

HIV PREVENTIVE RESEARCH AND MINORS*

ANNE POPE†

Senior Lecturer, Department of Private Law, University of Cape Town

INTRODUCTION

HIV preventive research is both necessary and urgent in sub-Saharan Africa and especially in South Africa where incidence and prevalence statistics reveal extraordinarily high rates of HIV infection. Young women between 15 and 24 years of age are particularly at risk, in part because of the escalating pattern of seduction by older men, especially those who offer money or other desirable material goods in exchange for sex.¹ Men's reluctance to use condoms makes 'the development of an effective microbicide or vaginal gel, that can be applied without a partner's consent, essential'.² Similarly, the development of a vaccine is regarded as vital for both male and female youth.³ Research with this group is thus seen as imperative to curb the catastrophic effect of the virus.⁴ Complex legal and ethical issues surround

* Based on a paper delivered at the Fourth World Congress on Family Law & Children's Rights held in Cape Town on 20–23 March 2005. Thanks to Ms Anita Cooke for excellent research assistance and to colleagues and the anonymous referee for helpful comments.

† LDipLib (Stellenbosch) BA LLB (Rhodes) PG Dip International Research Ethics (Cape Town). The writer is also a serving member of the UCT Health Sciences Faculty Research (Human) Ethics Committee

¹ According to the South African National HIV Prevalence, HIV Incidence, Behaviour and Communication Survey 2005, 'the HIV rate is 16.2% among those aged 15 to 49, up slightly from 15.6% in the 2002 HSRC [Health Sciences Research Council of South Africa] Survey . . . women aged 15 to 24 are four times more likely to have HIV (16.9%) than men that age (4.4%) . . . 57% of women aged 15 to 24 had never used any contraception', quoted in 'The young and the reckless' *Sunday Times* 4 December 2005. The latest HSRC household study demonstrates that in the 15 to 24 age group eight times more women than men are HIV positive. Prevalence for South African female youth (15–24 years of age) was estimated previously at 21.6 per cent and for male youth (15–24 years of age) at 5.8 per cent 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 Catherine Campbell 'Letting them Die': *Why HIV/AIDS Intervention Programmes Fail* (2003) 122; Tony Barnett & Alan Whiteside *Aids in the Twenty-First Century: Disease and Globalization* (2002) 119–21. See also <http://www.mrc.ac.za/hiv/projects10.htm> (last accessed on 27 May 2004).

² 'The young and the reckless' *Sunday Times* 4 December 2005.

³ 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' prepared for *Putting Third First: Legal Issues*, an official satellite meeting of the XIII International AIDS Conference, Durban 7 July 2000 available at <http://www.aidslaw.ca/publications/interfaces/downloadFile.php?ref=362> (last accessed on 23 February 2007).

⁴ See Susan Hunter 'Deaths soar as Aids drug rollout falters' *The Sunday Independent* 20 February 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' *Cape Argus* 7 April 2004; see also generally Barnett & Whiteside op cit note 1.

the inclusion of minors, currently⁵ persons under 21 years of age, as participants in HIV preventive research.⁶

One issue that remains unresolved in South Africa is whether minors may consent independently to participation in research as opposed to medical treatment. Legislation that governs minors and their ability to consent independently to medical treatment is silent on whether they can consent to health care research participation. Ethics guidelines, on the other hand, assume that minors can so consent, provided they understand the implications. The absence of binding authority on the interpretation of the various local ethics guidelines leads to informal interpretation thereof by medical scientists and legal commentators alike. A widely held view is that it is lawful for minors to consent independently to 'therapeutic' research participation⁷ and consequently ethics committees are frequently asked to waive the need for parental or guardian assistance in the informed consent process. The legal and ethical basis for this view remains elusive but, arguably, depends upon a conflation of the requirements for consent to treatment with those for research participation. Key differences exist between medical treatment and research participation that should not be overlooked or conflated, especially in relation to minors who are regarded internationally as a vulnerable group and thus in need of special protection.⁸ A failure in law and policy to make the appropriate distinctions can lead to inadequate protection for minors who are approached to participate in health care research, particularly that which is aimed at preventing the spread of HIV.

In this article the current legal and ethical framework that governs health care research participation by minors is explored. One tension that emerges is between the individual minor's right to privacy and confidentiality, based on her (increasing) autonomy, and the charge on research ethics committees⁹ to protect minors as vulnerable research participants. In exploring this tension, the concept of minority and the justification for protection of minors, taking into account both individual and societal interests, are examined. A further tension exists between urgent pressures to combat the HI virus for this group, so vulnerable to infection, on the one hand, and

⁵ The age of majority will change to 18 years when the Children's Act 38 of 2005 comes into effect. However, it should be noted that the principles under consideration here will still be pertinent after the change because, in all likelihood, researchers will want minors aged 15–17 to consent independently, using similar justifications.

⁶ See Ann Strode et al 'Ethical and legal challenges in enrolling adolescents in medical research in South Africa: Implications for HIV vaccine trials' (2005) 101 *South African Journal of Science* 224 at 224–8.

⁷ See e.g. Christa van Wyk 'HIV preventive vaccine research on children: Is this possible in terms of South African law and research guidelines?' 2005 (68) *THRHR* 35 at 40.

⁸ See Council for International Organizations of Medical Sciences International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002) (hereafter CIOMS (2002)) guidelines 13–17, World Medical Association Declaration of Helsinki (2000) point 8, Republic of South Africa Department of Health 'Ethics in Health Research: Principles, Structures and Processes' (2004) (hereafter DOH (2004)) point 5.

⁹ All research conducted with human participants must be subjected to ethical review prior to commencement. See below.

necessary caution about the involvement of minors because of little well-established scientific knowledge in adult research populations, on the other.

The second part examines some of the particular legal and ethical issues that pertain to HIV preventive research amongst minors. My contention is not that minors should be prevented absolutely from deciding independently whether to participate in HIV preventive research. Rather, I argue that the decision regarding waiver of the required parental permission should not be left to individual ethics committees, but that a national policy should direct these decisions; furthermore, that the status of minority should not be undermined lightly for reasons of expediency, convenience or discomfort. In the absence of such a national policy, in cases where sexual activity of minors is to be studied and evidence is provided that the community of parents and guardians together with the minors themselves hold the view that the minors can choose independently whether to participate in research, then ethics committees are better placed to assess whether the waiver of the need for assistance in the informed consent process is appropriate in the circumstances.

LEGAL AND ETHICAL FRAMEWORK FOR HEALTH CARE RESEARCH WITH MINORS

National legislation¹⁰ and ethics guidelines¹¹ require that 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.¹² Until the National Health Act, no South African legislation directly addressed participation by humans in

¹⁰ 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'.

¹¹ Guidelines include DOH (2004) op cit note 8; South African Medical Research Council Guidelines on Ethics for Medical Research Book 1: General Principles (2002) (hereafter MRC Book 1); International Conference on Harmonisation (ICH) Clinical Trial guidelines; and RSA Department of Health Guidelines for Good Practice in the Conduct of Clinical trials in Human Participants in South Africa: Clinical Trial guidelines (2000) (currently under revision) [hereafter DOH (2000)]; CIOMS (2002) op cit note 8; Declaration of Helsinki (2000).

