Chairman's statement on findings and recommendation

Good morning.

Lord Penrose has asked me to deliver this statement on his behalf.

Before doing so, however, it is right to acknowledge the circumstances which led to the Inquiry. Many people in Scotland were infected with Hepatitis C and HIV by blood transfusion and by treatment with blood products. These viruses cause life-threatening illness. Some of those who became ill following infection with one or both of these viruses have died as a result and others continue to live with serious ill-health.

On behalf of Lord Penrose and the Inquiry team, I would like to offer condolences to those who have lost loved ones in this way, and to express our sympathy to people struggling with the continuing symptoms of viral infection. I would ask you to stand, if it is comfortable for you to do so, and we will observe a minute's silence.

I will now read Lord Penrose's statement.

When I was appointed as Chair of this Inquiry in January 2009, I did not know how many years the Inquiry would take, nor did the loyal members of my team who have remained with the task. Some inquiries relate to a single event. In others, as in this Inquiry, there are multiple factors that evolve over time. This creates a complexity that can only be resolved by critical analysis to define the particular areas for study, followed by ingathering and evaluating evidence with a view to reaching conclusions on matters of fact and opinion. This type of Inquiry can lead to a wide ranging investigation and so it has proved in this case. Both the duration and the cost of Inquiries are often matters of public concern, but until the evidence is ingathered, it is impossible to know the full scope of the task. Terms of reference only intimate the direction of the investigation: it is the evidence which dictates the necessary journey.

Publication of the Final Report takes place following consideration of all the evidence put before me. The evidence was of immense scope, with over 13,000 pages of transcript, in addition to 200 witness statements and 118,000 documents in the Inquiry database. The Final Report builds on the Preliminary Report, which was published in September 2010, and which represented a factual account of relevant events during the principal period, namely 1974 to 1991. That narrative was used as the basis for investigation of particular topics at the oral hearings, between March 2011 and March 2012. In many instances, it has been possible to provide in the Final Report a more detailed factual account

of critical matters. On all issues, the assessment of the questions which arose on the evidence is also now included.

Inevitably, the Final Report is long. How this tragedy happened in the course of NHS treatment was a matter of serious public concern, and it was necessary to investigate many aspects of therapy with blood and blood products to try to understand and explain how it happened. Of equal importance was the need to examine the consequences of infection, both to enable the Inquiry to have a proper understanding of the effects of each virus and also to give those infected an opportunity to be heard.

In short, the means by which an individual acquired infection with HIV or Hepatitis C (or sometimes both) was from the donation of blood by a donor who carried the virus. In the case of blood transfusion, this occurred directly in the course of a transfusion of donated blood required because of illness or injury, or during childbirth or surgery. In the case of haemophilia therapy, it occurred as a result of infusions with blood products, made from large pools of donations and given to remedy the deficiency of clotting factor in a patient's blood. It should be emphasised that blood used in Scotland for transfusion or for the manufacture of blood products was blood donated in Scotland.

Therapy with factor concentrates became widespread from the mid 1970s, with large pool concentrates having become available from commercial companies in the USA in the early part of the decade. Manufacture of such concentrates was also carried out by the NHS, both in Scotland and in England.

It will be apparent from this brief summary that there are a number of stages in the collection and use of blood at which, in theory, it might be possible to prevent the transmission of infection. Ascertaining the accurate factual and scientific detail of therapy with blood and blood products, and of such opportunities as actually existed to prevent infection, formed a major part of the investigation carried out by the Inquiry.

The task of the Inquiry was set by terms of reference, numbering twelve in all. These were both particular and general. The particular part of the task was the requirement to investigate the deaths of four named individuals namely: the Reverend David Black, Mrs Eileen O'Hara, Mr Alexander Black Laing and Mr Victor Tamburrini. These individuals had suffered from Hepatitis C, which they appeared to have acquired through treatment with blood or blood products. The deaths of the Reverend Black and Mrs O'Hara played an important role in the genesis of the Inquiry, as their relatives pursued the right to an independent investigation of their deaths, and were successful in that claim in court proceedings.

The Inquiry found that Mr Black probably acquired Hepatitis C from haemophilia therapy in the 1960s, his infection with the virus being inevitable given his need for haemophilia treatment. Mrs O'Hara acquired Hepatitis C from a blood transfusion during surgery in the 1970s, at which point it was not possible to detect the virus. Mr Laing acquired Hepatitis C in 1990, from a blood transfusion during surgery, but the only tests for Hepatitis C which were then available would not have detected the virus in the donation transfused to him. Mr Tamburrini was found not to have acquired the virus from NHS treatment, the cause of his infection being unknown.

Much effort has been expended in the investigation of the four deaths and it is to be hoped that their relatives obtain some comfort from this work.

The general aspect of the Inquiry's task was the requirement to examine the following:

- the collection of blood by donation, and the preparation and supply of blood products;
- the steps taken to prevent the supply of infected blood and blood products to patients;
- the information provided to patients about the risks of infection through treatment;
- the testing of patients for the presence of viral infection;
- the numbers of patients infected with one or both viruses;
- the steps taken to trace patients who had acquired infection;
- the provision of information and treatment to those who had acquired infection;
- the effects of such infection on individuals and their families.

