



The impact of HIV/AIDS on blood transfusion practice in South Africa: some ethical issues

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Blood transfusion has become an essential component of modern medical practice. However, worldwide epidemics of viral diseases – in particular, HIV/AIDS – have made the practice of blood transfusion therapy hazardous, motivating scientists to devise techniques and strategies to ensure the supply of safe blood and blood components for clinical use. The challenges are particularly great in sub-Saharan Africa, where clinicians have become so accustomed to using blood transfusion that it may be difficult for them to reduce their dependence on it. A number of ethical issues raised by the practice of blood transfusion in medicine are raised and discussed.

Historical background

Medical intervention involving blood is of some antiquity, though originally more likely to involve its voiding than its administration. Even towards the end of the 19th century, the removal of circulating blood from the body (blood-letting) was a recognised therapeutic practice, but as knowledge of the function of blood and its physiology developed and extended, so did the awareness that blood-letting was illogical, unnecessary, and more often than not deleterious, and it fell into disuse. Attempts to inject blood, both human and animal, into patients rather than to remove it had already been made, but the outcome was more often injurious rather than beneficial; only with the discovery of the ABO blood groups by Landsteiner did it come to be understood why these attempts had so frequently been catastrophically unsuccessful. Subsequently, it was gradually established that addition of the anticoagulant sodium citrate would prevent clotting without risk to the recipient, and that glucose would lengthen the survival of the red cells, and methods were devised for enabling the safe storage of blood from donors. Since donors were not invariably plentiful, it came to be accepted that the transfusion of whole blood was the treatment of choice for acute haemorrhage, but that shock due to blood loss called in the first place for restitution of blood volume by the transfusion of appropriate colloidal or crystalloidal preparations. Problems

involving the deficiency of a blood component were best solved by supplementation with that component. In many (if not most) cases, this would involve the administration of a product derived from the fractionation of donated blood.

Disease transmission

Quite early on in the history of blood transfusion, it was realised that diseases might be transmitted together with transfused blood, or a fraction, from a diseased donor; this often resulted in the destruction of diseased donations, while sometimes retaining one or more fractions for future use. In the past, the majority of such transmissions which were missed at the time of reception of the donation or during its subsequent testing, most likely comprised infections which could be treated fairly easily, or even ignored. Difficulties were first acknowledged in some tropical environments where viral diseases such as hepatitides were endemic, and only gradually became generally unmanageable with the emergence of HIV/AIDS as a global pandemic of prospectively interminable duration. For quite simple epidemiological reasons, the severity of the pandemic has varied greatly from one region to another, with Africa being especially affected. However contracted, the disease has been found to be readily transmissible through transfusion. In South Africa, one of the most advanced and prosperous countries of the continent, this fact is a major cause of concern, not only from the standpoint of public health but also from the effect on the practice of blood transfusion.

Many countries in sub-Saharan Africa have HIV-positive prevalence rates in adults of up to 30%. In most of these countries, blood transfusion services have collapsed; in those still boasting of a blood transfusion service, it is estimated that 5 - 10% of HIV-positive individuals have acquired the infection from blood transfusion – which is not surprising, since at least 25% of blood transfused in Africa is not screened for HIV.¹ Ironically, the main indication for blood transfusion in Botswana is AIDS-induced anaemia. As South Africa 'rolls out' a large-scale antiretroviral therapy programme, the blood transfusion needs of these patients are increasing and placing stress on the South African National Blood Service (SANBS).²

Many African countries do not offer population screening for HIV; even in those that do, such as South Africa, the degree of cognisance given to the test is, regrettably, still extremely low. Fear of stigmatisation, denial of the problem, and a fatalistic view of life are among the factors contributing to this attitude. Blood can be lethal to the patient receiving it – not only from incompetent cross-matching or mislabelling or careless

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misidentification of the patient, but also from the risks of disease transmission. Since 1982, HIV/AIDS has been the most feared of blood transfusion risks. If prospective donors have not acknowledged their recent 'high-risk' behaviour (on the form which is obligatory to complete before the blood donation is actually collected), or are not aware of a partner's HIV status or 'high-risk' behaviour, the donated blood could be issued to someone already afflicted, with disastrous consequences. The life of the recipient depends on the honesty of donors (and their sexual partners). In a society such as South Africa at present, the alarmingly high HIV rate is accompanied by endemic denial, which does not encourage individuals to seek counselling and/or testing.