¹² See s 73(2)(a) of the National Health Act 61 of 2003. For several years, controversy has raged in bioethics and research ethics circles about first world researchers using third world research participants, especially for drug trials, whose communities do not or cannot benefit from the gain in scientific knowledge for reasons including the ultimate cost of the drugs developed. Such failure to benefit is regarded as evidence of exploitation.

health care research.¹³ Although not yet in effect, s 71 of the National Health Act governs ‘research on or experimentation with human subjects’.¹⁴ Research on minors is provided for expressly.¹⁵ In particular, ‘non-therapeutic’¹⁶ research on minors may be conducted only with ministerial and parental or a guardian’s consent.¹⁷ Furthermore, the Minister may not consent where the research is unlikely to ‘improve scientific understanding of the minor’s condition, disease or disorder. . .’¹⁸ Existing ethics guidelines are aspirational¹⁹ rather than prescriptive, not having the force of law, which means that ad hoc and inconsistent decision-making by ethics committees is possible. In addition, the various guidelines are not consonant with one another, which fact gives rise to differing interpretations that are at best confusing and at worst leave minors exposed to possible exploitation and harm. For example, the age at which independent consent to participate in health care research may be given by a young person is stated variously as 14 years,²⁰ 16 years²¹ and 18 years,²² notwithstanding that the age of majority in South Africa is still 21 years.²³

‘Therapeutic’ versus ‘non-therapeutic’ research

The National Health Act fails to define these terms but prevailing ethics guidelines indicate that ‘therapeutic’ research is that which is ‘aimed at benefiting the individual research participant by treating or curing his or her

¹³ Research ethics committees have existed for several decades, however, and have conducted their work to review proposed health care research in the public sector in accordance with international and local ethics guidelines. See MRC Book 1 op cit note 11 Preface.

¹⁴ Act 61 of 2003. This section has not yet been proclaimed for want of its accompanying regulations.

¹⁵ Section 71(2) and (3).

¹⁶ See below.

¹⁷ Section 71(3)(a)(ii) and (iii). Strictly speaking, the *permission* of a parent or guardian should be sought since ‘consent’ is inherently personal.

¹⁸ Section 71(3)(b)(ii).

¹⁹ See Medical Research Council of South Africa (MRC) (2004) Book 5: HIV Preventive Vaccine Research (hereafter MRC Book 5) at 2: ‘The current document aims to present aspirational guidelines for the conduct of HIV vaccine trials.’

²⁰ See MRC Book 1 op cit note 11 point 5.3.1.2.1: ‘Therapeutic research. . . may be undertaken with the consent of a minor over the age of 14 years. . .’; MRC Book 5 op cit note 19 point 18.7.2 and 18.7.2.1; Van Wyk op cit note 7 at 41; Strode et al op cit note 6 at 227.

²¹ See Health Professions Council of South Africa (HPCSA) Guidelines for Good Practice in Medicine, Dentistry and the Medical Sciences (2002) Booklet 15: Seeking Patients’ Consent: the Ethical Considerations para 6.4.1(a) ‘at age 16, a young person can be treated as an adult and can be presumed to have capacity to decide. . .’. Note that, although these guidelines pertain to medical treatment rather than research, their influence on researchers who are also physicians is considerable. See also ‘Girls bunk school to cash in on HIV trials’ *Sunday Times* 13 November 2005 where it is reported that the Medicines Control Council gave ‘approval to conduct the study in women over 16 years without parental consent because they recognized that the younger age group was the most vulnerable to contracting HIV/Aids’. The latter council is not an ethics committee: Its remit is to enforce the regulation of medicines, including those which are experimental and thus unregistered for general use. Its expertise is thus in the scientific and pharmacological spheres rather than in ethics.

²² See MRC Book 1 op cit note 11 point 5.3.1.2.1. International research ethics guidelines require that capacity to give informed consent follows the applicable national law. See e.g. CIOMS (2002) op cit note 8 guideline 14.

²³ The parliamentary process in respect of the passage of the Children’s Act has exacerbated the confusion. Publicity given to the approval of the Bill last December led many to believe that the age of majority was henceforth 18 years; that the Act will not come into force until at least 2008, when the other part of the Bill is due to be put before Parliament, was not given sufficient publicity.

condition'.²⁴ In essence, classing research as 'therapeutic' is based on the hope that the desired potential benefit will materialize, rather than that a known direct benefit will materialize. 'Non-therapeutic' research, on the other hand, has no potential for direct benefit for the participant and is aimed at the acquisition of generalizable knowledge. Classification of research as 'therapeutic' or 'non-therapeutic' is ethically unsound, since it fails to acknowledge that all research involves some 'non-therapeutic' interventions and also it fails to distinguish between the probability of harm occurring and the magnitude of the harm itself if it does occur. HIV preventive research is, in principle, 'non-therapeutic' since participants are HIV negative at enrolment. To regard prevention as 'therapeutic' in the circumstances is to stretch the concept inappropriately and leads to conflation of the requirements for consent to medical treatment and for research participation.

Differences between medical treatment and health care research

The tendency to regard research that includes a direct benefit for (some) participants ('therapeutic' research) as analogous to treatment is unsound. It blurs important distinctions between the two enterprises.

One such distinction affects the relationship between the clinician and the patient. In the treatment context, this relationship is directed towards making the sick patient better. The relationship between a researcher and a research participant has a different goal, namely, the acquisition of generalizable knowledge. By definition there can be no individually orientated goal of improving the participant's own well-being. This is because scientific research requires that the protocol be followed exactly in order to ensure lack of bias, scientific integrity in the analysis of and reproducibility of results. It should be noted, however, that an individual participant may not be mistreated, exploited or otherwise unfairly disadvantaged, as this would make the research unethical. It is regrettable, therefore, that the National Health Act has retained the categorization of research as either 'therapeutic' or 'non-therapeutic' in relation to minors and that it fails to define either term.²⁵ Whole projects cannot be classified properly into these categories, since by definition both types include interventions that are beneficial and those that are non-beneficial as part of the scientific approach to acquisition of knowledge. The legislation should direct the focus to what is in the best interests of the minor in so far as the beneficial and non-beneficial interventions involved in the research are concerned. Instead it draws the focus to classification of the particular research project as either therapeutic or non-therapeutic.²⁶

²⁴ See e.g. MRC Book 1 op cit note 11 par 2.1.2.1.

²⁵ This categorization has been abandoned in CIOMS (2002) op cit note 8 and also the US Code of Federal Regulations. See also Ann Strode et al 'How well does South Africa's National Health Act regulate research involving children?' (2005) 95 *South African Medical Journal* 265 at 267.

²⁶ See also Catherine Slack & Mariana Kruger 'The South African Medical Research Council's *Guidelines on Ethics for Medical Research* – Implications for HIV-preventive vaccine trials with children' (2005) 95 *South African Medical Journal* 269 at 271.