In relation to the last point, the effects of infection on individuals and their families, the Inquiry heard evidence from the relatives of those whose deaths were being specifically investigated and from others whose loved ones had died of AIDS or Hepatitis C. Evidence was also given by individuals living with HIV and living with Hepatitis C. The testimony of these witnesses was profoundly moving. It greatly enhanced the Inquiry's understanding of the reality of infection. In addition, many others assisted the Inquiry by providing statements of the effects of infection on them personally, or on their relatives. The Inquiry wishes to pay tribute to all who helped in this way.

I will now make brief reference to the specific issues covered in the Final Report.

A priority for the Inquiry was ascertaining the numbers of people who acquired each virus, whether by blood transfusion or through therapy with blood products. In short, it is concluded that 478 people acquired the Hepatitis C virus from

blood product therapy in Scotland, and 2,500 acquired the virus from blood transfusion in Scotland between 1970 and 1991. Sixty patients acquired HIV from therapy with blood products, and 18 from blood transfusion in Scotland.

Another essential part of the work of the Inquiry was to chart the history of each virus, from the time when its existence was first suspected, through its discovery and up to the present day. The state of knowledge in relation to each virus informed the Inquiry's assessment of the actings of doctors and of those responsible for the NHS at various points in the history of events.

Turning to focus specifically on HIV/AIDS, the period during which this serious potential consequence of treatment with blood or blood products was present occurred in the first half of the 1980s. Testing for HIV, whether in donated blood or in treated product, was not possible prior to discovery of the virus. HIV was first identified in Paris in 1983, although international acceptance that this was the virus which caused AIDS did not crystallise until 1984. Although the name HIV was utilised only from 1986, references to the virus in the Report have used that name for reasons of consistency. For the period when HIV was a potential hazard of therapy with blood and blood products, the Inquiry scrutinised the criteria for rejection of donors and the manufacture of blood products. The development of heat treatment of those products sufficient to kill HIV, and the introduction of screening of donations once the virus had been identified was also considered.

Much of the comment made over the years on the topics discussed in the Final Report has reflected strongly-held beliefs. Some commentators believe that more could have been done to prevent infection in particular groups of patients. Careful consideration of the evidence has, however, revealed few respects in which matters should, or more importantly could, have been handled differently.

In relation to HIV/AIDS, it appeared to the Inquiry that, when actions in Scotland were subjected to international comparison, they held up well. Once the risk had emerged, all that could reasonably be done, was done, in the areas of donor selection, heat treatment of blood products and screening of donated blood. Other than by a general cessation of therapy with concentrates, the infection of haemophilia patients with HIV over the period 1980 to 1984 could not have been prevented.

In relation to Hepatitis C, however, one area where it is concluded that more could have been done to prevent the infection of patients is in the delay in the introduction of screening of donated blood for the virus. Because of the significance of this area, I will comment on this in more detail.

The science of the Hepatitis C virus was not understood for many years after its existence had first been postulated in the mid-1970s. At that time, discovery of the Hepatitis A and Hepatitis B viruses had revealed that there must be at least one further virus, since some patients with hepatitis tested negative for type A and type B. This unexplained liver disease was named non-A, non-B Hepatitis. Identification of the causative virus did not take place until 1988, when the Chiron Corporation announced that they had discovered proteins from what became known as the Hepatitis C virus, although details of the discovery were not published until 1989. It became apparent that this virus was the cause of most cases of non-A, non-B Hepatitis associated with blood and blood products.

As with HIV, it was not possible to test donated blood for the virus until the virus had been discovered, although alternatives, involving testing for other suggested indicators of infection, were adopted in some other countries. The first test kits for the Hepatitis C virus only became available from the USA in November 1989, when an export permit was granted and the test kits could therefore be supplied for diagnostic use in other countries.

At the beginning of the 1980s, although there had been medical literature pointing out that concentrates appeared to carry a risk of chronic liver disease, non-A, non-B Hepatitis was still considered by haemophilia clinicians to be a mild form of the disease and not to be a contraindication to therapy with concentrates. There was also a perception that commercial concentrates were more likely to cause hepatitis than NHS products, because of the reliance on paid donor recruitment. The view that a risk/benefit comparison for factor concentrates favoured the continued use of these products was destined to shift in the 1980s, firstly due to the arrival of HIV and, secondly, as appreciation of the potential seriousness of Hepatitis C increased. The period when non-A, non-B Hepatitis was a perceived risk of therapy with blood and blood products lasted from the early 1970s until 1991, when testing of donated blood for the virus was introduced in the UK. For this period, the Inquiry therefore scrutinised the criteria for rejection of donors, the manufacture of blood products and development of heat treatment sufficient to kill the Hepatitis C virus, and the introduction of screening of donations.

