

**Witness Name: Professor Marc Turner**  
**Statement No.: 1**  
**Dated: 11 February 2011**

**THE PENROSE INQUIRY**

**Witness Statement of Professor Marc Turner**

I, Professor Marc Turner say as follows:-

## **Practice in Scotland in Respect of the Collection, Testing, Processing and Distribution of Blood**

### **Introduction.**

The collection, testing, processing and distribution of blood, tissues and cells in Scotland is the responsibility of the Scottish National Blood Transfusion Service (SNBTS). The organisation is no longer structured on a regional basis but as a set of national functional Directorates which manage blood donor recruitment, testing and manufacturing; tissue and cells; clinical services; research and development; quality management; information systems and other Head Office functions. The Directors of these national services are accountable to the SNBTS National Director and Management Board. SNBTS is itself a Division of the Common Services Agency (CSA), now known as National Services Scotland (NSS). Several centralised functions such as human resource management, finance, estates and IT are provided by NSS. NSS is accountable through its Chief Executive and Board (with attendant governance committees) to the Director-General Health and Chief Executive of the NHS in Scotland.

SNBTS, along with the other UK Blood Services, has developed professional guidelines on issues such as donor selection criteria, microbiological screening and components preparation through the UK Blood Services Joint Professional Advisory Committee and its Standing Advisory Committees [[www.transfusionguidelines.org.uk](http://www.transfusionguidelines.org.uk)].

Ministers and Health Departments of the UK Government and Devolved Administrations take advice from the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO). SaBTO replaced the Committee on the Microbiological Safety of Blood, Tissues and Organs (MSBTO) from the beginning of 2008, but unlike its predecessor its members have been independently appointed through the Appointments Commission. The remit of SaBTO is to provide independent advice to Ministers on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion / transplantation taking into account [*inter alia*] sufficiency of supply, the impact on both donors and recipients and cost effectiveness and takes account of scientific uncertainty and assumptions in reaching its conclusions ([www.dh.gov.uk/ab/SaBTO](http://www.dh.gov.uk/ab/SaBTO)).

SNBTS provides around 250,000 blood components *per annum* as well as a number of tissue and cell products such as bone, tendon, heart valves and haematopoietic stem cells. Standards for blood collection, testing, processing and distribution are embedded in the EU Blood Quality and Safety Directives 2002/98/EC and 2004/33/EC which were transposed into UK legislation through the Blood Safety and Quality Regulations 2005, and 2005/61/EC and 2005/62/EC which were transposed into UK legislation through the Blood Safety and Quality (Amendment) Regulations 2006. These regulations apply to both blood establishments and hospital blood banks both of which are inspected for compliance by the Medicines and Healthcare products Regulatory Agency (MHRA). Tissue and cell products are regulated under the EU Tissues and Cells Directive 2004/23/EC transposed into UK legislation as the Human Tissue (Quality and Safety for Human Application) Regulations 2007 against which tissue and cell Banks are inspected by the Human Tissue Authority.

How and where blood is collected in Scotland, including the use of regular and one off donors, and sessions held within and outwith the transfusion centres.

Scotland has an active donor base of around 180,000 people, who donate through a combination of 5 fixed sites (in Edinburgh, Glasgow, Inverness, Aberdeen and Dundee), mobile donating centres and community sessions. Donor recruitment and administration is managed on a National basis with Donor collection teams based in the 5 regional centres reporting to the National Donor Services Manager. At any one time around 85% of donors are repeat donors, the remainder new or returning after a gap. Anyone between the ages of 17 and 65 is welcome to present as a new donor and people who are established donors can continue to donate up to the age of 70 and beyond provided they remain fit. Donor selection criteria are agreed on a UK-wide basis and are published in the public domain ([www.transfusionguidelines.org.uk](http://www.transfusionguidelines.org.uk)). They are relatively complex and are driven by the dual duty of care to the donor and the recipient whilst protecting sufficiency of supply. Approximately 30% of first-time donors are deferred and the average deferral rate for all donors is currently around 16%. Blood and platelet donations are no longer accepted from donors who themselves might have received a blood transfusion since 1980 (a variant CJD risk reduction measure introduced in 2004).

Donors are non-remunerated volunteers and whilst supply is usually sufficient, SNBTS does experience problems during holiday periods and severe weather particularly in maintaining supplies from the 'universal donor' of O Rhesus D negative blood group. However, SNBTS has not had to declare a shortage of blood requiring emergency appeal since October 2003. Both donors and staff show great dedication to maintaining the blood supply as evidenced during the recent arctic weather conditions.