In HIV preventive research, the potential participants are not HIV patients, since by definition they must be free from HIV infection in order to participate. In the case of microbicide trials, the potential participants are likely to suffer from a sexually transmitted infection (for which they are seeking treatment), but they must be HIV negative. Some researchers argue, however, that, because the minor may consent independently to necessary treatment for her sexually transmitted infection, the fact that the medication is dispensed in a research context should not make any difference. But treatment for sexually transmitted infections is available and is not dependent on participation in a trial. It is unclear that the public interest would be served better if ethics committees were to accept this justification for permitting minors to participate in the research, without the knowledge and permission of their parents or guardian, so that they can receive treatment at the same time.

Furthermore, it would be anomalous to require parental or a guardian's permission for enrolment in HIV vaccine trials but not for microbicide trials. This could happen if an ethics committee classified a microbicide trial as 'therapeutic' but a HIV vaccine trial as 'non-therapeutic'. Risky sexual behaviour is inherent to the design of both types of research, but parental permission would be required for only one type. The failure to distinguish treatment from research, as well as the arbitrary designation of research as 'therapeutic' or 'non-therapeutic', is not in the best interests of minors. Society's primary obligation towards minors is to provide protection, and it should do so even-handedly, which means that anomalies like these must be avoided.

A particularly thorny problem is the minor who is orphaned or living in a child-headed household.²⁷ Frequently, researchers indicate that these minors are particularly vulnerable to infection with HIV and should be studied. They use the impossibility of obtaining parental or guardian consent to justify independent consent by the minor. This argument is seductive but dangerous: it completely ignores the reason for the status of minority, namely, to protect minors. The situation does not properly involve impossibility of obtaining consent. It is true that parents or guardians may not exist or be inaccessible, but this does not prevent the High Court from being seized with the matter as upper guardian in appropriate cases. It can never be argued that it is *necessary* for an individual to participate in research, but it may be in her best interests in particular circumstances. In the absence of parental or guardian guidance on the matter, the High Court is the appropriate arbiter of the best interests of the minor.

²⁷ The situations are not necessarily synonymous: The minor may be living with relatives while her parents live and work elsewhere; she may have run away from home; or in fact she may be (maternally) orphaned. The sad reality for many minors is that they do not know who their fathers are.

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 generally do 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.²⁸

Who are minors? Article 1 of the United Nations Convention on the Rights of the Child (UNCRC)²⁹ 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 Africa, majority is attained at 21 years,³⁰ notwithstanding that the Constitution provides that a child is someone younger than 18 years.³¹ This means that, generally speaking, the permission of a parent or guardian should be required for the minor to participate in research as part of the parent’s responsibility and duty to protect the interests of the minor. This position is supported by the wording in the National Health Act which refers to minors rather than children in the relevant provision.³²

In the HIV/AIDS context, however, the apparently important distinction between childhood and adulthood is blurred by the age categories used to report and publish statistics. UNAIDS, the World Health Organization (WHO), the World Bank and other agencies distinguish children from adults at 15 years in their reports. Thus anyone who is 15 and older is counted as adult when incidence, prevalence, or death statistics relating to HIV/AIDS are published. No mention is made of majority or adolescents. Yet international instruments like the United Nations Convention on the Rights of the Child (UNCRC) and other conventions differentiate between children and adults at 18 years, while national law stipulates the age at which majority is attained. To confuse matters further, research proposals focus on participants designated children, adolescents or adults.

²⁸ See e.g. Barnett & Whiteside op cit note 1 at 331.

²⁹ Ratified by South Africa in June 1995.

³⁰ In terms of s 1 of the Age of Majority Act 57 of 1972, which was not repealed by the Constitution.

³¹ The Constitution of the Republic of South Africa Act 108 of 1996 s 28(3). The Children’s Act 38 of 2005 (not yet in effect) repeals, amongst others, the Age of Majority Act and changes the age of majority to 18 years.

³² See s 71.

Who are adolescents? The United States of America regards adolescents as young people between 14 and 18 years.³³ The assumption appears to be that these are young people who have reached puberty but are not yet adult, majority being achieved at 18 years. Adolescents retain their status as minors, therefore, which means they do not have full legal capacity and cannot give informed consent. One could infer similarly, therefore, that South African adolescents are aged between 14 and 18 years,³⁴ but majority is attained only at 21 years. In terms of international law, the distinction between children and adults is explicit and particular obligations are imposed on states vis-à-vis children.

International and constitutional protection for minors

The United Nations Convention on the Rights of the Child (UNCRC)³⁵ decrees that the best interests of the child must be a primary consideration in all matters concerning the child.³⁶ The responsibilities, rights and duties of parents must be respected.³⁷ The child is entitled to 'the highest attainable standard of health'.³⁸ From the perspective of an ethics committee, these rights and obligations appear to indicate that parental responsibility for protection of the interests of a minor should not be overridden lightly. Article 34 requires prevention of 'inducement or coercion of a child to engage in unlawful sexual activity'. A South African minor under the age of 16 who engages in sexual activity, whether willingly or not, does so unlawfully since she is legally unable to consent thereto.³⁹ That she should engage in sexual activity that exposes her to risk of fatal infection, makes manifest that her best interests are not served by the developmental limitations to her ability to assess risk and to make good choices. These limitations are of course the very basis for the legal status of minority which recognizes the incremental nature of maturation from child to adult. Ethics committees should therefore guard against being seen to facilitate potentially harmful research in the name of science.

The African [Banjul] Charter on Human and Peoples' Rights⁴⁰ 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'.⁴¹ Should an ethics committee class HIV preventive research as 'therapeutic' and hence also permit minors to consent independently, necessarily and inevitably families will be under-

³³ See eg Rhonda G Hartman 'Coming of age: Devising legislation for adolescent medical decision-making' (2002) 28 *American Journal of Law and Medicine* 409.

³⁴ See, however, Strode et al op cit note 6 at 225 who regard adolescents as persons between 13 and 18 years of age.

³⁵ Ratified by South Africa in June 1995.

³⁶ UNCRC Article 3.

³⁷ UNCRC Article 5.

³⁸ UNCRC Article 24.

³⁹ The Sexual Offences Act 23 of 1957 s 14.

⁴⁰ Ratified by South Africa in June 1996.

⁴¹ African Charter on Human and People's Rights Article 18.

mined. Those with parental responsibility will not even know of their children's involvement. Is this in accordance with the obligation of the state to assist families? Independent consent is compatible with the dominant approach that emphasizes autonomy above other values. But minors are legally not (fully) autonomous and they are members of families, whether the latter are dysfunctional or not. States are obliged to assist families, not make them more fragmented.

South African children's rights are set out in s 28 of the Constitution⁴² which stipulates that the best interests of the child⁴³ 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 concomitant responsibility to provide family and parental care. While clearly it is not within the remit of an ethics committee to provide such care, arguably it is obliged to insist that parents or guardians be given the opportunity to carry out their responsibility to provide parental care. In the HIV context, given its primary vehicle of transmission, such responsibility includes parental responsibility for counselling their children about the risks attendant on early initiation of sexual activity and unsafe sex more generally. It goes without saying that, in order to carry out their responsibility, parents and guardians themselves need to be properly informed with accurate and comprehensive information, something that unfortunately cannot be relied on currently, especially in relation to HIV/AIDS.

