization* Palgrave Macmillan.

to infection.⁵ Research in this group is thus seen as urgent and necessary to curb the catastrophic effect of the virus.

In seeking approval for HIV/Aids related research amongst young people regarding their sexual activity, researchers often request that the REC should waive the usual parental or legal guardian consent for the informed consent process, which includes consent to an HIV test. Sexual activity is regarded generally as a private matter and the view is that this attitude should apply also to minors.

This paper argues that the REC should not waive parental or legal guardian consent without strong evidence that the justifications presented for waiver are acceptable to the community concerned.

The context

In the context of the HIV/Aids pandemic, the amount of health care research being conducted in sub-Saharan Africa has increased hugely. South Africa is a particularly attractive site for such research, given its relatively good health care infrastructure (in comparison with other parts of sub-Saharan Africa) and its very high HIV infection count. The impact of large numbers of deaths of the young, educated, economically active sector of a population on the country concerned ought to be self-evident. Research in this group is thus seen as urgent and necessary to curb the catastrophic effect of the virus.

That HIV/Aids is more than a disease seems to be clear from social research, which indicates that the presence of risk environments⁶ that include lack of

⁵ Prevalence for South African female youth (15-24 years of age) has been estimated at 21.6% and for male youth (15-24 years of age) at 5.8% by Dorrington et al (2002): cited in HIV AIDS Vaccine Ethics Group (HAVEG), University of Natal, Report on Stakeholder Consultation (Final Version) August 2003. See also eg C Campbell (2003) *Letting them Die: Why HIV/AIDS Intervention Programmes Fail* (African Issues) Double Storey Juta, 122; T Barnett & A Whiteside (n 4) 119-121. See also <http://www.mrc.ac.za/hiv/projects10.htm> [accessed 27 May 2004].

infrastructure, inadequate resources, poverty and unemployment, gender inequalities, sexual identity stereotyping, misinformation about the virus, poor communication between parents and children, and the impact of orphanhood, foster the spread of the virus. Furthermore, that the virus is spread primarily at an intimate individual contact level, ie through sexual intercourse, exacerbates the matter, since one's own or another's sexual activity is usually treated as a private matter and may be a taboo subject for discussion and hence intervention. The almost universally different response to HIV/Aids in comparison with other epidemics of infectious diseases is significant. Other infectious diseases with the potential to spread and cause harm in the way that HIV has, are regarded as public health matters requiring urgent intervention despite the possibility of individual human rights violations. For example, the recent responses to Sudden Acute Respiratory Syndrome (SARS) included, in many ways, violations of individual human rights. For example, personal details of travellers who allegedly carried the virus from the point of origin to other parts of the world were revealed in the media. The speed of transmission of the virus as well as that of progression from infection to death was so rapid, however, that there was no time even to formulate a human rights analysis of the events, let alone to act on such an analysis. That it did not involve any act, let alone a sexual act, on the part of the person who became infected is significant. On the other hand, the history of the development of the HIV pandemic demonstrates that the primary transmission vehicle of the virus, viz sexual intercourse, together with the relative slowness of progression from infection to death has made discussion, policy development and intervention very difficult and contentious.

Developing a preventive HIV vaccine is seen to be an important way to curb the further spread of the virus.⁷ Prevention methods, including education aimed

⁶ See Barnett & Whiteside (n 4) 80-156.

⁷ The rationale flows from the successful deployment of vaccines for other serious infectious diseases like smallpox and poliomyelitis: see D Patterson 'Resolving legal, ethical and human rights challenges in HIV vaccine research' in "Putting Third First: Legal Issues" Durban 7 July 2000. <http://www.aidslaw.ca/durban2000/e-durban-vacc.htm> [accessed 8 February 2005].

at behaviour and attitude change, are said to be failing to curb its spread.⁸ UNAIDS, amongst other agencies, regards the involvement of young people in research to test candidate HIV vaccines as necessary.⁹ Clinical trials have begun in different parts of Africa, as well as in other parts of the world, to test candidate vaccines with adult research participants. Strict regulation of recruitment of participants for these trials is accepted as necessary, given the experimental nature of the research.

The responsibility of the REC includes ascertaining that the proposed research is scientifically sound, that the risk/benefit ratio is favourable to participants, that the research will benefit the host community and, when minors are to be involved, that their best interests are served.

