Policy and decision making by blood transfusion services in South Africa

A regulatory authority is an essential component of a well-structured national blood transfusion service. Such an authority should be located in the Department of Health (DoH), where the Minister should be accountable for the health of the nation, including the provision of supporting services such as a blood system. In the national blood system the regulatory authority would be responsible for relevant policies, regulations, standards and guidelines. The Minister may delegate all or some of the operational activities to another institution, or the service may be provided by the State. In South Africa, the Minister of Health regulates blood transfusion, but the operational activities have been delegated to and are the responsibility of non-profit independent companies, viz. the South African National Blood Service (SANBS) and the Western Province Blood Transfusion Service (WPBTS).

The weakness of the South African system is the lack of a clearly defined regulatory authority for blood transfusion in the DoH. According to the National Health Act[1] (the Act) the Minister is responsible and issues a licence to a national blood transfusion service to provide the service to the country. Compliance with the legal provisions described in the Act and the supporting regulations and standards is monitored by regular inspection.

The Act and regulations do make provision for a statutory body, the National Blood Committee (NBC) that advises the Minister on issues related to blood transfusion. Currently, however, the NBC is constituted inappropriately to perform such a task effectively and authoritatively. Representatives of the blood services dominate the NBC and are the only members who are experts in the field of transfusion medicine. The Minister therefore is in effect advised by the blood services themselves and the DoH has little independent objective scientific view on important policy matters. This is obviously an unhealthy situation and should be rectified as a matter of urgency.

The present system is, however, not entirely dysfunctional. The WPBTS and SANBS (and in the past the other independent blood transfusion services) have always collaborated with the DoH and thus ensured that appropriate and high standards for blood transfusion are maintained in South Africa. This was achieved by the development of appropriate policies, regulations, standards and guidelines based on international best practice, taking into account local circumstances, health policies and priorities. These policies and standards have been in accord with the mission statements of the blood services focusing on providing sufficient and safe high-quality blood products that are affordable and equitably available to all patients.

A good example of such co-operation is the publication of the guidelines for leucodepletion of blood components published elsewhere in this issue of the *SAMJ*.[2] These guidelines have been discussed and accepted by the blood services and the NBC. Appropriately, the recommendations are not in favour of universal leucodepletion, but support the view that selective leucodepletion is more appropriate for South Africa. The recommendations take into account the cost of the filters and the technology and objectively assess the clinical advantages of leucodepletion. The recommendations for the use of this technique are thus based on scientific evidence and restrict the use of this expensive technology to conditions where the patient will benefit and the additional cost can be justified. Health practitioners and prescribers of blood would therefore be wise to follow these guidelines.

There are, however, instances in which the disadvantages of a system where the legislative authority is not clearly defined are obvious. In such cases blood policies are not made by the DoH and the blood services are held accountable for policy and decision-making. There is a conflict between the DoH and the blood service if the two bodies disagree on such policies, of which there are two recent examples.

In response to the threat that the HIV/AIDS pandemic poses to the safety of the blood supply, the then SA Blood Transfusion Service in 1999 implemented a risk management policy triaging blood donations according to window period risk.[3] The statistically most significant risk indicator was the race of the donor. This policy could be justified scientifically, but was politically unacceptable. The blood service had published the policy and justified it on both patient safety[4,5] and legal grounds.[6] This policy was not challenged by the Minister of Health until December 2004, when the issue was vigorously debated in the public media and judged as racist and unconstitutional.[7] The outcome was that the public image of SANBS was severely tarnished.

It should be noted that SANBS adheres to the general principles of policy-making that put the interest of the patient first. Such policy-making, which is based on universally accepted criteria, regards the rights of the blood donor as secondary to the rights of the patient to have access to safe blood.[8]

Fortunately the DoH and SANBS were able to resolve the issue to the satisfaction of all stakeholders. SANBS developed a new risk management model,[9] based on the statistical observation that a donation from a regular blood donor is less likely to be in the infectious window period. However, this model could only be implemented because the technology to test large numbers of individual donations with nucleic

acid amplification technology (ID-NAT) had recently become available. ID-NAT is significantly more sensitive than screening donations for the presence of HIV infection by testing for HIV antibody or HIV p24 antigen. ID-NAT may decrease the infectious window period to as little as 5.6 - 12 days, compared with 22 days for HIV antibody and 16 days for p24 HIV antigen. It should, however, be noted that this is a statistical model that still has to be validated, and its impact on the safety of the blood supply will only be confirmed after extensive monitoring and analysis of donor and patient data. The implementation of the new risk model has significantly increased the cost of blood and can be criticised on the grounds that it cannot be justified in the context of the health priorities of South Africa.

The other example is the recent confrontation between gay and lesbian associations and the blood transfusion services. Men who have had sex with another man are universally barred as blood donors because this is recognised as high-risk behaviour for HIV infection and transmission. The issue was debated in the public media.[10] The gay community took the stance that the blood service was discriminating against gay men in contravention of the Bill of Human Rights of the South African Constitution. This view was publicly supported by the South African Human Rights Commission and also by the President of the Medical Association of South Africa.

The blood services again took the view that the rights of the blood donor are subservient to the rights of the patient. SANBS recognises that there are no local data to support the view that in South Africa, as elsewhere, men who have sex with men pose a significant risk to the blood supply. Also, the service acknowledges that the risk this poses to the blood supply has not been quantified in South Africa. The blood services, however, adhere to the so-called precautionary principle,[11] which states that 'The balancing of risks and benefits of taking action should be dependent not only on the likelihood of the risk materializing but also on the severity of the effect if the risk does materialize, on the number of people who could be affected, and on the ease of implementing protective or preventive measures. The more severe the potential effect, the lower the threshold should be for taking action.'

It should, however, be recognised that it is now opportune to revisit the issue in the light of the availability of sensitive screening tests such as ID-NAT that shorten the infectious window period significantly. It may therefore be possible to decrease the period of deferral of a donor who has participated in high-risk behaviour. This could include men who have had sex with men, or donors who have been exposed to situations where there is an increased likelihood of transmission of HIV or other transmissible agents.

The outcome of the public debates of these scientific issues was that the image of SANBS was tarnished. The situation would have been different if the high-level policies had been developed at a level higher than the blood service. All stakeholders could then have debated the scientific basis for such policy decisions.

These are difficult issues and it is important to balance science, ethics and socio-political elements when making policy decisions.[12] It is, however, important to adopt an evidence-based approach and to ensure that, if public debate is unavoidable or necessary, it is handled responsibly.

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