What happens to a donation once collected?

Most donors give whole blood collections of around 475mls. Normally, whole blood donors can give up to 3 times per annum provided they are well and their haemoglobin levels (tested by hemocue on a capillary sample) meet legal minimum levels. Separate samples are taken at the time of the donation to be tested for blood group (ABO and Rhesus D and sometimes more minor groups) and microbiology markers (syphilis, HIV, HCV, HBV and HTLV by serology and HIV, HBV and HCV by nucleic acid testing). All platelet donations are also tested for bacterial contamination. Discretionary testing is also carried out for a variety of other infectious agents such as malaria or CMV. Testing technology has advanced considerably over the past few decades with enhanced sensitivity and specificity of 3<sup>rd</sup> or 4<sup>th</sup> generation serology assays and the introduction of highly sensitive nucleic acid testing, information technology and automation. Donor samples which are initially reactive on screening are subject to a series of further tests to determine whether the test result is true or a false positive. True positive donors are informed, counselled and deferred from further donation. The residual risks therefore of HBV, HIV, HCV and HTLV transmission through blood transfusion in the UK are now calculated at around 1 in 1.25 million, 1 in 5 million, 1 in 82 million and 1 in 17 million, respectively. It is important to understand however that there are many other viral and bacteriological agents in the general population, many of which are of uncertain or unknown pathogenicity. It is estimated that worldwide there are some 50 – 60 new and emerging infections which may or may not prove to be transfusion transmissible and include known pathogens extending to new countries due to the combination of international travel, globalisation of trade and climate change (such as West Nile Virus

and Chikungunya Fever), and new pathogens such as variant Creutzfeldt Jakob disease and Xenotropic Murine Leukaemia Virus-related Virus (XMRV).

The different components a donation is divided into and the time, place and method(s) of such division.

Blood donations are returned to one of two central processing sites in Scotland - Gartnavel Transfusion Centre in Glasgow and the Lauriston Building in Edinburgh. They are processed within 24hrs to form a red cell concentrate in optimal additive solution (*i.e.* with the majority of the plasma removed) and plasma which may be manufactured into Fresh Frozen Plasma (FFP) or pooled Cryoglobulin precipitate (*cryo*). Alternatively, a different blood pack assembly can be used to produce a red cell concentrate, a buffy coat (which can be used to manufacture pooled buffy coat derived platelets), and plasma. The majority of platelets are however now collected by a process termed apheresis, where the donor is connected to a machine which processes his/her blood in real time, retaining the component of clinical value and returning the rest to the donor. Smaller numbers of bespoke blood components are manufactured for use in specific applications e.g. red cells for intra-uterine or neonatal exchange transfusion. All blood components except Granulocytes are leucodepleted using a filter which reduces the leucocyte (white cell) content by  $10^3$ - $10^4$   $\log_{10}$  as a variant CJD risk reduction measure. A number of components are subjected to secondary processing such as irradiation or washing, and some are sourced from commercial suppliers such as Solvent-Detergent treated plasma for patients undergoing plasma exchange, or from other Blood Services such as imported methylene-blue treated plasma and *cryo* for children under the age of 16 years. Blood components do therefore differ from those produced during the time frame under consideration by the Inquiry in terms of the (reduced) plasma and leucocyte content of red cells, the predominant use of single donor (leucodepleted) platelets, and leucodepleted plasma and cryoprecipitate. UK plasma is no longer used for fractionation because of variant CJD risk.

How, where and for how long the different components of a donation are stored.

Blood components are normally ready for release within around 24-48 hrs from collection on completion of testing and processing. SNBTS IT systems will not permit release of a component for use if testing is incomplete.

Red cell concentrates can be stored for up to 35 days at +4°C, whereas platelet concentrates can only be stored for up to 5 days at +22°C and must be continually agitated. FFP and cryoprecipitate are stored frozen at -30°C or colder for up to 2yrs.

The transfer of packs to individual hospitals

Blood components are distributed to 42 hospital blood banks throughout Scotland and a temperature controlled cold chain is maintained throughout. Five of these are directly managed by SNBTS - the Royal Infirmary of Edinburgh, Aberdeen Royal Infirmary, Raigmore Hospital in Inverness, Gartnavel Hospital in Glasgow and Ninewells Hospital in Dundee. The remainder are managed by the territorial NHS Health Boards. SNBTS also supplies blood to the small number of private hospitals in Scotland. NHS Scotland hospitals are not charged for blood components, private hospitals are charged at cost recovery (not for profit). The SNBTS centres also carry out other specialised transfusion work such as red cell reference serology and histocompatibility and immunogenetics.