The problem

In seeking approval for HIV/Aids related research amongst young people regarding their sexual activity, eg in preparation for possible enrolment in preventive vaccine trials, researchers often request that the REC should waive the usual parental or legal guardian consent for the informed consent process, which includes consent to an HIV test. Potential participants must test HIV negative in order to be enrolled in such a trial. The purpose of HIV vaccine trials in minors would be to find out whether the candidate vaccine works, ie does it prevent transmission of the virus through sexual intercourse? In other words, a necessary component of the trial is the continued risky sexual activity of the minor.

The researchers justify their request on the ground that insufficient numbers of participants would be recruited for testing and possible enrolment if potential

⁸ See eg Campbell (n 5) chapters 7 & 8.

⁹ See UNAIDS Guidance Document (2000) guidance point 18: Children; see also <http://www.saavi.org.za/challenges.htm> [accessed 27 May 2004]; MRC Guidelines on Ethics for Medical Research: HIV AIDS preventive vaccine trials (Draft Book 5 May 2002).

participants were to have to inform their parents about their sexual activity. Moreover, they argue that the need for the scientifically gathered information is so urgent that other considerations, such as the law governing the age of consent and protection of minors should give way. Further justification is provided on the basis that the emerging adulthood of the young people and their right to autonomy and hence privacy regarding their sexual activity should be acknowledged and protected. In other words, the appeal is for the protection of the individual potential participant's interest in having her sexual activity kept private. On another tack, the public interest in the benefit for youth in general from the successful development of a vaccine is invoked. Since young people are the most likely to benefit, their involvement in vaccine trials is cast as a matter of justice.

Would the REC act in the best interests of minors by permitting them to consent independently and thus to keep their sexual activity secret from their parents? Put differently, would the requirement of parental consent violate minor children's rights?

The tensions

One tension that emerges is between the individual minor's right to privacy and confidentiality and the charge on the REC to protect minors as research participants. Exploration of this tension requires consideration of the concept of minority and the justification for protection of minors, in regard to both individual and societal interests, insofar as medical treatment is not synonymous with research. An examination of pertinent rights and responsibilities for both children and adults as set out in international instruments and national law is also examined in the analysis.

A further tension exists between urgent pressure to find ways to combat the virus and to keep it at bay, if not to eradicate it, for the group that is very

vulnerable to infection and necessary caution about the involvement of minors because of little well-established scientific knowledge in adult research populations. Consideration of this tension requires clear thinking, free from commercial and political pressures, about the ethical and legal implications of the various viewpoints and options.

The main focus of the paper is on the first tension, ie between the minor's individual interest and society's interest in protecting minors, given the human rights matrix of rights and responsibilities.

Rights and responsibilities

International instruments

The university REC is an 'organ of state', being a committee of a publicly funded institution. Thus, it is bound to abide by conventions and charters ratified by South Africa as well as by the national law.

*United Nations Convention on the Rights of the Child (UNCRC)*¹⁰

The Convention decrees that the best interests of the child must be a primary consideration in all matters concerning the child.¹¹ The responsibilities, rights and duties of parents must be respected.¹² The child is entitled to 'the highest attainable standard of health'.¹³ From the perspective of the REC, these rights and obligations appear to indicate that parents' responsibility for protection of the interest of their minor child should not be overridden without more. Article 34 requires prevention of 'inducement or coercion of a child to engage in unlawful sexual activity'. A minor under the age of 16 who engages in sexual activity does

¹⁰ Ratified by South Africa in June 1995.

¹¹ UNCRC Art 3.

¹² Ibid Art 5.

¹³ Ibid Art 24.

so contrary to the law. That she should engage in sexual activity that exposes her to risk of fatal infection, makes manifest that her best interests are not served. If the REC approves waiver of parental consent, does it collude in the continued risky behaviour and thus not act in the best interests of the minor?

*The African [Banjul] Charter on Human and Peoples' Rights*¹⁴

This Charter designates the family as 'the natural unit and basis of society'; and furthermore, that the State must 'assist the family which is the custodian of morals and traditional values recognized by the community'.¹⁵ Was the REC to approve waiver of parental consent, would it act in violation of the obligation to assist families? Approval of waiver of parental consent in effect grants permission to continue to act as before, ie in isolation from the family unit. Should the REC consider the minor as a member of a family unit rather than only as an individual participant? The minor's right to autonomy conflicts directly with the right of the family under the Charter. What factors should be weighed in the determination of whether it is in the best interests of a minor to be isolated from her family?

National law

*The Constitution of the Republic of South Africa*¹⁶

Children's rights are set out in s 28, which stipulates that the best interests of the child are paramount in any matter concerning the child. Furthermore, each child has the right to family care or parental care. This means that there is a responsibility to provide family and parental care. While clearly it is not within the remit of the REC to provide such care, arguably it is within its remit to insist that

¹⁴ Ratified by South Africa in June 1996.

