Ensuring the safety of blood transfusion in South Africa

The importance of safe blood transfusions cannot be overemphasised.

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Although the contribution of transfusion-transmitted infection to the HIV epidemic has not been accurately assessed, according to the World Health Organization, globally an estimated 5 - 10% of HIV infections are due to blood transfusion.[1] Since breaking onto the scene 26 years ago, HIV has proven an indefatigable foe. Over 60 million people have been infected with this retrovirus, and 25 million have already died of AIDS. HIV infection is hitting the hardest in the developing world.[2] AIDS was first recognised in the summer of 1981. Young gay men began falling ill and dying of opportunistic infections their immune systems should have fended off.[3] By late 1982, epidemiological evidence indicated that AIDS was an infectious disease transferred by bodily fluids and by exposure to contaminated blood or blood products.[4] Without a test for AIDS, blood banks had difficulty safeguarding the blood supply, and most refused to screen donors for homosexuality. Surrogate markers, such as hepatitis B core antigen, proved imperfect at best. Thus, the blood supply remained unsafe for years, and many people were transfused with contaminated blood.

Approximately 15 000 haemophiliacs in the USA became infected with HIV as a result of transfusion with contaminated blood products between 1981 and 1984.[5] Likewise, a cohort of 198 patients attending haemophilia clinics in Johannesburg was tested for HIV. This cohort of patients had been treated with locally produced (South African) blood products from volunteer donors, except for a 15-month period in 1982 - 1984 when, owing to a shortage of locally produced material, an imported large donor-pool USA factor VIII concentrate was used. Not all patients received this material. Of the haemophilia A patients who received the imported factor VIII concentrate, 85% were seropositive, while only 3% of the patients who received locally produced small donor-pool products were seropositive.[6]

Countries around the world, including South Africa, took swift action in order to keep their blood supply safe. The lessons learned from this epidemic and the related safety measures set the stage for the development of nationwide monitoring systems that track adverse events and incidents associated with collections from blood donors and transfusion to recipients, namely haemovigilance programmes.

The practice is that a recipient of blood transfusion who tests positive for HIV after receiving a blood transfusion reports the event to the haemovigilance officer.

Haemovigilance is a 'quality process' which aims to improve quality and increase safety of blood transfusion, taking into account that haemovigilance covers and surveys all activities of the blood transfusion chain from donor to recipient (vein to vein). It is also a risk management, voluntary, confidential system for reporting adverse transfusion reactions, monitoring the safety, adequacy, reliability and blood wastage; promoting effective guidelines for blood usage and recommending alternatives where appropriate.

To monitor and improve blood safety in South Africa the South African National Blood Service (SANBS) and the Western Province Blood Transfusion Service (WPBTS) established a national haemovigilance programme in 2001.

Objectives

In ensuring the safety of blood transfusion in South Africa, the objective of this article is to review the number of transmissions of

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human immunodeficiency virus (HIV) by blood transfusion in South Africa between 2001 and 2005 that were reported to the South African national haemovigilance programme. During this period, HIV antibody and HIV p24 antigen tests were used to screen all blood donations in the country. In October 2005 a more sensitive HIV nucleic acid amplification test (NAT) for blood donations was introduced in South Africa to identify donations made during the window period before seroconversion.

Methods

The haemovigilance programme also monitors adverse blood transfusion reactions and other transfusion-transmissible diseases in the country. The practice is that a recipient of blood transfusion who tests positive for HIV after receiving a blood transfusion reports the event to the haemovigilance officer. The officer initiates an investigation to determine how many units of blood products the patient received as well as the identity of the donors of the transfused blood products. Once identified, the donors are recalled for retesting for HIV (and other viral infectious diseases such as hepatitis B, C). If positive for HIV, the viral phylogenetic testing between donor and recipient is done.

If the donors cannot be traced for a period of more than 12 months the case is reported as a *possible* transfusion-related HIV infection.