Blood testing strategies

Until early 2005, the SANBS employed a policy of placing blood donors into risk categories, using race as a synonym for high-risk behaviour.³ Those categorised as being 'high risk' were largely black African donors. However, race is associated with many variables, including culture, health beliefs (many Africans, when sick, consult traditional healers and/or practitioners of allopathic medicine), language, and, particularly, socio-economic status. The SANBS practice was discriminatory and possibly illegal in terms of the South African constitution, unless the mode of discrimination were to be deemed not unfair by the Constitutional Court. (Census statistics, incidentally, still use race as a category – but with the objective of employing these data to monitor and redress the consequences of past discrimination.)

More relevant, however, are the strategies which have already been adopted to satisfy (or perhaps circumvent) the imposition of more stringent restrictions on blood transfusion. Following the publicity surrounding the exposé of the allegedly 'racist' practices of the SANBS, the Minister of Health ordered the SANBS to treat blood donated by all South Africans in the same manner. That meant, *inter alia*, testing all donated blood for HIV by the sensitive nucleic acid technology (NAT) test. This, it was predicted, would significantly reduce the 'window period' (when the blood is infective even though the conventional test for HIV is negative) from weeks, or even months, to 5–11 days. In addition, greater emphasis would be placed on encouraging regular donations – a strategy known to reduce the proportion of donors who are HIV-positive or in the 'window period'.

Two years into the new policy concerning blood transfusion safety, the SANBS assessed the safety of the blood supply.⁴ The model, based on donor status (i.e. regular repeat, lapsed, or first-time donor) as the major risk indicator, was introduced on 3 October 2005. It is '... underpinned by donor education, exclusion of donors who have been exposed to high-risk behaviour and individual NAT screening for HIV, HBV and HCV of all donations'.⁴ During the initial 6-month period

reviewed, 362 129 donations were screened by NAT systems; 56.2% of the total were from regular repeat donors, and these were assigned for extraction of components. Of a further 106 533 (29.4%) donations from other repeat donors, only the red cell donations were utilised for the transfusion of red cell concentrates and quarantine fresh frozen plasma, but not for the manufacture of platelet concentrates. The minority of donations (52 130 – 14.4%) were procured from first-time and lapsed donors and were used for the manufacture of quarantine fresh frozen plasma, although a proportion of these (31 047 – about 60%) were for 'limited release', i.e. the red cells were made available for transfusion if the need arose. The remaining 21 083 (5.8%) donations, from first-time donors, were used only for quarantine fresh frozen plasma.

The results of this policy were very impressive. The prevalence of HIV was lowest among component donations (0.01%) and red-cell-only donations (0.06%); the prevalence was significantly higher (0.53%) in donations from first-time donors.

Perceived need versus real need

During the debate concerning race and blood donation, there was no consideration of a perception that doctors behaved irresponsibly when they prescribed blood transfusions far too readily and without cogent indications. The traditional training of doctors has tended to neglect 'transfusion medicine' in the curriculum.

'Is blood transfusion advantageous?' is a necessary question when considering prescribing such a treatment – especially with the present significantly high risk of viral disease transmission, a state of affairs likely to persist in Africa for the foreseeable future. What is needed in the first instance is a re-orientation of ideas held by the medical profession. Blood transfusion is all too often viewed as a simple, relatively inexpensive, and straightforward way of overcoming the problem of blood loss. This attitude may arise and persist even when the reduction in the circulating volume is relatively small and the loss of blood constituents has been promptly compensated. Those who initially decide on the necessity for a blood transfusion are invariably the clinicians treating the patient. Their motives in coming to a decision are likely to be primarily based on what they've been taught as being the correct treatment for the case concerned, but may also be governed to some extent by demands made by patients and their relatives and friends. Not unexpectedly, when transfusion of blood provides an easy and professionally justifiable answer, blood would typically be procured, cross-matched and transfused.

As the hazards of blood transfusion increase, so does the need for finding alternatives. A number of factors, however, militate against this. Perhaps the main one is the fact that



the present generation of clinicians has grown up in a milieu in which the need for, and the availability of, blood for transfusion is taken for granted. Also pertinent is the fact that the voluntary donation of blood is now no longer as widely acknowledged as it used to be as a good deed. Voluntary blood donation in much of the developing world is not adequate for the practice of high-quality modern medicine; and the proportion of black donors presenting to the SANBS is much smaller than that of white donors. Many years of racial discrimination is undoubtedly responsible for this *status quo*. There have been no sociological studies on local blood donors since the 1966 study commissioned by the then Natal Blood Transfusion Service.⁵ Titmuss⁶ defined the black donors of Natal as 'captive donors' – they had often been coerced, by their employers or teachers, into donating their blood! Perhaps it is time to consider carrying out a new study into '... the attitudes and motivation of present-day South African blood donors'.