¹⁵ African Charter on Human and People's Rights Art 18.

¹⁶ Act 108 of 1996.

parents be given the opportunity to carry out their responsibility to provide parental care.

*The Child Care Act*¹⁷

Amongst other provisions, this Act includes the obligation to report suspicion of ill-treatment or injury of a child is imposed on health care workers, teachers and others. This obligation has a direct impact on assurances regarding confidentiality that are given to potential minor research participants insofar as minors under 16 years cannot in law consent to sexual activity. If the REC approves waiver of parental consent, what effect would it have on the obligation to report? Would it compromise the relationship between the health care worker researchers and the participants? Can the REC be confident that the obligation would be acted upon even if this would negatively affect the research project?

*The Children's Bill*¹⁸

Currently before Parliament, this Bill seeks to modernise and bring together in one place the various pieces of legislation that govern children. The spirit of the constitutional provision for children's rights informs much of the thinking in the Bill. Particularly relevant to this discussion are those provisions that seek to foster family care, encourage parental responsibility and ensure that the best interests of the child are considered. Thus, the Bill provides that where it is in the best interests of the child, the family must be afforded the opportunity to make input in a matter concerning the child.¹⁹ 'Best interests' include the need for a 'stable family environment'.²⁰ In addition, the person 'who has parental responsibilities...must be informed of the action or decision which significantly

¹⁷ Act 74 of 1983.

¹⁸ [B 70 – 2003 Reintroduced].

¹⁹ Section 5(4) of the Bill.

²⁰ In terms of s 6(1)(i) of the Bill.

affects the child'.²¹ Who should determine what is in a particular child's best interests is not specified. That enrolment as a participant in HIV/Aids related research involves a decision that significantly affects the minor should be obvious.

Read together, therefore, these provisions seem to indicate that the REC would act contrary to the best interests of the child if it was to ignore the family's interest by elevating the minor's right to autonomy to the paramount consideration.

Minority and research participation

Minority

Minority is a legal construct designed to protect those regarded as vulnerable because of age. It is the mechanism whereby the law withholds full legal capacity in the best interest of the young person for her protection. The public interest in maintaining the mechanism of minority lies in ensuring that young people have a reasonable chance to learn how to conduct themselves as adults, protected from the full consequences of their actions and decisions. Because of lack of experience and information, minors may not perceive personal risk appropriately. This is demonstrated in the HIV/Aids context by studies that show that, despite relatively high levels of factual knowledge about the virus and its transmission, many youth fail to comprehend that they are at risk of infection. Their perception is that the likelihood of infection is small.²²

Legal restrictions on minors' capacity to act are relaxed in some instances. For example, the provisions of the Choice on Termination of Pregnancy Act²³ and the

²¹ Section 5(6) of the Bill.

²² See eg Barnett & Whiteside (n 4) 331.

²³ Act 92 of 1996.

Child Care Act²⁴ create exceptions to the rule that a minor cannot give informed consent by outlining specific circumscribed instances when a minor can give consent. The Child Care Act, which specifically states that ‘child’ does not have the same meaning as ‘minor’ in terms of the Age of Majority Act,²⁵ confers power on (but does not compel) minors to consent to medical treatment in two age categories, viz those who are 18 years and older may consent to an operation, while those who are 14 years and older may consent to medical treatment. The purpose of these provisions is to ensure that a child is given proper medical care. Medical treatment, though not defined in the Act, is interpreted generally as non-invasive interventions, but including blood or blood product transfusion and excluding tooth extraction.²⁶ Similarly, the Wills Act²⁷ permits a minor to make a will at age 16; the Sexual Offences Act²⁸ provides that sex with a minor under the age of 16 is a criminal offence. The existence of these provisions is often used in support of arguments that minors should consent independently to participation in research. More especially, that any pregnant female, regardless of age, can consent to an abortion, without her parents’ knowledge or consent, in terms of the Choice on Termination of Pregnancy Act, is regarded widely as a justification for permitting adolescents to consent independently to participation in research into sexual activity. However, when a statute confers power on a minor to act in particular circumstances, it does not alter the minor’s status for all purposes.

Who are minors? Article 1 of the United Nations Convention on the Rights of the Child provides that ‘...a child means every human being below the age of eighteen years unless...majority is attained earlier.’ A clear distinction between childhood and majority or adulthood is thus discernible in the Convention. Arguably, therefore, the distinction is significant and has meaning. In South

²⁴ Act 74 of 1983.

²⁵ Act 57 of 1972.