The retention, if any, of samples of individual donations.

The Blood Safety and Quality Regulations stipulate that documentation should be archived for 30 years but make no stipulation around donor samples. In fact SNBTS strives to retain documentation and blood samples from donors in perpetuity. The current sample archive goes back to the mid-1980s.

The testing and release of blood by hospital blood banks.

Patients requiring red blood cells require typing for ABO and RhD group, screening for irregular blood group antibodies and a cross-match. Around 2% of the general hospital population have antibodies to the red cells of other people, usually due to previous transfusion or pregnancy, and these people require more complex cross-matching. Transfusion of incompatible blood can have very serious clinical consequences and is

now the most serious hazard associated with transfusion ([www.shotuk.org](http://www.shotuk.org)). ABO compatible platelets are given with no routine requirement for antibody screening or cross-match. Plasma and cryoprecipitate are likewise administered on an ABO compatible basis.

It is important to appreciate that some patients with, for example, a ruptured aneurysm or a placental abruption (in which the placenta detaches from the inside of the uterus during birth) can exsanguinate with alarming speed. Hospital blood banks are staffed on a 24/7 basis to provide very rapid response in the case of an emergency whilst ensuring the compatibility of blood.

#### The indications for transfusion of the different components of blood.

Red cell concentrates are used to enhance the oxygen carrying capacity of a patient in clinical scenarios in which this is compromised either due to reduction in overall circulating blood volume or due to reduction in red blood cell concentration (anaemia) in the context of normal circulating blood volume. Examples of the former are acute haemorrhage due to trauma, surgery, childbirth or rupture of an aortic aneurysm. The latter can be due to chronic low grade blood loss (for example from a gastrointestinal lesion), breakdown of the blood (haemolysis), some forms of nutritional deficiency (such as lack of iron or vitamin B12) or bone marrow failure such as that seen in acute leukaemia. The modern medical and surgical treatment of many conditions such as acute leukaemia or liver transplantation is dependent upon adequate blood component supply.

Platelet concentrates are used to enhance primary haemostasis in patients with low platelet concentration who are either actively bleeding or thought to be at risk of bleeding. Low platelet concentration can occur acutely in the context of major haemorrhage due to the dilutional effect of transfusing large volumes of red cell concentrate and / or due to consumption of platelets due to general activation of the coagulation system (termed disseminated intravascular coagulation). More chronic reduction in platelet concentration can occur due to excess destruction or failure of production by the bone marrow as seen (for example) in leukaemia.

Plasma is used to enhance secondary haemostasis in patients with low coagulation factor concentrations in the context of major haemorrhage (*vide supra*) or in the context of failure of production as seen in liver failure.

Cryoprecipitate is used specifically to enhance fibrinogen levels in the (rare) patients with congenital hypofibrinogenemia and more commonly in patients with acquired hypofibrinogenemia as noted above. In other countries fibrinogen concentrate is used for this purpose.

#### The contra-indications for transfusion.

There are very few absolute contra-indications to transfusion except, of course, refusal of patient consent for the procedure. Some patients with chronic anaemia, renal or cardiac failure are at risk of circulatory overload and may be treated in a different way. Some patients have antibodies to antigens expressed on the surface of other people's red cells and one would normally avoid transfusing incompatible blood whenever possible.

However, in the majority of circumstances blood transfusion represents a clinical judgement on the balance between risk and benefit.

Adverse blood transfusion events are reported through SNBTS and territorial health board clinical governance structures and also to the UK Blood Services' Serious Hazards of Transfusion and to the Medicines and Healthcare products Regulatory Agency.

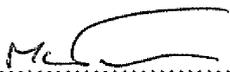
SNBTS has an active Better Blood Transfusion programme to limit errors in the clinical transfusion process through education and training, audit and incident management.

#### The records kept of transfusion in patients' notes and elsewhere.

Under the Blood Safety and Quality Regulations which came into force in November 2005, hospital blood banks maintain records of all transfusions for 30 years allowing full traceability of blood from donor to recipient. Most blood banks in Scotland are approaching 100% compliance with this standard. The patient's medical notes are also supposed to have a written record of the transfusion including the reason for transfusion and the patient's consent.

**Statement of Truth**

I believe that the facts stated in this witness statement are true.

Signed.....  .....

Dated..... 11<sup>th</sup> February 2011.....