Informed consent and privacy

Donors can certainly expect to be informed of the details of the procedures involved in donating, and also to be given some idea of how a donation is likely to be used, though without mention of a specific patient. They are told of the confidential nature of the interview prior to acceptance as a donor; an experienced interviewer should be available to elicit an accurate history of possible high-risk behaviour, residence in countries where tropical diseases are common, etc. Potential donors should understand that tests for HIV, hepatitis B and C (employing the new NAT test), and other pathogens, will be carried out on the blood, and the results conveyed to them, emphasising the need for post-test counselling. This coupling of pre- and post-test counselling with voluntary HIV testing has become an integral part of blood transfusion services in developing countries in Africa. At least 25% of blood transfused in Africa is nevertheless not screened for HIV,¹ and there is clearly an urgent need for community-based national blood services to be established and to recruit panels of voluntary non-remunerated donors. Some success in this regard has been achieved in Botswana and Nigeria⁷ and, I understand, in Zimbabwe, Zambia and Malawi.

Whether all individuals have the right to donate blood, irrespective of their sexual orientation or of their population's 'risk profile', is a moot point. The issue with respect to sexually active homosexual men admits of different answers in different countries. Brooks,⁸ discussing the situation in the USA, opined that allowing openly homosexual men to donate blood for transfusion would increase the risk of HIV transmission. Such a dilemma is part of the broader issue of the responsibilities of blood services to donors and recipients, and Brooks concluded rather banally that, 'Blood services should base decisions regarding donor suitability on science rather than on their

donors' desires. Blood services must recognize that the rights of blood recipients should supersede asserted rights of blood donors.' He might preferably have restated the fact that it is clinicians who make the decisions about whether patients need blood.

Schuklenk⁹ posed the question: 'Do men who have sex with men in South Africa really have a higher prevalence of HIV infection than other groups of people in the country?' The data probably do not exist – and may be very difficult to ascertain – but the main issue he highlights is that some categories of heterosexual women and men have a very high prevalence of HIV (approaching or even exceeding 30% in many areas of the country), and yet they are not at present excluded from donating in terms of the new policy. If the laboratory testing of donated blood is refined to the extent projected, then most donors in the window period of HIV and hepatitis B and C infections will be detected, and yet whole blood and certain blood products from these donors would not be used for transfusion purposes. Schuklenk suggests that current policies in South Africa with respect to homosexual male donors may not be equitable. Jenkins¹⁰ also argues that '... gay men may be valuable blood donors if they are in a stable relationship with a single (non-promiscuous) partner ...' and the SANBS responded positively to these arguments. The new questionnaire completed by prospective blood donors has no references to 'male-to-male sex' and 'anal and oral sex performed without protection', and simply refers to 'anal and oral sex', and is thus applicable to heterosexuals and homosexuals.

Medical practitioners are extremely lax about the ethical requirement (which, incidentally, is also a legal requirement!) for obtaining informed consent from a patient before administering a blood transfusion. One would think that the prescribing doctor would discuss with the patient the indication for transfusion and the consequences of not consenting to it. It's also important that the patient clearly understands the necessity for the treatment (if it's a life-saving procedure, there's likely to be no discussion!) as well as the risks.

I must emphasise that the patient's signature on admission, 'consenting' to everything that might be done to him/her in a hospital, does not constitute 'informed consent'; in fact, a signature at the bottom of a form does not in itself establish 'valid consent'.

Allocation of scarce resources

The new model adopted by the SANBS in 2005 to use the blood donated by all population groups ('races') was facilitated, to a large extent, by NAT testing of every unit of blood donated for transfusion, thus significantly increasing the cost of each unit by 20% – a total expense of R120 - R150 million per year. This is a significant amount in view of the shortfall of money available



for health care for the majority (about 80%) of people in South Africa who cannot afford private health care, while the State's health care service has difficulties in coping with the demands placed on it. Another consideration is that of trained State personnel who move to the private health care sector (for better pay and working conditions) or leave the country (another ethical issue!) which is more deserving of consideration.¹¹

About half the blood available is used in the private sector, which caters for about 20% of the population; consequently, members of medical insurance schemes have to pay more for cover; similarly, the public sector's health budget will also have to be increased or economies made elsewhere. This raises ethical issues regarding the allocation of scarce resources – or distributive justice. Does this modification to the practice of blood transfusion medicine (NAT testing of every unit of blood) justify the 20% increase in cost? Could the former model have been retained and the money put to better use? The practice of collecting blood and then not using the donation for the stated purpose because the donor belonged to a 'high-risk category' was deceitful and ethically unacceptable.

