Joint UKBTS / HPA Professional Advisory Committee (1)

Position Statement No 10

Blood donor selection to minimise risk of transfusion transmissible infectious agents entering the blood supply

07 November 2011

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This document will be reviewed whenever further information becomes available. Please continue to refer to the website for in-date versions.

The highest priority of the United Kingdom Blood Transfusion Services (UKBTS) is to ensure that blood provided for patients is as safe as possible. The UK adopts a highly precautionary approach to blood safety. The guiding principle is that if the best available evidence shows that there are reasonable grounds to believe that a course of action will improve the safety of blood, this action should be taken. Decisions must, however, recognise the need for an adequate supply of blood to meet patients' essential needs.

Donor selection guidelines help to protect not only against those infections that are tested for in every blood donation, but also against other infectious agents, both known and unknown that could be transmitted by blood and other body fluids. The guidelines have developed over the years, and have been revised and updated to take account of scientific and medical knowledge and advances.

Donor selection guidelines to minimise the risk of transfusion transmissible agents were first introduced when the risk of hepatitis B virus, and other infections such as malaria, were recognised to be associated with certain specific situations, such as non-sterile needles and travel to certain areas of the world. Over time, the guidelines have grown in complexity as more infections are identified and overseas travel has increased.

Donor selection guidelines to protect the blood supply from HIV were first formulated early in the 1980s, based on the best evidence then available. At that time, no blood tests were available to detect HIV infection and hepatitis C infection had not been identified. Since then, tests for HIV, hepatitis C and HTLV have been introduced to supplement those for hepatitis B and syphilis infection, and all tests have been regularly improved through scientific and technological advances. Despite these advances, UKBTS donor selection guidelines, in common with those of many other countries, permanently bar from blood donation any individual who has ever injected drugs or accepted payment (in money or drugs) for sex.

Despite the availability of high quality blood tests which can be applied to blood donations, there remains a risk that an infectious donation could escape detection in the tests used. There is a very low failure rate for every test. The main risk is that an infection goes undetected because the donor has attended very early in the incubation period of the infection, very soon after infection, and the infection cannot be detected no matter how good the test may be. This situation is known as a "window period". Donor selection guidelines take account of the window period for the tests used and in many situations require a period of time between possible exposure to the infection and the time when blood tests would be reliably expected to detect any infection which is tested for.

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UKBTS regularly analyses the numbers of infections detected in blood donors, and uses these figures to calculate the risk of an undetected infection. Furthermore, information provided by infected donors helps to identify where and how the infection was picked up. This information can then be used to improve and strengthen the donor selection guidelines.

In the period 1995 to 2010 HIV infections detected in blood donors in the UK were most often sexually transmitted. Hepatitis B infection was predominantly related to place of birth or parents' birth, since the infection is very widespread in some countries, while hepatitis C was mainly associated with injecting drug use

Re-attending donors provide about 80% of all donations in the UK. An infection such as HBV, HCV or HIV detected in such a donor must have occurred at some time following the earlier donation. Furthermore, the fact that an individual has recently become infected is evidence that he or she has been exposed to some risk during the period between the two donor attendances.

Among re-attending donors, during the period October 1995 to 2010, a substantial proportion of the individuals found to have HIV infection (with known risk exposures) were males who had attended, completed the donor health check as eligible to donate blood, but who stated in a subsequent clinical interview that they had had anal or oral sex with a man.

Males constitute about 50% of donors. Research carried out in the UK during 2000 indicated that about 6% of males report a homosexual experience during their lifetime, but that half of these may have had only a single homosexual experience, often many years ago. It can therefore be concluded that a relatively small number of male donors accounts for a disproportionately large number of new HIV infections detected among donors.

In 2011 a major review by the Advisory Committee for the Safety of Blood, Tissues and Organs (SaBTO) resulted in a change in donor selection guidelines relating to risk for infections which can be transmitted by blood transfusion. The latest available data about infections among donors and in the general population was considered, together with findings from research looking at how well potential donors complied with the donor selection guidelines.

The previous guidelines had stated that men who had ever had sex with other men should be excluded from blood donation permanently. The change introduced following the review states that such individuals must not donate for at least 12 months after sex (even if a condom or other protective is used) with another man.

The changes in the guidelines are not expected to alter the excellent safety record of UK blood transfusions, but it remains vitally important that all donors clearly understand and comply with existing guidelines in order to maintain this record.

⁽¹⁾ **Joint U**nited Kingdom Blood Transfusion Services and Health Protection Agency **Professional Advisory** Committee