BLOOD ISSUES

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Editorial

Blood Services internationally use a combination of mechanisms to ensure the overall safety of blood components. This involves exclusion of donors who are at increased risk of acquiring major blood borne viruses and then testing of all blood donations using the most sensitive tests available. Despite this a small risk of transmission of infection remains. In New Zealand this risk is currently estimated to be in the order of 1 in 2 million for HIV and HCV infections. This equates to one possible transmission every ten years.

In recent years the ongoing requirement for donor exclusion criteria has been challenged in many countries including New Zealand. Advocates for change argue that the availability of highly sensitive tests removes the need for the exclusion or that the period of exclusion could be reduced significantly. A number of gay men believe that the ongoing use of the criteria is unnecessary and discriminatory.

During 2007 NZBS commissioned an independent expert group to review the ongoing appropriateness of using the behavioural donor exclusions. The review was initiated in response to three complaints to the Human Rights Commission from gay men alleging that some of the deferral criteria are discriminatory. The expert group was chaired by Professor Charlotte Paul of the Otago University Department of Preventive and Social Medicine. The Review Group has now completed its report. This recommends a number of changes to the deferral criteria. These are based on changes in the pattern of HIV infection in New Zealand and recent medical and scientific data.

The final report was assessed by a Queen's Counsel, who has indicated that the recommendations comply with relevant legislation including the Bill of Rights. Approval is currently being sought from Medsafe to progress implementation of the recommended changes.

The Executive Summary from the report, including the main recommendations, is included in this edition of Blood Issues. A full copy of the report is available on the NZBS website (www.nzblood.co.nz).

Dr Peter Flanagan
NZBS Medical Director

Executive Summary from the Report on the Behavioural Donor Deferral Criteria Review

The New Zealand Blood Service (NZBS) asked a group to review the current criteria for the deferral of people from blood donation based on behaviour. This relates to sexual and drug using behaviour which may put people at risk of transfusion transmissible infections (TTIs). There may be some risk to recipients of blood and blood products if these people donate blood. The Review Group was independent of the NZBS. Dr Peter Flanagan, Medical Director NZBS, provided expert input into the review, but did not participate in the decision making.

The principal task of the Review Group was to review the ongoing appropriateness of exclusion of donors on the basis of current and/or past behaviour to ensure the safety of blood and blood products in New Zealand. Particular emphasis was put on: (a) the appropriateness of ongoing exclusion of men who have had sex with men (MSM), (b) possible approaches to the risks associated with heterosexual activity in relation to geographic areas of high prevalence, (c) sex work and (d) advice on the development of effective communication tools.

Relevant Issues

The NZBS was established in 1998 by the Health Amendment Act. In discharging its responsibilities it is required to take all reasonable precautions to ensure that blood is safe for use. It is also required to meet a number of international standards. The first review of donor deferral criteria was undertaken in 1999. Regular reviews are required because of changes in the operation of the NZBS and in the external environment. In addition, questions have been raised about the justification for the current donor deferral criteria.

There are four steps involved in ensuring the safety of blood. Prior to presentation at a blood service people may self-defer. Self-deferral occurs when a person is aware the NZBS will decline their offer to donate blood. Once a potential donor presents there is a three tier combination approach to safety: a questionnaire on behaviour followed by an interview, tests that are highly sensitive and specific are carried out on the donated blood, and (for manufactured plasma products) the use of physical and/or chemical methods to inactivate infectious agents.

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The reason for asking a potential donor not to donate at this time ("donor deferral") is to further reduce the risk that an infectious agent will be transmitted in a blood donation. The specific reasons are: (a) because if they have an infection in its very early stages it will not be detectable by testing (the window period); (b) because the test may, very rarely, miss a longer standing infection which is present or the blood service system may inadvertently fail to remove such an infected donation from the system; and (c) because of the possibility of unknown or untested for infectious agents.

At present HIV, hepatitis B and hepatitis C infections pose a potential risk of transmission. People who have shared injecting drug use equipment also have a higher prevalence of other transfusion transmissible viruses. The major risk behaviour for hepatitis C in New Zealand is injecting drug use. For hepatitis B, the main risk relates to new window period infections and hence recent sexual or injecting drug using behaviour is relevant. For HIV (which is the most severe disease), the risks of transfusion relate to both new window period infections ("incident infections") and established infections ("prevalent infections"). The risk for the latter arises because of potential errors in testing or in the quality system. Hence behaviours that place individuals at risk of both incident and prevalent infections are relevant.

Deferral for other reasons apart from sexual or drug using behaviour is already in place in New Zealand. For instance, because of a theoretical risk of variant Creutzfeldt-Jakob Disease (vCJD) and the lack of a blood test for the infectious agent, people who resided in the UK during the time of the epidemic of Bovine Spongiform Encephalitis (BSE) are asked to defer from donating blood. This review does not address these wider issues. Nevertheless this deferral does illustrate the current level of precautions taken to protect the safety of the blood supply. In addition, potential donors will be deferred following activities such as ear piercing or tattooing. Many individuals are deferred for their lifetime if they are known to have certain conditions, if they have received certain treatments in the past, or for other medical reasons. Overall approximately 12% of all people who present to donate blood are deferred.