The Children's Act⁴⁴ seeks to modernize 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 Act.⁴⁵ Particularly relevant to this discussion are those provisions that seek to foster family care and encourage parental responsibility,⁴⁶ and to ensure that the best interests of the child are considered.⁴⁷ Thus, the Act 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.⁴⁸ 'Best interests' include the need for a 'stable family environment'.⁴⁹ In addition, the person 'who has parental responsibilities. . . must be informed of the action or decision which significantly affects the child'.⁵⁰ Who should determine what is in a particular child's best interests is not specified. That enrolment as a participant in HIV preventive research involves a decision that significantly affects the minor should be obvious, especially to the researchers and ethics committees.

⁴² Constitution of the Republic of South Africa, 1996.

⁴³ Persons under 18 years of age in terms of s 28(3) of the Constitution.

⁴⁴ Act 38 of 2005 (not yet in effect).

⁴⁵ See s 2, which sets out the 'Objects of the Act'.

⁴⁶ Section 2(b)(i).

⁴⁷ Section 2(b)(iv).

⁴⁸ Section 6(3).

⁴⁹ In terms of s 7(1)(k).

⁵⁰ Section 6(5).

Statutory exceptions to protection of minors

Legal restrictions on minors' capacity to act are relaxed in some instances.⁵¹ For example, the provisions of the Choice on Termination of Pregnancy Act⁵² and the Child Care Act⁵³ create exceptions to the rule that a minor cannot give informed consent by outlining specific circumscribed instances when a minor can give consent independently. The Child Care Act confers power on (but does not compel) minors to consent to medical treatment in two age categories, namely, those who are 18 years and older may consent to a surgical operation, while those who are 14 years and older may consent to medical treatment.⁵⁴ 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.⁵⁵ The Children's Act removes the distinction between medical treatment and surgical operation and changes the age at which a child may consent independently to 12 years, provided the child 'is of sufficient maturity and has the mental capacity to understand the benefits, risks, social and other implications of the treatment'.⁵⁶ Similarly, the Human Tissue Act⁵⁷ permits blood donation by minors from age 14; the National Contraception Policy of 2001 permits children of any age to approach a clinic for sexual and reproductive health information and condoms. Girls must be at least 14 years, however, to be supplied with oral contraceptives without their parents' knowledge or permission. The Wills Act⁵⁸ permits a minor to make a will at age 16 and to witness a testator's signature at age 14. The Sexual Offences Act⁵⁹ stipulates that sex with a minor under the age of 16 is a criminal offence.

The existence of these and other exceptions is often used to support 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,⁶⁰ in terms of the Choice on Termination of Pregnancy Act, is regarded widely as a justification for permitting minors to consent independently to participa-

⁵¹ Emancipation (i.e. attaining majority before the age of 21 years) is not dealt with here.

⁵² Act 92 of 1996.

⁵³ Act 74 of 1983. This Act will be repealed when the Children's Act comes into effect, but the latter includes (changed) provisions regarding minors and consent to medical treatment.

⁵⁴ Section 39(4).

⁵⁵ See Belinda van Heerden, Alfred Cockrell & Raylene Keightley *Bobeg's Law of Persons and the Family 2* ed (1999) 253n58.

⁵⁶ Section 129(2) of the Children's Act. Specific provisions govern also HIV testing, consent thereto, confidentiality of result, and access to contraceptives: see ss 130–4. Who should judge whether 'sufficient maturity' exists and on what basis are not stipulated.

⁵⁷ Act 65 of 1983.

⁵⁸ Act 7 of 1953 s 4.

⁵⁹ Act 23 of 1957 s 14.

⁶⁰ The Choice on Termination of Pregnancy Act 92 of 1996 permits abortion on demand for any pregnant female. In *Christian Lawyers Association v Minister of Health (Reproductive Health Alliance as Amicus Curiae)* 2005 (1) SA 509 (T), the Pretoria High Court held that girls under 18 years need not have parental consent for an abortion.

tion in research into sexual activity. Access to minors is relatively easily achieved through schools which are requested to permit researchers to provide information preparatory to recruitment. Parents are not necessarily informed of these activities at school. It was ironic, therefore, to learn that the Western Cape Education Department requires express permission from parents or guardians before learners' hair may be examined for the presence of head lice,⁶¹ while schools in other provinces appear to have permitted information sessions and perhaps even recruitment for microbicide clinical trials without notification to parents or guardians.⁶²

Arguably, the tensions between acknowledging the minor's autonomy in relation to medical treatment and the need for protection in regard to research participation will be heightened even more when the Children's Act comes into effect and the age for independent consent to treatment is 12 years. However, it remains true that when a statute confers power on a minor to act in particular circumstances, it does not alter the minor's status for all purposes. It is especially important, thus, that the requirements for medical treatment and research participation are not conflated so as to blur the distinctions. The statutory exceptions that permit a minor to consent independently to medical treatment before attaining majority should not apply *mutandis mutandi* to independent consent to research participation without clarity on the justification therefor. Balancing the minor's autonomy against society's interest in the protection of minors, on the one hand, and in scientific advancement in the war against HIV, on the other, requires careful consideration of complex issues.

Individual versus societal interests

That a minor is permitted legally to seek medical treatment and to consent thereto flows from society's recognition of the developing maturation of the minor and her capacity to make decisions that best serve her interests, including her need for privacy, in so far as medical care is concerned. Medical treatment is focussed on serving the individual's best interests within the available resources. Thus the minor's rights to privacy, to dignity, to access health care and so on are acknowledged by the relaxation of the restrictions otherwise placed on minors' capacity to perform legal acts.

In the research context, however, it is society's interests that are served primarily rather than the interests of individuals. It is not plausible, therefore, to argue that it is *necessary* for someone to participate in research for her own well-being. Research participation relies heavily on charitable or altruistic motivations, albeit often coloured by desperation in the case of particularly sick patients for whom little other hope remains.⁶³ While it is true that research with minors is necessary in order to serve their treatment interests

⁶¹ Personal communication from parent of primary school learner November 2005.

⁶² See *Sunday Times* 13 November 2005 op cit note 22.

⁶³ Very sick patients are also regarded as especially vulnerable participants and thus research involving them requires very careful scrutiny.

better, for example by ensuring that medicines have actually been tested on minors rather than only on adult populations, it is doubtful that such research should be authorized without giving very careful consideration to all the complexities involved.

A minor is not solely autonomous, but is also a member of a family. In line with the international and national instruments (discussed above) that seek to foster family units, a balancing of interests must occur: the individual interest of the minor, the collective interest of the family and the interest of the community or society at large must all receive consideration. 'An overemphasis on individual rights may result in the dilution of the interests of the family, which are then accorded inadequate attention.'⁶⁴ In considering whether minors should participate in HIV preventive research and, if so, whether they should be permitted to consent independently, the preliminary question is, therefore, whether the individual minor's interests ought to be subjugated to society's interest in furthering knowledge about HIV and its transmission.