Consequences of new policy

The new policy governing blood donation is intended to ensure a safe and adequate supply of blood for the whole country, but we cannot ignore the phenomenally high prevalence of HIV and the estimate that 500 000 individuals are infected with HIV each year. The epidemic shows no signs of abating. If the number of transfused patients being infected with HIV or hepatitis increases, due to the failure of NAT technology to detect individuals who had only very recently been infected with the virus, or due to other changes in policy being ineffective, one may argue that the State ought to accept responsibility. The SANBS will most likely be unable to secure insurance cover for such an eventuality – which they did obtain prior to adopting the new policy. Consequently, would the health care services, for example, give priority to such inadvertently infected patients for enrolment in their anti-retroviral (ARV) programme, which at present reaches only a small proportion of AIDS patients?

Directed or designated donor blood transfusion

Some private hospitals in the USA have their own blood banks and are well placed to deal directly with patients who may choose to have directed blood donors supply their transfusion needs. I have met a number of medical colleagues who, fearful of a decline in the quality of local blood transfusion services because of the new policy, say that they would elect to have directed blood donations for themselves and family members, if the need arose.

It seems unlikely that a private hospital-based, directed blood donation service would be licensed in South Africa; it

would be at variance with the stated policy of having only one licensed national blood donation service.

If the new model of donor safety which was implemented in October 2005 turns out to be less safe than the former practice of the SANBS, it is possible that the private health care service, which caters for the needs of about 20% of the South African population (including a disproportionately large number of 'white' citizens), might be tempted to set up its own blood transfusion service, claiming that it uses directed blood donors. Such a dichotomy would widen the gap between the private and the public health sectors even further, with the poor and disadvantaged members of society being the main losers.

Blood substitutes

In 2001, the South African Medicines Control Council (SA MCC) established South Africa as the first country in the world to approve a product for use as a blood substitute.¹² The product was Hemopure, a cell-free polymerised haemoglobin solution, which is still used in the country. For certain well-defined conditions, it has been a success, contributing to a reduction in the use of fresh blood and its components. Levien¹³ has reported on the clinical details, method of administration, clinical outcome, and safety and efficacy in a cohort of 336 patients treated since April 2001. It was found that Hemopure was well tolerated and obviated the need for administering blood in 89% of patients; and that blood transfusion could be limited to patients with large or rapid haemorrhage and to those who failed to show recovery of their red cell mass after Hemopure treatment – due to the presence of an underlying chronic disease state.

Experience in using Hemopure led clinicians to administer it for its tissue oxygenation effect rather than as a red cell substitute. 'Properly controlled randomized prospective trials are needed to confirm its role as an enhancer of tissue oxygen delivery as well as its enhancement, of wound healing'.¹³

Population profiling and public health risk

The racial profiling used by the SANBS for several years prior to the introduction of its new policy in October 2005, was widely criticised in South Africa by the Minister of Health, the Human Rights Commission, the president of the South African Medical Association, human rights groups, and many other individuals and social groups.

Profiling was considered to be racist and reminiscent of the worst practices of the South African government and its agencies during the apartheid era. Race classification was a tool used by the exclusively white government to subjugate the black population and the relatively small groups of 'coloureds' (people of mixed ancestry), and 'Indians or Asians'. The scientific basis for such a classification was obscure, and the genetic profiles of these populations were not clearly demarcated from each other, as discovered by the 'race



classification boards' and the courts which sat in judgment on such cases during the apartheid era.

The identity of these major population groups is not clear-cut; the overlap in gene frequencies between the groups reflects the long history of intermarriage and miscegenation between them. Nevertheless, the names given to the four groups were entrenched in laws passed by the apartheid government, and resulted in group identities which are in common usage to this day in census returns and for gathering health statistics. Blood transfusion services in South Africa were required by law to collect the blood of people belonging to these different racial/ethnic groups in separate facilities; the 'race' of the donor had to be stated on each unit of blood. The various racial/ethnic categories are associated with a range of other variables, causally and incidentally, and can sometimes serve as a substitute for other variables (such as HIV status) although, in the view of many people, the use of race/ethnicity for the profiling of blood donors is considered to be a stigmatisation of black donors.

But HIV status has nothing to do with genetics (which determines race/ethnicity). HIV status is a reflection, rather, of the discrimination and structural violence perpetrated against the majority population subjugated by an elite minority for hundreds of years. In the case of HIV in South Africa, '... this would involve emphasizing the role that apartheid played in the differential spread of HIV and in the legacy of inequalities in education, income, health and access to health care that continue to influence the impact of HIV/AIDS'.¹⁴

It is a great pleasure to participate in honouring Hendrik Koornhof, a valued colleague and friend for over 40 years. His contributions

to science have had a significant impact on our understanding, prevention and treatment of a number of infectious diseases; his modesty and humility are an emulatory challenge to us; his integrity is legendary; and his compassion for the downtrodden and disadvantaged has made him a role model for colleagues and students. May you long continue to challenge and inspire us, Hendrik.

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