The epidemiology of HIV in New Zealand shows that new diagnoses have increased since 2002 and that this increase is equally among homosexually and heterosexually acquired infections.

Most heterosexual infections were acquired overseas. Incident infections in New Zealand – as judged from new diagnoses – were mostly acquired through male-to-male sex (82% for 2003-2006). For prevalent infections the only information is from people attending sexual health clinics. Among this group, in 2005/6, the prevalence of undiagnosed HIV infections was 40 times higher among MSM (20.1 per 1000) than among heterosexuals (0.5 per 1000). Prevalence will also be relatively high amongst people who have migrated to New Zealand from countries with generalised HIV epidemics, though no measure is available.

The current behavioural deferral criteria are that MSM are deferred for 10 years since last male-to-male sexual contact. This is shorter than the UK, US and Canada (lifetime or from 1977) but longer than Australia (one year). Detailed evaluations of deferral periods have been reviewed. There is no published evaluation from Australia. The evaluations show that adherence to deferral is high and that the current risks of transmission of HIV by transfusion are extremely low. Modelling approaches suggest that shortening the deferral period to one year (from lifetime) would increase the already very low risk slightly (in the range of 8 to 66%). There is evidence that a five-year deferral period is as safe as a 10-year deferral period. This comes from data on the very small residual risk of HIV transfusion estimated from current deferral criteria (and hence any hypothetical safety margin will be immeasurably small); secondly from the indirect evidence about HIV prevalence in current US donors who didn't self defer (that men who had abstained from male to male sex for longer than five years did not have raised HIV prevalence); and thirdly that five years is estimated by experts to be long enough to detect novel pathogens.

Similar issues arise for any population in which there is a high prevalence of HIV infection (>1 percent). A short deferral period (for example, one year) will eliminate the risk of "window period" infections, but a longer deferral period will reduce the small risk of not detecting a "prevalent" infection. This applies to MSM and to heterosexuals from countries with high HIV prevalence.

The legal matters which are relevant include the Code of Health and Disability Services Consumers' Rights Regulations 1996 and the New Zealand Bill of Rights Act 1990. The policy approach taken in this report is to determine whether deferral criteria are justified on health and safety grounds. In particular, if there is to be different treatment of a group on behavioural grounds, these must be justified and proportionate and not able to be met reliably in any less restrictive way.

Ethical principles were used to consider whether a change in policy would represent an overall improvement, taking both harms and benefits into consideration. It is appropriate to give significant priority to non-maleficence (doing no harm) because recipients face involuntary risks from blood products. Policy and practice concerning blood donation should not impose levels of risk on recipients of the blood supply that alternative policy and practice would not impose. Strictly speaking, donor deferral does not restrict offers to donate, only acceptance of such offers, and the view that there is no right to donate follows from this. Even so, donating blood is a valued social activity. Policies of donor deferral are thus restrictive practices because they generate a form of social exclusion and potentially add to stigma. Therefore, the central question, both legally and ethically, is whether the extent of the restriction is proportionate to the health and safety objective.

Recommendations

(a) The deferral criteria for people who have injected themselves with drugs not prescribed by a doctor should remain (lifetime deferral).

(b) The current ten-year deferral period for men who have had male-to-male sex should be shortened to five years. The grounds are that a change to a five-year deferral will not increase risk to the blood supply, either from incident or prevalent HIV infection or from undetected novel infections. The reduction in the period of exclusion aims to attain the least restrictive method of maintaining the safety of the blood supply.

The wording of the question on the "Donor Questionnaire" for MSM should be changed to improve clarity around the use of the word "sex". This should be changed to: "…you have had oral or anal sex with or without a condom."

It is not practicable at present to further define specific sexual activities among MSM that should result in exclusion from donation. Lower-risk activities than unprotected anal intercourse, for example, anal intercourse with a condom or oral sex, are still associated with small risks of HIV transmission, and the absolute risk of transmission depends also on the prevalence of HIV among sexual partners, which is considerably higher for MSM than for heterosexuals. Nevertheless, it is the activities not sexual orientation that is the central issue.

(c) The deferral criteria for heterosexuals who have lived in, or who come from, specified countries should be modified. The list of countries and map should change to better reflect the areas with generalised heterosexual HIV epidemics: i.e. an estimated prevalence of HIV of >1% in the population. Such lists and maps are available through UNAIDS. As the geographical criteria now clearly define countries with a higher prevalence of HIV, a deferral period of five years from leaving a high prevalence country is recommended.