Development of a preventive HIV vaccine is important to curb the further spread of the virus. Similarly, finding out whether microbicides do in fact diminish the likelihood of HIV infection should have high priority. Other preventive methods, including education aimed at behaviour and attitude change, are said to be failing to curb the spread of the virus.⁶⁵ UNAIDS, amongst other agencies, regards the involvement of young people, including minors, in research to test candidate HIV vaccines as necessary.⁶⁶

In democratic South Africa, such matters ought to be debated in the public arena, rather than left to individual ethics committees to decide, especially when medical opinion tends to regard medical treatment and 'therapeutic' research as synonymous, a view that influences committee deliberations. In principle, an ethics committee would seem to 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 and thus to waive the requirement of parental or a guardian's permission.

Consent by minors to health care research

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 Children's Act does not include specific provisions for health care research, providing merely that every child who is capable of doing so is entitled to participate in any matter concerning that child.⁶⁷ By implication, the National Health Act⁶⁸ governs all health care

⁶⁴ Brigitte Clark 'My right to refuse or consent': The meaning of consent in relation to children and medical treatment' (2001) 64 *THRHR* 605 at 617.

⁶⁵ See e.g. Campbell op cit note 1 ch 7 and 8.

⁶⁶ See UNAIDS Guidance Document (2000) guidance point 18: Children; see also <http://www.saavi.org.za/challenges.htm> (last accessed 27 May 2004); MRC Book 5 op cit note 19 point 18: Children.

⁶⁷ Section 10 of the Children's Act.

research. Reference to ‘minors’ rather than ‘children’ in the subsections of s 71⁶⁹ that deal with research and minors, seems to indicate a deliberate and material focus on the legal status of young persons. This points clearly to the difference between consent to participation in research, on the one hand, and consent to medical treatment, governed by the Children’s Act which refers to ‘child’ in s 129, on the other.

Current opinions, however, draw parallels between the fact that minors can consent independently to medical treatment and the view that ‘therapeutic’ research⁷⁰ is tantamount to medical treatment and conclude that minors are able to consent independently to ‘therapeutic’ research participation.⁷¹ Ethics guidelines generally stipulate that clinical trials are regarded as ‘non-therapeutic’ to ensure that more stringent scrutiny of proposals is required. Some commentators speculate, however, that ethics committees might regard a HIV vaccine trial as ‘therapeutic’ and thus make the consent requirements less stringent.⁷² As will be discussed below, such parallels are dubious, particularly in regard to HIV preventive research and are probably not in the best interests of minors. For HIV preventive research, participants have to be HIV negative and not pregnant. This means that none of the minors would be seeking medical treatment for HIV at the time of recruitment to a candidate vaccine trial, which therefore precludes an analogy between medical treatment and ‘therapeutic’ research. In the case of a microbicide trial, the minor is probably seeking treatment for a sexually transmitted infection.⁷³

Requirements for ethical research

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)(c), which provides that ‘everyone has the right not to be subjected to medical or scientific experiments without their informed consent’.⁷⁴ But this does not mean that obtaining informed consent is sufficient. Informed consent is a necessary but insufficient requirement for ethical research. Various other equally necessary requirements must be complied with. The ethical responsibility of the ethics committee, therefore, includes ascertaining that the proposed research is

⁶⁸ Act 61 of 2003.

⁶⁹ One subsection (s 71(2)(c)) refers to ‘child’: ‘with the consent of the parent or guardian of the child’, which has led some commentators to infer that ‘minor’ and ‘child’ are used interchangeably. See e.g. Strode et al op cit note 25 at 267.

⁷⁰ That which confers a direct benefit on the research participant.

⁷¹ See e.g. Van Wyk op cit note 7.

⁷² See MRC Book 5 op cit note 19 point 18.7.2.1.

⁷³ The hypothesis for such a trial is that the microbicide diminishes the vulnerability to HIV infection of the young woman currently infected with a different sexually transmitted infection (STI). It is fairly well established that the presence of STIs increases female vulnerability to HIV infection.

⁷⁴ Constitution of the Republic of South Africa, 1996.

scientifically sound,⁷⁵ that participants give informed consent to participation, that the harm/benefit ratio is favourable to participants,⁷⁶ that the research will benefit the host community⁷⁷ and, when minors are to be involved, that their best interests are served.⁷⁸ Research must also be lawful in order to be ethical. Thus the ethics committee is also obligated to know and work within the legal framework, which includes the various international instruments ratified by South Africa. The composition of ethics committees requires at least one legally trained person, who should be well acquainted with the relevant law, especially that concerning minors.

Waiver of requirement for parental or guardian permission

Sometimes circumstances are such that the requirement of informed consent prior to enrolment may be waived when the benefit of doing the research (societal interest) outweighs the individual's right to choose whether to participate. These circumstances are outlined in the ethics guidelines. Minority is not listed amongst them. Waiver of the requirement of informed consent is 'uncommon and exceptional' and must always have been approved explicitly by an ethics committee.⁷⁹ Are the circumstances surrounding South African adolescent sexual activity 'exceptional' so as to justify ethics committee waiver of parental permission? A major difficulty is the lack of legal clarity which flows partly from the fact that the distinction between the capacity to understand (linked to maturity) and legal competence is not adequately explained in either common law or legislation. Properly construed, informed consent requires both capacity and legal competence,⁸⁰ which is why minors must be assisted by parents or guardians. In their absence, the High Court is upper guardian. Apart from very specific exceptions – such as in emergency medical interventions – nobody else is empowered to override these protections. In particular, research ethics committees are not so empowered. Furthermore, considering the express requirement of informed consent in the National Health Act together with circumstances outlined in the CIOMS guidelines where exceptions to the requirement of informed consent are discussed,⁸¹ the conclusion must be that a South African ethics committee would be hard-pressed to justify a decision to approve independent consent by minors without better evidence that this would be legally tolerable. While convenience and expediency may

⁷⁵ Scientifically unsound or invalid research is unethical.

⁷⁶ See below for a discussion of the assessment of risk of harm and benefit in relation to minors.

⁷⁷ Recent developments in international research ethics pay particular attention to the avoidance of the perception of exploitation of vulnerable communities in developing countries.

⁷⁸ Section 28(2) of the Constitution provides that 'a child's best interests are of paramount importance in every matter concerning the child'.

⁷⁹ See CIOMS (2002) op cit note 8 guideline 4; anticipated circumstances include acute incapacity to consent (e.g. in emergency or trauma conditions) or where medical records are sought to be audited anonymously.

⁸⁰ See *Castell v De Greef* 1994 (4) SA 408 (C) 425, where the requirements for informed consent are set out.

⁸¹ See commentary to CIOMS (2002) op cit note 8 guidelines 4 & 6.

be served by permitting such independent consent, it is not clear that a minor's best interests are served. An ethics committee should thus act to protect minors before it bows to other pressures.

