Joint UKBTS / NIBSC Professional Advisory Committee ([1])

Background Paper to Position Statement No. 10

Methods employed by United Kingdom Blood Transfusion Services to minimise risk of transfusion transmissible infectious agents entering the blood supply

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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.

Background

Patients who need transfusion in the course of their care expect that the blood that they receive will be safe and free from infection. Over the years, as new medical and scientific information comes available, United Kingdom Blood Transfusion Services (UKBTS) have developed and used donor selection criteria that are intended to identify and exclude individuals who, according to scientific (epidemiological) data, have an increased risk of being infected with a transfusion transmissible infection. The risk may relate to an individual's personal behaviour, or result from other causes such as accidents.

Transfusion transmissible infections and sexually transmitted infections

Many infectious agents can be passed on by blood. These are referred to as transfusion transmissible infections. Every blood donation in the UK is tested for infectious agents that are known to be capable of causing serious illness in transfusion recipients. The natural history of these infections generally includes a prolonged asymptomatic phase of infection in the host. The length of the asymptomatic phase determines the period during which an individual who has become infected may appear well and fit to donate blood.

Human Immunodeficiency Virus (HIV), which is one of the infections that have caused most harm to transfusion recipients, is principally sexually transmitted. Other infections known to pose a threat to blood safety may also be sexually transmitted.

A person may become infected with a transfusion transmissible infection by various means that include:

- Receiving a transfusion of a blood product (i.e. blood component or in the past, certain plasma derivatives), a transplant of tissue or an organ transplant.
- Injecting drug use with contaminated needles, syringes, or other equipment.
- The use of non-sterile instruments for tattooing, piercing, acupuncture or for delivering medical care such as the reuse of syringes used for medical injections.
- The exchange of body fluids, usually through sexual intercourse.
- Having an infected mother who passes on the infection during pregnancy, childbirth or infancy
- Spending time in an area where infections may be transmitted by insects

Blood safety policies must take account of the possibility that individuals could be infected asymptomatically with new and emerging infectious agents that are transmissible by

transfusion and for which the risk is unknown. It is worth emphasizing the history of HIV/AIDS (Acquired Immune Deficiency Syndrome). This virus had been spreading in some communities for a number of years before its existence was suspected. By the time it was recognized as a cause of disease it had infected many recipients of blood products and caused a substantial burden of infection in other individuals. These events harmed many patients and have had a profound and long lasting effect on public trust in the Blood Services.

Steps in obtaining safe blood for transfusion

The UKBTS regularly reviews its blood donor selection policies in the light of available information. The UK Departments of Heath receive policy guidance on blood safety matters from the Advisory Committee on Microbiological Safety of Blood, Tissues and Organs (MSBTO).

The Blood Services discharge their duty to provide safe blood and promote safe transfusion therapy by means of the following safety steps:

- Informing the public and potential donors of reasons why some persons are asked not to donate.
- Assessing the suitability of volunteers by questionnaire and interview.
- Testing blood donations for laboratory evidence of infective agents.
- Processing blood to remove or inactivate infective agents.
- Assisting doctors and nurses to use blood safely and effectively in the treatment of their patients.

Information to donors

The first essential of providing safe blood is to ensure that potential blood donors are aware of reasons that could make their blood harmful to a patient who received it. Therefore the Blood Services provide information to the public to inform those who may be at increased risk of having a transfusion transmissible infection that they should not donate blood.

When an individual attends to give blood, the Blood Services must obtain further information (by questionnaire, interview or other means) to identify and exclude, before donation, anyone who may be at increased risk of having a transfusion transmissible infection. The criteria for exclusion of blood donors are intended to:

- Be based on current epidemiological evidence of relevant infective risks.
- Take account of behavioural and environmental factors that are known to contribute to the spread of such pathogens. These factors include receipt of blood and blood products, use of non-sterile injecting equipment, exposure through high-risk sexual behaviours, e.g. sex between men, commercial sex work, sexual contact with people from areas of high prevalence of sexually-transmitted infections.
- Take account of the risk that there may be new and emerging transfusion transmissible infections

- Take account of likely compliance of donors and potential donors with donor selection criteria
- Take account of the performance of routine donation testing procedures and (where relevant) process that reduce infectivity in finished blood components
- Not discriminate in matters other than factors that affect blood (or donor) safety
- Be compliant with European Union and UK law (EU Blood Directives and Blood Safety and Quality Regulations 2005)
- Take due account of relevant international norms and practices
- Take account of the impact on blood supply and the consequences of inadequate supplies for individual and public health.
- Be based on a coherent view of the levels of safety required and the costs that can be accepted to achieve them.

In the UK, all blood donations are tested for:

- Hepatitis B,
- Hepatitis C,
- HIV,
- Human T-cell leukaemia virus (HTLV),
- The bacterium that causes syphilis *(T.pallidum)*.

Testing procedures for these infections are highly effective but there are no procedures that can detect absolutely every infectious donation. This is because in the days immediately after a person is exposed to a virus, the virus may be undetectable by the current screening tests even though the person's blood may be infectious. (This is the so-called window period of early infection).

Blood donations are *not* tested for all infectious agents that are known to be transmitted by blood. In most cases, this is because there is no evidence that they cause disease in transfusion recipients. MSBTO and the UKBTS continue to review new information about such infections and assess the need for any change in procedures to maintain the safety of the blood supply.

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