²⁶ See Van Heerden et al (1999) *Boberg’s Law of Persons and the Family* 2nd ed. Juta 253 n 58.

²⁷ Act 7 of 1953, s 4.

²⁸ Act 23 of 1957.

Africa, majority is attained at 21 years,²⁹ notwithstanding that the Constitution provides that a child is someone younger than 18 years.³⁰ This means that, generally speaking, the consent of a parent or guardian is required for the minor to participate in research. This requirement is part of the parent's responsibility and duty to protect the interests of the minor.

In the HIV/Aids context, the apparently important distinction between childhood and adulthood is blurred by the age categories used to report and publish statistics. UNAIDS, WHO, the World Bank and other agencies distinguish children from adults at 15 years. Thus anyone who is 15 and older is adult when incidence, prevalence, or death statistics relating to HIV/Aids are published. No mention is made of majority or adolescents. Yet the conventions differentiate between children and adults at 18 years, the national law stipulates the age at which majority is attained and, furthermore, research proposals focus on participants designated children, adolescents or adults. Who are adolescents? The United States of America regards adolescents as those young people between 14 and 18 years.³¹ The assumption appears to be that these are young people who have reached puberty. One could infer similarly, therefore, for South African adolescents. Note, however, that they retain their status as minors, which means they do not have full legal capacity and cannot give informed consent.

In principle informed consent is required before a person's bodily or psychological integrity may be interfered with lawfully. This freedom right in regard to health care research is enhanced in the South African context by the constitutional guarantee in s 12(2), which provides that 'everyone has the right not to be subjected to medical or scientific experiments without their informed

²⁹ In terms of s 1 of the Age of Majority Act 57 of 1972, which was not repealed by the Constitution.

³⁰ The Constitution of the Republic of South Africa Act 108 of 1996 s 28(3). The Children's Bill [B 70-2003 Reintroduced] (currently before Parliament) will repeal, amongst others, the Age of Majority Act and will change the age of majority to 18 years.

³¹ See eg Rhonda G Hartman 'Coming of Age: Devising Legislation for Adolescent Medical Decision-making' 2002 (28) *Am J L & Med* 409 (<http://international.westlaw.com> [accessed 18 Nov 2004]).

consent'. All the ethics guidelines in principle require informed consent prior to enrolment.

Research participation

Whether the provisions in the Child Care Act regarding consent to medical treatment extend to consent to participation in health care research has caused considerable confusion. The National Health Act³² refers to 'minors' rather than 'children' in s 72, the provision that deals with research with human subjects. Impliedly, therefore, consent to medical treatment differs from consent to participation in health care research. The Children's Bill does not include age categories relating to consent, providing merely that every child who is capable of doing so is entitled to participate in any matter concerning that child.³³ Needless to say, this lack of consonance makes the review process of protocols involving minors difficult.

The general rule is that minors should participate in health care research only if their participation is indispensable, ie if the research could not be done as effectively in an adult population.³⁴ In principle, only research that will directly benefit the individual participant³⁵ causing no more than minimal risk of harm³⁶ is permitted. The scientific validity of the research is vital. In regard to HIV vaccine trials, there is no consensus about whether enough established scientific data exist to support undertaking clinical trials for candidate vaccines amongst adults and about the consequences for participants in unsuccessful trials. There appears to be 'substantial doubt...as to whether [present candidate vaccines] could actually prevent HIV infection or reduce the impact of infection'.³⁷ Commercial interests and political pressure do not help to make it easy to

³² Act 61 of 2003.

³³ Section 10 of the Children's Bill.

³⁴ See CIOMS Guideline 14; Declaration of Helsinki 24.

³⁵ Also called 'therapeutic research'.

³⁶ Some guidelines refer to 'negligible risk'.

³⁷ See Patterson (n 9).

determine the scientific validity of clinical research.³⁸ These disputes cannot be ignored by the REC. Caution must be exercised, therefore, when deciding about the inclusion of minors in such trials, notwithstanding the urgency of finding a suitable vaccine.

CIOMS guideline 4 states that 'Waiver of informed consent is to be regarded as uncommon and exceptional...'.³⁹ Are the circumstances surrounding South African adolescent sexual activity 'exceptional' so as to justify waiver of parental consent?

A well-established cultural and legal norm is that parents have primary responsibility for the care and nurturance of minors. Research findings indicate that initiation of sexual activity occurs at about 14-15 years.⁴⁰ In general terms, young people engage in sexual activity secretively; ie they do not inform their parents or guardians that they are about to engage in sexual activity. Alarming findings such as the fact that young girls in particular begin sexual activity reluctantly or against their will,⁴¹ and that 'one-half of [Johannesburg] high school students believe forced sex is not sexual violence'⁴² make the task of deciding whether to approve waiver even more difficult. How should the REC determine whether this state of affairs is in the best interests of minors?