PARTICULAR ASPECTS OF MINORS' PARTICIPATION IN RESEARCH

Participation is directly relevant to minors

The general ethical rule is that minors should participate in health care research, especially clinical trials, only if their participation is indispensable, that is, if the research could not be done as effectively in an adult population.⁸² Thus far, Phase I trials⁸³ have tested candidate HIV vaccines with healthy adult research participants. Strict regulation of recruitment of participants for these trials was accepted as necessary, given the experimental nature of the research. For example, in South Africa one of the requirements is that 12 years of schooling have been completed to ensure that the individual has adequate general education and knowledge to properly assess the merits of participation or not. Necessarily, minors under 18 years are unlikely to have completed 12 years of schooling. Recent reports in the media indicate that current HIV preventive research in South Africa includes microbicide studies and Phase II HIV vaccine studies and that participants include or are intended to include minors. The justification includes urgency in light of the escalating infection rate and the dearth of knowledge about HIV in young people.⁸⁴ Usually clinical drug trials are conducted with minors only when Phase II trials with adults have provided a reasonable probability of safety and effectiveness of the drug under investigation. To conduct Phase II trials with minors concurrently with the adult trials is thus controversial.

Phase II trials usually are controlled, randomized and blinded, i.e. they will be conducted with at least two arms: participants in one arm receive the drug

⁸² See CIOMS (2002) op cit note 8 guideline 14; Declaration of Helsinki point 24; DOH (2004) op cit note 8 point 5.1; MRC Book 5 op cit note 19 point 18.4.

⁸³ See CIOMS (2002) op cit note 8 Appendix 3: Vaccine development trials go through at least three phases: A Phase I trial is when the candidate vaccine is tested first on a relatively small number of human volunteers for initial determination of its safety and biological effects, including immunogenicity. Phase II trials test effectiveness (efficacy) and immunogenicity in a larger number of volunteers, while Phase III trials test more comprehensively in multi-centre controlled studies for safety and effectiveness in the prevention of the disease. Needless to say, all the volunteers are free from the disease for which the vaccine is sought. See also MRC Book 5 op cit note 19 point 8. Drug development trials also go through phases: A Phase I trial tests the drug on healthy volunteers to establish the levels at which toxicity is observed; further studies test for safety and effectiveness. Phase II trials (controlled) are conducted on relatively small numbers of patients to demonstrate effectiveness and relative safety. Phase III trials take place only after 'a reasonable probability of effectiveness of a drug has been established' to determine specific indications and drug-related adverse effects. Such trials may be controlled or uncontrolled. A controlled trial is one that has at least two arms, one of which gets the drug and the other a placebo.

⁸⁴ See e.g. Jerome Amir Singh et al 'Enrolling adolescents in research on HIV and other sensitive issues: Lessons from South Africa' (2006) 3 *Public Library of Science: Medicine* available at <http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0030180> (last accessed on 23 February 2007).

under investigation and the participants in the other receive a placebo.⁸⁵ Distribution of individuals to the two arms is random and usually double-blinded, ie neither the researcher nor the participant knows to which arm she is randomized. In a microbicide or candidate vaccine trial, therefore, some participants are not given the drug under investigation. All participants are counselled to practice safe sex using condoms as part of the pre-enrolment informed consent process. However, the design of such a trial – in accordance with standard scientific principles – requires that the participants actually do practice unsafe sex, at least sometimes. The hypothesis cannot be proven otherwise. The bald implication is that certain numbers of minors are expected to become infected with HIV and thus would be ‘sacrificed’ to the greater cause of generating knowledge about transmission of HIV in the presence or absence of the microbicide or of the candidate vaccine.⁸⁶ A decision to classify such a protocol as ‘therapeutic’ and thence to permit the minor to consent independently would be questionable. The MRC HIV Preventive Vaccine Research guidelines stipulate that ‘enrolment of children in HIV vaccine research. . . requires informed consent from a parent or legal guardian, and assent from the child, according to his or her evolving capabilities’.⁸⁷ However, speculative mention is made of the fact that an ethics committee could classify ‘an entire HIV vaccine trial protocol as “therapeutic research”’, in which case ‘it is possible that independent consent for participation could be secured from children who are 14 years and older’.⁸⁸ Evidence exists that ‘clinical trials’, ‘research’, ‘randomization’ and ‘placebo’ are poorly understood by lay persons.⁸⁹ The problem is exacerbated in contexts where English is not the first language of participants and the vernacular does not include similar terminology. It is imperative that potential participants should understand properly that they might not get any drug, that the drug they might get may do nothing to prevent transmission of the virus, that the medium to long term effects of the drug are as yet unknown. Proper understanding of all of this is a tall order for a hormonally challenged 14 year old!

Acceptable risks of harm versus likelihood of direct benefit

In principle, only research that will directly benefit the minor participant causing no more than minimal risk of harm⁹⁰ is permitted. Minimal risk of

⁸⁵ An inert substance packaged to closely resemble the investigative drug.

⁸⁶ Were the minor to become infected with HIV, the impact on her and her family is self-evident. Note that it is not possible to become infected by a candidate vaccine since live-attenuated vaccines are not under investigation. However, condom failure and unsafe sex generally could result in infection, especially if the participant does not fully understand that the microbicide or candidate vaccine is not proven to prevent infection.

⁸⁷ MRC Book 5 op cit note 19 point 18.7.1.1.

⁸⁸ Ibid point 18.7.2.1.

⁸⁹ See Richard E Ashcroft et al ‘Implications of socio-cultural contexts for the ethics of clinical trials’ (1997) Health Technology Assessment 1997; 1 (9) available at <http://www.nchta.org/fullmono/mon109.pdf> (last accessed 15 November 2005).

⁹⁰ Some guidelines refer to ‘negligible risk’. Rather confusingly, the National Health Act s 71(3)(b)(iv) uses the term ‘significant risk’ which is not defined; it is also not used in any research ethics guidelines.

harm is that which is 'no more likely and no greater than the risk attached to routine medical or psychological examination of children',⁹¹ or the risk 'commensurate with daily life'.⁹²

Commonly, the approach is to assess all of the risks of the research together with all of the potential benefits and, if the risks are thought to be reasonable in relation to the potential benefits, then the risks are found to be justified. This approach is flawed, however, as it fails to distinguish between the two types of risk of harm. The better approach is to analyse risk of harm in terms of the two types.⁹³ Some interventions are included only to obtain generalizable knowledge, rather than to benefit the person. Risks of harm from such interventions must be the smallest possible ('minimal' or 'negligible')⁹⁴ in the circumstances. Other interventions are part of standard treatment. Risks of harm from these interventions in respect of both probability and magnitude will vary according to the specific context. For example, some treatments present considerable risk of serious harm but this is regarded as acceptable in the circumstances.

Thus participation by minors would be appropriate if the risk of harm posed by the components of the research that do not offer potential benefits for the participants is small in probability and the magnitude of the harm could be no more than the smallest possible amount ('minimal') and there is clear justification for their involvement based on the importance of the knowledge to be gained. In respect of HIV preventive research, the risks of harm include 'discomfort from vaccine administration; unknown risks related to the vaccine product itself; the potential for testing false-positive on standard HIV tests; anxiety and discomfort from intrusive questions relating to risk behaviour; stress from repeated HIV testing; discomfort from blood draws for a range of tests; and potential for stigma or discrimination should participation be disclosed'.⁹⁵ Furthermore, given the possibility of being randomized to the placebo arm and the likelihood of continued risky sexual behaviour, it is probable that some participants will become infected with HIV notwithstanding the mandatory counselling to practise safe sex as a result of for example broken condoms. Regarding the candidate vaccine, much is still to be learned, such as whether it makes the person more vulnerable to later infection and less responsive to currently available anti-retroviral treatment. It is thus doubtful that these risks of harm can properly be seen as 'minimal'.