During 2001 and 2005, HIV 1 and 2 antibodies (with a window period of about 22 days) and HIV p24 antigen tests (with a window period of about 16 days) were used to screen all blood donations. The window period is the early infection period when the donor is HIV infected but the HIV antibodies and antigens blood concentrations are too low to be detected by regular tests.

In October 2005 a more sensitive HIV-1 individual testing (non-pooled) nucleic acid amplification test (ID NAT) for blood donations was introduced in South Africa, to further reduce the window period before seroconversion to 6 - 11 days. The NAT test amplifies and detects a 142-base target sequence located in a highly conserved region of the HIV gag gene.

If any of the regular donors becomes HIV positive in a subsequent blood donation, the programme initiates a look-back process of identifying the recipients of previous donations, in order to test them to ensure that a previous donation was not in an HIV window period.

The number of HIV transmissions by blood transfusion in South Africa between 2001 and 2005 reported to the haemovigilance programme was then reviewed.

Results

Between 2001 and 2005 a total of 4 341 343 units of blood products were transfused from voluntary non-remunerated donors in South Africa. During that 5-year period, 8 cases of HIV transfusion-related infections were reported to the haemovigilance programme. Between 2001 and 2003, 2 cases of HIV transfusion-related infections were reported for each year. In 2004 and 2005 only 1 case per year was reported. Of the 7 cases reported between 2001 and 2004 all the implicated donors were traced and found to be repeat donors who were in the window period of their infections. Initially their donations tested negative for HIV antibody and HIV p24 antigens, but subsequently became positive in follow-up tests. All the implicated donors denied participation in high-risk behaviour during the blood donation interview and selection process. The case of HIV transfusion-related infection in 2005 was reported as a *possible* transmission, because of the 6 donors implicated in the transfusion history of the patient, 4 donors were traceable and subsequently tested negative in the follow-up tests. Two of the implicated donors were untraceable and hence the case was classified as a *possible* transfusion-transmitted HIV-1 infection. All 4 donors who were traced were *repeat* donors.

Discussion

South Africa has a high HIV-1 prevalence rate, estimated to be 29.1% in antenatal clinic attendees. This has required SANBS and WPBTS to implement additional measures

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in safeguarding the blood supply against transfusion-transmitted HIV-1 infection. Between 2001 and 2005 the national haemovigilance programme in South Africa was successful in identifying the implicated donors who transmitted HIV infections through blood transfusion during the window period of their infections. During this period the reported rate of transfusion-transmissible HIV infections in South Africa was 1.8:1 000 000. The risk of HIV transmission by HIV antibody and antigen-tested transfusions is extremely rare. To further reduce the risk of HIV transmission by window period donations, the SANBS introduced the individual (non-pooled) nucleic acid-amplification testing (NAT) in October 2005. In addition to NAT testing, blood donations continue to be screened with antibody tests for HIV to ensure the safety of the blood supply.

Apart from the haemovigilance programme which includes look-backs, and which is constantly vigilant for possible transmissions and ways to prevent them, a number of risk management strategies have been implemented in order to minimise the risk of transfusion-transmissible infections, particularly of HIV. The donor expansion programme has proceeded in parallel with more stringent donor selection criteria, the revision of the self-exclusion criteria on the donor questionnaire and more rigorous testing, keeping the prevalence of HIV among donors low. Fig. 1 gives the prevalense rate of HIV among SANBS donors. Fig. 2 depicts the HIV prevalence rate among SANBS donors compared with that among women attending antenatal clinics.