(d) A one year deferral should remain for a woman who has had sex with a bisexual man, and for those who have had sex with a person who carries the hepatitis B or C viruses, or an injecting drug user, a sex worker, a person with haemophilia or related condition, or with a person who has lived in or comes from a country with high HIV prevalence.

(e) The current deferral criteria for sex workers should be amended. People who have worked as sex workers only in New Zealand should not give blood for one year. People who have worked as sex workers in any other country should not give blood for five years.

(f) The NZBS Collection Standards should be amended in the light of this review.

(g) Effective communication tools are required to improve overall understanding of and adherence to behavioural donor criteria. Public information is required to increase self-deferral. The NZBS should work with other relevant bodies (for example, the New Zealand AIDS Foundation) to produce information explaining the reasons for behavioural deferral criteria.

The donor questionnaire will need to be revised in the light of Recommendations (a) – (e). At that time it should be reviewed for clarity and ease of understanding. The "three box" layout for Special Questions 1 of the health questionnaire was raised in the consultation process as a cause of potential stigma for those in certain risk categories. Altering the layout to a "single box" format (if this is feasible without losing effectiveness) and asking once whether any of the above apply might be a way of overcoming the issue. For donors who are deferred at the blood service, a clear explanation needs to be provided as to the reasons why. There should be written information, but ways of enabling potential donors to discuss the issues with someone with sufficient expertise should be explored.

(h) There should be a review of these recommendations in five years. In the future the epidemiology of Transfusion Transmitted infections including HIV may change in New Zealand. Detailed data from Australia on the effects of a one-year deferral should by that time become available. Viral inactivation techniques for whole blood may be developed and implemented, and validated ways of questioning about specific sexual behaviours may have been developed.

Progesa – Planning for The Future

In December, 2007, NZBS attempted to implement an upgrade to the Progesa Blood Management System. As previously explained, the implementation was unsuccessful, and the original version of Progesa was restored.

Since then NZBS has been working closely with MAK-System, the Progesa vendor, to both investigate the cause of the failed upgrade and also to define the most appropriate way forward.

The problems identified during the attempted upgrade have been reproduced in the test system. Unfortunately however MAK-system have been unable to identify the root cause of the problems and hence are unable to confidently avoid their recurrence. The problems appear to relate to the interactions between the flat file system used by Progesa with the Oracle database. This particular feature is not present in other Blood Services that have successfully implemented the upgrade. Based on this assessment NZBS has decided that the plan to upgrade the current system to the new version will not proceed.

The current system continues to work well. A number of problems do however exist. Firstly the software is now 10 years old. MAK-System has made it clear that this version of Progesa is increasingly difficult for the company to support. Secondly the hardware is also 10 years old and needs to be replaced.

The preferred way forward will be to implement a new version of the system, marketed as eProgesa. This eProgesa represents the future direction for MAK-System, and the company is investing in further development. NZBS has been closely monitoring implementations of the new system in other blood services. There were issues with eProgesa in its earliest implementations, but it has now been implemented successfully by some of the blood services which NZBS works with on IT issues.

eProgesa does offer improvements in functionality and technology, and would move NZBS into the mainstream of Progesa users. NZBS has commenced an evaluation of eProgesa and once complete will develop a business case for its implementation. This will be a major project for NZBS and will require considerable pre-planning. This will commence in 2009, implementation is unlikely to occur before the end of 2010.

In the meantime, NZBS is evaluating whether to move the current software onto a new hardware platform. This would reduce the risks which stem from the age of the current equipment. If this is successful, NZBS could either move the current system to the new hardware, or keep this option open as a contingency. This project is less complex than the attempted upgrade in December. The project would involve moving the current software and database to the newer hardware (the upgrade involved a newer version of the software, and changes to the database). Nevertheless, extensive testing is needed to ensure that the system will work correctly. The plan is to complete this process to support implementation on the new hardware by the end of November, 2008. More information will be provided to Progesa users once the decision on whether to proceed with this has been made.

Evidence Based Guidelines on The Clinical Use of Intravenous Immunoglobulin

Demand for intravenous immunoglobulin continues to grow at a rate of 8% per year in New Zealand. This mirrors the pattern of demand in other developed countries. Demand for intravenous immunoglobulin is now the driver for collection of blood and plasma in New Zealand. In December 2007 the Australian National Blood Authority published a set of Criteria for the Clinical Use of Intravenous Immunoglobulin in Australia. This excellent and comprehensive document reviews the evidence base for use of the product. Copies of the criteria can be found on www.nba.gov.au/ivig.

NZBS Transfusion Medicine Handbook 2008 Edition

A new edition of the NZBS Transfusion Medicine Handbook was published earlier this year. This provides information on the products and services provided by NZBS. An electronic version is available on the NZBS website (www.nzblood.co.nz). Printed copies should be available from your local hospital Blood Transfusion Department or Transfusion Nurse Specialist. Additional copies can be obtained (free of charge). Please contact jillian.sinden@nzblood.co.nz, giving your contact details.