⁹¹ MRC Book 5 op cit note 19 point 18.6.1.

⁹² DOH (2004) op cit note 8 point 5.2.

⁹³ Described as component analysis; see Charles Weijer 'The ethical analysis of risk' (2000) 28 *Journal of Law, Medicine and Ethics* 344.

⁹⁴ MRC (2002) 9.12.4.3 uses 'negligible risk' to mean the 'probability and magnitude of physical or psychological harm that is normally encountered in the daily lives of people in a stable society or in the routine performance of physical or psychological examination or test'; 'minimal risk' can exist in two situations – an expected but trivial reaction to an intervention (mild headache or feeling of lethargy) and a very remote chance of serious injury or death (comparable to being a passenger in a scheduled aircraft). Other South African guidelines are unhelpful, stating in broad terms only, that 'a risk/benefit analysis should precede the research itself' (see DOH (2004) op cit note 8 and DOH (2000) op cit note 11).

⁹⁵ Strode et al op cit note 6 at 225.

During the course of the trial, participants would be carefully monitored and provided with valuable educative information, which may be the only direct benefits. However, after the trial is over, if they have been permitted to consent independently, the minors will be dependent on their own initiative, probably without familial support.

Scientific validity

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 even 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'.⁹⁶ On the other hand, the hope is that the current candidate vaccines will 'act. . . by reducing viral loads, hence reducing both transmission to sexual partners and progression to AIDS'.⁹⁷ Competing commercial interests and political pressure make it difficult sometimes for ethics committees to assess the scientific validity of proposed clinical research⁹⁸ in the climate of urgency created by the horrific statistics that are proffered time and again. These disputes and conflicts should not be ignored by ethics committees when deliberating about including minors in early phase clinical trials.

Confidentiality

A strong argument for permitting minors to give independent consent to research participation flows from the requirement that participants must be assured that their personal medical information is confidential. This means, for example that HIV test results may not be disclosed to any outsiders, including parents and sexual partners, unless authorized by the participant. However, the Prevention of Family Violence Act⁹⁹ imposes on health care workers, teachers and others the obligation to report suspicion of ill-treatment or injury of a child. This obligation impacts directly on assurances regarding confidentiality, in so far as minors under 16 years cannot in law consent to sexual activity and (suspicion of) statutory rape has to be reported.

⁹⁶ See Patterson *op cit* note 3.

⁹⁷ Singh *et al op cit* note 84.

⁹⁸ See e.g. Dennis R. Burton *et al* 'Sound rationale needed for Phase III HIV-1 vaccine trials' (2004) 303 *Science* 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.

⁹⁹ Act 33 of 1993, s 4.

The social context of HIV preventive research

That HIV/AIDS is more than a disease is clear from social research,¹⁰⁰ which indicates that the presence of risk environments¹⁰¹ fosters the spread of the virus. Such environments include lack of social and economic infrastructure, inadequate resources, poverty and unemployment, gender inequality, sexual identity stereotyping, misinformation about the virus, dysfunctional families, poor communication between parents and children, and the impact of orphanhood. It is in these environments that minors, especially female adolescents, are making unassisted decisions about risky sexual behaviour. Furthermore, that the virus is spread primarily at an intimate individual contact level, that is, through sexual intercourse, exacerbates the matter, since it may be a taboo subject for discussion and hence for intervention. Generally, sexual activity is regarded as a private matter and it is argued by many that this attitude should apply also to minors. While this argument is plausible in so far as minors who seek medical *treatment* are concerned, the same is not true of their participation in research, which enterprise has a wholly different primary endpoint. Individual care and treatment is the endpoint of medical treatment, while acquisition of generalizable knowledge is the endpoint of research, which by definition excludes care directed primarily to the best interests of the individual.

The different response to HIV/AIDS, particularly at policy-making levels, compared with the response to 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 that require urgent intervention despite the potential for violation of individual human rights.¹⁰² For example, the speed of transmission of the SARS virus as well as the rapid progression from infection to death was such that individual human rights were barely a consideration. That transmission of the virus did not involve any act, let alone a sexual act, on the part of the person who became infected may be significant in so far as a normative judgment of that person's behaviour was not possible. On the other hand, the history of the development of the HIV pandemic demonstrates that the primary transmission vehicle of the virus, namely, sexual intercourse, together with the relative slowness of progression from infection to death has made discussion of the disease and its context, policy development and appropriate

¹⁰⁰ 'The AIDS pandemic in Southern Africa is not only a major public health crisis but also a threat to economic development and social solidarity.' Nicoli Natrass *The Moral Economy of AIDS in South Africa* (2004) 1.

¹⁰¹ See Barnett & Whiteside *op cit* note 1 at 80–156.

¹⁰² Tuberculosis, Sudden Acute Respiratory Syndrome (SARS), Ebola Virus, Congo Fever, etc are all treated as public health matters. Infected individuals may be isolated, treated and, if they refuse treatment, even incarcerated to protect the rest of society. Recently a West Coast resident infected with multi-drug resistant tuberculosis (MDR TB) was incarcerated because she refused to take treatment and the rest of the community was at considerable risk of infection. Her right to refuse treatment was subjugated to the right of the community at large to avoid infection. Similarly, the emergence of extensively drug-resistant tuberculosis (XDR TB) has led to speculation that involuntary detention of infected persons may be necessary. The Gauteng Health Department won an interdict recently, in terms of which infectious patients were required to remain in hospital for the duration of their treatment.

interventions very difficult and contentious because of the (often unstated) normative assumptions and judgements that prevail.¹⁰³

Parental responsibility

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.¹⁰⁴ In general terms, young people engage in sexual activity secretly; that is, 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,¹⁰⁵ and that ‘one-half of [Johannesburg] high school students believe forced sex is not sexual violence’¹⁰⁶ make the task of assessing whether independent consent is appropriate even more difficult for ethics committees.

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. These sorts of evidence as well as statistics of teenage pregnancy, prevalence of HIV and other sexually transmitted infections seem persuasive and supportive of the view that minors should be participants in research. However, it is not clear that the interventions should exclude parents or guardians from the informed consent process. Unless the contrary is established, parents or guardians are presumed to be best able to determine what is in their child’s best interests.¹⁰⁷

Because of a general reluctance to talk openly about sex, however, South African 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, albeit unspoken, that young people experiment with sexual activity and a nebulous hope that they will come to no harm. Yet social science research shows that early initiation of sexual activity, teenage pregnancies and young parenthood impact significantly on families. Often the young woman is prevented from completing her schooling, which in turn has a direct and negative effect on her ability to provide for herself and her child. Add HIV to this historical data and the result is even more dire. All of this is already known. Literature from the abortion debates indicates that many women later express regret at not having shared their angst and grief in the family context. Yet South African

¹⁰³ Interestingly, though, other sexually transmitted infections like syphilis and gonorrhoea are public health matters and hence are notifiable infections, leading to contact tracing and treatment.