Because of a general reluctance to talk openly about sex, society does not appear to demand that parents act on their responsibility to protect their child's interests by intervening where early sexual activity is concerned. Instead, there seems to be an acceptance by society at large, albeit unspoken, that young

³⁸ See eg D R Burton et al (2004) 'Sound Rationale needed for Phase III HIV-1 Vaccine Trials' in *Science* 2004 (303) 316 who question the US Government's sponsorship of a phase III trial in Thailand of a vaccine, shown elsewhere in phase I and II trials to be poorly immunogenic at best.

³⁹ For example, CIOMS guideline 4.

⁴⁰ See eg Kaiser Family Foundation/South African National Youth Survey 2000 cited in G Gray 'Adolescents, sex and Vaccine trials' (Perinatal HIV Research Unit).

⁴¹ See Campbell (n 5) 129.

⁴² 'Beijing betrayed?' in *Mail & Guardian* March 4-10 2005.

people experiment with sexual activity and a nebulous hope that they will come to no harm.

When individual parents do try to intervene, they may find that the law prevents them from so intervening, as occurred in the well-known *Gillick* case.⁴³ The emphasis on individual human rights seems to override the public interest in protecting minors. However, the distinction between the minor seeking advice and treatment independently and consenting to participate in research is an obstacle not overcome by the *Gillick* decision, which held that the *Gillick* daughter was free to seek family planning advice and products without her parent's consent or knowledge, given her level of maturity and understanding. Whether she would have been permitted to consent independently to participation in research that sought to establish whether she had a sexually transmitted infection or was HIV negative is not known.

Researchers argue that early initiation of sexual activity, high rates of sexually transmitted infections, unprotected sexual exposure (low prevalence of condom use), transactional sex, and coerced or forced sex all point towards the urgent need for unimpeded access to minors for research purposes. That these phenomena require urgent intervention is quite clear and is not disputed. However, it is not clear that intervention should exclude parents from the informed consent process. Unless the contrary is established, parents are presumed to be best able to determine what is in their child's best interests. Without input from parents, it is inappropriate, in my view, for the REC to determine whether it is in adolescents' best interests to enrol as participants in research into sexual activity without their parents' knowledge or consent. Some argue, however, that, because the minor may consent without parental consent to treatment necessary for her condition, eg a sexually transmitted infection, the fact that the dispensing of the medication occurs in the context of research

⁴³ See *Gillick v West Norfolk and Wisbech AHA* [1986] AC 112, [1985] All ER 402, (1985) 2 BMLR 11 (HL).

should not alter the matter. Clearly, the dilemma is not simple. What is the public interest in relying on the REC to protect minors by following the letter of the law? Would the public interest be served better if the REC were to accept that there is justification for permitting the minor to participate in the research, without the knowledge and consent of her parents, so that she can receive treatment at the same time? In other words, should the REC ignore the status of the minor? What empirical evidence is there to support the view that the REC should favour the minor's right to privacy over society's interest in protection of minors and in stable healthy family units?

Conclusion

How seriously should the REC take its obligations in terms of the Convention, the African Charter and the national law? If the distinction between childhood and adulthood actually has meaning, then I argue that the REC must act to protect minors before it bows to other pressures. How should the REC do this? In the short term, decisions have to be made. The volume of research proposals for review is considerable. They cannot be put aside until such time as there is data demonstrating what South Africans think about the matter. To guide the REC, the following framework is suggested.

The REC must be persuaded by the investigators

- That the proposed research cannot be done as effectively amongst adults;
- That it investigates a problem of relevance to adolescents;
- That clear justification exists for why adolescents should consent unassisted;
- That the nature of the research would not, in the opinion of the REC, cause parents, legal guardians or the community at large to object to adolescents giving consent independently. The opinion of the REC must be informed by evidence gathered

from the community concerned and by contributions from the lay members of the committee.

- If justification for unassisted adolescent consent is found to exist, the research may impose no more than minimal risk, ie risks encountered in ordinary daily living;
- The REC should impose rigorous on-going monitoring and review requirements to ensure that the best interests of minors are not compromised.

If these steps are followed, then the REC, with reasonable confidence, can carry out its responsibility, in terms of the Convention and other law, to protect minors and also to promote access to improved health care for all South Africans by facilitating ethical research.