Conclusion

Between 2001 and 2005 the haemovigilance programme was successful in identifying the implicated donors who transmitted HIV infections through blood transfusion during

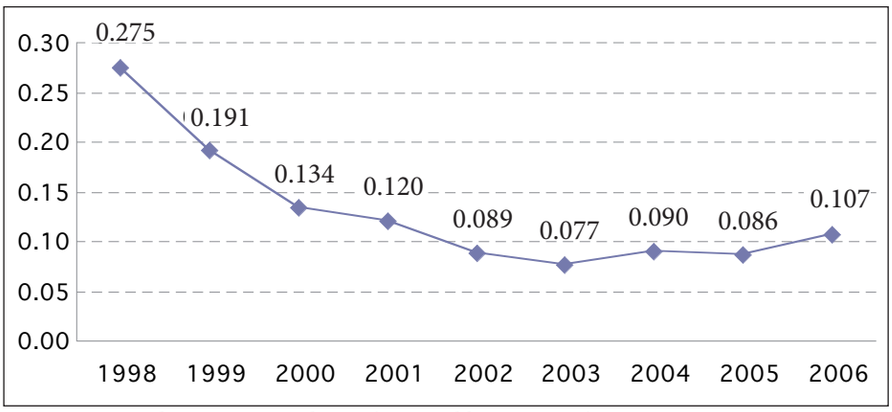

Fig. 1. HIV prevalence in SANBS donors (Swanevelder R, SANBS).

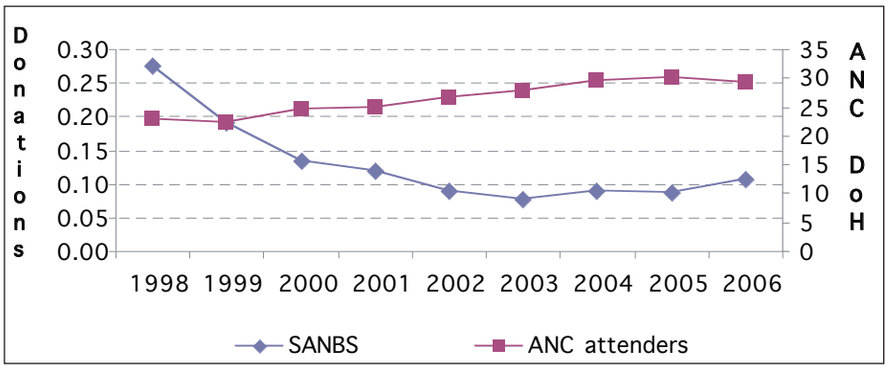

Fig. 2. HIV prevalence rate among SANBS donations compared with that among antenatal clinic attendees (Swanevelder R, SANBS).

the window period of their infections. During this period the reported rate of transfusion-transmissible HIV infections in South Africa was 1.8:1 000 000. The risk of HIV transmission by HIV antibody and antigen-tested transfusions is extremely low. To reduce the risk of HIV transmission by window period donations the SANBS and the WPBTS introduced NAT testing in October 2005. The safety of blood transfusion in South Africa is further enhanced by ID NAT testing rather than pooling blood (generally undertaken as a cost-reduction measure). NAT testing will further reduce the HIV window period to about 6 - 11 days; the window period was responsible for HIV transfusion-related HIV infections between 2001 and 2005.

Since the introduction of NAT testing in October 2005 no HIV transmission by blood transfusion has been reported to the haemovigilance programme. It is recommended that the SANBS and the WPBTS continue the national haemovigilance programme to ensure the safety of blood transfusion in South Africa.

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In a nutshell

- The article reviews the number of transmissions of human immunodeficiency virus (HIV) by blood transfusion in South Africa between 2001 and 2005 reported to the SANBS haemovigilance programme.
- During this period, HIV antibody and HIV p24 antigen tests were used to screen all blood donations in South Africa.
- Between 2001 and 2005, a total of 8 cases of HIV transfusion-related infections were reported to the haemovigilance programme of the SANBS.
- All the implicated donors who were traced were found to be repeat donors who were in the window period of their infections.
- Since the introduction of NAT testing in October 2005 no HIV transmission by blood transfusion in South Africa has been reported to the haemovigilance programme.