¹⁰⁴ See e.g. Kaiser Family Foundation *South African National Youth Survey 2000* (copy on file with author).

¹⁰⁵ See Campbell *op cit* note 1 at 129.

¹⁰⁶ Colleen Lowe Morna ‘Beijing betrayed?’ *Mail & Guardian* 4–10 March 2005.

¹⁰⁷ See *McCall v McCall* 1994 (3) SA 201 (C) at 204–5 for factors that should be considered in determining the best interests of a minor.

society seems set to continue to turn a blind eye to the (self-) destructive behaviour of its adolescent women.

When individual parents do try to intervene, they may find that the law prevents them from so intervening, as occurred in the well-known case of *Gillick v West Norfolk and Wisbech AHA*, which held that the Gillick teenage daughter was free to seek family planning advice and products (which would class as medical treatment) without her parent's consent or knowledge, given her level of maturity and understanding.¹⁰⁸ Put differently, the emphasis was placed on the individual human rights, particularly autonomy, of the maturing minor, thus overriding the public interest in her protection. The rationale was that the older the minor, the higher the probability of her increasing maturity and ability to exercise autonomy, and hence the need for her parents to relinquish control commensurately over her actions. The prevailing focus on (developing) autonomy as the cornerstone of informed consent underpins this rationale. However, the *Gillick* decision does not deal with the distinction between the minor independently seeking medical advice and treatment and her consenting to participate in research. Whether the court would have permitted Ms Gillick to consent independently to participation in HIV preventive research that included an HIV test and its concomitant implications is not known.

Possible reasons for requesting waiver of parental permission

Given the express requirement for parental or guardian consent for minors' participation in 'non-therapeutic' research in the National Health Act, why would researchers request a waiver of the requirement? One reason could be that the research would proceed more conveniently as far as ease of recruitment of young persons is concerned. The strongly held perception amongst researchers is that recruitment would be very difficult if parental permission were to be required. Schools and family planning clinics provide captive audiences to whom researchers can impart accurate and pertinent information about HIV/AIDS, which is an attractive feature. Whether empirical evidence exists that young people would actually refuse to participate if parental permission is required is not known.

A further reason could be that researchers are not equipped to manage the difficult process of communicating to parents or guardians that their minor children are sexually active and thus at high risk of infection. This is plausible in so far as the researchers are usually medical doctors and scientists, not social workers or counsellors. Research proposals seldom include social workers or counsellors as project staff. Another reason might be that the budget for the project would require additional resources if the preparatory phase of a study must be lengthened so that parental views can be canvassed.

¹⁰⁸ See *Gillick v West Norfolk and Wisbech AHA* [1986] AC 112, [1985] All ER 402, (1985) 2 BMLR 11 (HL). In this matter Mrs Gillick lost her claim that doctors could not lawfully give contraceptive advice to underage girls without parental consent.

A compromise position

In line with the general reluctance to talk openly about sex, it could be argued that parents do not want to know that their children are sexually active and that forcing them to deal with this fact would not be in the best interests of minors because of possible conflict and abuse that could ensue at home. This may be true at an individual level. For this reason, it may thus be more prudent find out whether a more generalized 'consent' is preferable to communities, one that avoids the need for direct individual confrontation with reality but nonetheless deals with the facts in a transparent manner. This could be achieved by requiring researchers to canvas opinion in a general way to establish local parental views on the matter of whether they would regard it as acceptable for minors in their community to consent independently to participation in research that investigates (risky) sexual activity and more particularly that seeks to test new drugs to prevent or contain the spread of HIV. In other words, the suggestion is that the communities in which the research is proposed should be consulted directly. This approach is the cornerstone of the preparation for the HIV vaccine trials.¹⁰⁹ In this way, communities can decide through an open and democratic process whether, in particular circumstances, both the best interests of minors as well as the public interest would best be served by permitting independent consent by minors. However, the community's decision would be insufficient by itself, since the ethics committee must still review each research proposal. But on the basis of the canvassed opinions, evidence-based policy can be drawn up to direct ethics committees in their work. Such a policy should dictate and outline the factors that must be considered in making the determination of whether in the circumstances the potential participants can consent independently. These factors should deal with how to assess the harm/benefit ratio in regard to HIV preventive research, the type and extent of supportive monitoring during the course of the trial that would be required, and the extent of community-based health care services that are available in the community concerned. Researchers should provide this information to ethics committees because it is crucial to the deliberations on whether there is sufficient justification to permit minors to consent independently in the circumstances.

Those who would complain that this suggestion places an unfair burden on researchers and their sponsors or that gathering information in this way is not medical research would do well to consider their own position. As a parent or as a person with affectionate ties to a teenager, would you be content to discover that your teenager has been engaging in unsafe sex and has enrolled in a clinical trial without your knowledge? Or would you prefer to know that teenagers from your community will be approached, that both you and they understand what the issues and implications are and thus that

¹⁰⁹ The South African AIDS Vaccine Initiative (SAAVI) has spent several years training community workers who consult with and prepare communities for possible participation in these trials.

you are reasonably confident that your teenager will be able to make a decision in a mature and considered manner?

In the current absence of a national policy, a framework to guide ethics committees is suggested according to which research proposals to involve minors can be assessed. The usual ethical requirements must be satisfied including that the researchers must persuade the ethics committee that the proposed research cannot be done as effectively with adult participants; and that it investigates a problem of particular relevance to an adolescent population. Particularly importantly, a full and clear justification must be provided for why the adolescent participants should consent independently and should include evidence gathered from the community concerned to indicate that parents, guardians and the community at large accept the tolerability of independent consent by minors. The cost of gathering this evidence must form part of the budget for the study. If the ethics committee is persuaded that such evidence exists and that the justification is otherwise sound, it should insist, nevertheless, that the research interventions that offer no direct benefit to the participants may impose no more than minimal risk of harm, that is, no more harm than is likely to be encountered in daily living. Furthermore, the ethics committee should impose rigorous on-going monitoring and review requirements to ensure that the best interests of minors are not compromised in the course of the study.

CONCLUSION

While it is obvious that only further research will expand current knowledge about HIV, using unassisted minors as research participants without acceptable justification is seriously questionable. Minority is an important legal construct that serves to protect vulnerable persons, notwithstanding that they often resent being limited in their actions. It is up to adults to remember why it is important to protect young persons, especially adolescent women, and to take responsibility for insisting that expediency and other pressures are not permitted to erode the available protection. International instruments like the UNCRC, the Constitution and various pieces of domestic legislation lay down the guiding principles according to which communities, including ethics committees, can protect their young people. Interpretation of these principles should be consonant with the spirit of the provisions, which means that, even though it may be awkward and discomfiting, greater participation of parents and guardians must be required in the decision-making that may allow minors to consent independently to clinical research participation; this despite the urgency of needing to find ways to curb the HI virus from further spreading amongst young people.