It is the view of the Inquiry that a decision by the Advisory Committee on the Virological Safety of Blood to recommend the introduction of screening should have been taken by the middle of May 1990, rather than in November 1990. The Inquiry also examined the issue of why it took 10 months after the decision in principle had been taken for screening actually to start. Although preparations were in hand in the individual transfusion regions in Scotland from the end of November 1990, progress slowed in the first half of 1991. The Gulf War was an unexpected development, and accounted for some of the delay at this time. There were also unresolved issues in England and Wales as to how screening

was to be funded. Against this background, the policy of a uniform start date throughout the UK was not altered, despite some areas being ready to begin considerably earlier than others. The delays over the period March to September 1991 in Scotland were exclusively a result of adherence to this policy.

The Inquiry identifies steps which could have been taken and which could have led to earlier introduction of screening in Scotland. For that to occur would have required the responsible Minister in Scotland to depart from the policy of a uniform start date across the UK. It is not certain that that would have happened, but the Secretary of State for Scotland and his Ministers should have been alerted to the situation by civil servants in order that they could take a decision as to the most appropriate course of action.

In the event, screening across the whole UK did not begin until 1 September 1991 although, within Scotland, it commenced earlier in some regions, due to their involvement in testing of kits or to a desire to have all components tested and ready for 1 September.

The Inquiry also examined in detail evidence about the collection of blood donations from prisoners in Scotland. This has been an area of particular concern for some commentators.

In the 1970s and early 1980s, there was uncertainty about classifying prisoners as 'drug addicts', but there was clear evidence that some prisoners had been convicted of drugs offences and had admitted to having a drug habit. Annual reports were produced to Parliament on prisons and other penal institutions. These included data on the number of prisoners dependent on drugs at the time of admission. Evidence from the period showed a significant, and continuing, increase in drug dependency among prisoners, especially in 1983 and 1984. It was only from the 1981 report onwards that the authorities began to admit to an increasing number of prisoners with a history of drug abuse entering the system.

With regard to the blood supply, the percentage of total blood donations in Scotland collected from prisons fell from 2.38% in 1975 to 0.11% in 1984, the last year in which donations were collected from prisons in Scotland. It appeared to the Inquiry that ceasing to collect prison donations would not have caused an insurmountable problem with the blood supply.

The role of government in the policy of collection from penal institutions was also explored. Documents from the 1970s appeared to indicate that the Home Office favoured blood donation in prisons, as this allowed prisoners to make restitution to society. For Scotland, a former Deputy Chief Medical Officer denied that the Scottish Home and Health Department had considered the issue; decisions would have been left to the Scottish National Blood Transfusion Service Directors.

Witnesses from the Scottish National Blood Transfusion Service agreed that donor selection policy was primarily for the Blood Transfusion Service as transfusion experts.

On the question of whether collection from prisons should have stopped earlier, the Inquiry heard evidence from Scottish National Blood Transfusion Service witnesses and from a leading transfusion expert from Finland. They were all of the view, with the benefit of hindsight, that blood collection from prisons was inadvisable and should have been stopped earlier. The Inquiry concludes that it is unfortunate that the Scottish National Blood Transfusion Service did not consider stopping this practice until 1982. Given the limitations in the information available at that time it is not clear, however, that earlier consideration would have stopped the practice.

The provision of information in relation to the risks of treatment, and in relation to testing patients for viral infection and imparting the results of those tests, was a significant issue. Many people who contacted the Inquiry felt that there had been deficiencies in this area. There was a great deal of dissatisfaction on the part of patients about the information provided to them. Considerable effort was devoted to examining what patients were told, from pronouncements made by government about the general risks of infection, particularly in relation to AIDS, to individual doctor/patient conversations.

The length of time which had passed since the events addressed by this Inquiry was unusually long. We were constantly aware of the need to understand the conditions prevailing at the time and not to judge events by today's standards. This was found to be true especially in relation to the doctor-patient relationship which was acknowledged to be paternalistic at the beginning of the period. This was found to be a combination of genuine lack of information as the understanding of the conditions developed, and the nature of the relationship in which doctors were not used to sharing all information available with patients in the way they do today.

Much of this Inquiry has been about the adverse consequences experienced by those who were infected by HIV/AIDS and or Hepatitis C. The impact on their lives and those of their loved ones has often been devastating, as set out in the Report. I would also comment on the often forgotten suffering of clinical staff, who were to discover that the treatments they thought were beneficial to patients actually caused them to become infected with life-threatening conditions. This is the stuff of nightmares, and they too have suffered, especially when accused of knowing or deliberate attempts to harm patients, of which the Inquiry found no evidence. One doctor with experience of prescribing the new concentrate products which offered so much to patients with haemophilia, only

to discover the threat of AIDS, referred eloquently to 'waves of hope, followed by waves of despair'.

The position in relation to the risks of transmission of HIV and Hepatitis C by blood and blood products has altered significantly since the period investigated by the Inquiry. Heat treatment of factor VIII concentrate from December 1984 and of factor IX from October 1985 ended the transmission of HIV by Scottish NHS blood products. Commercial products were also HIV safe from around that time.

Screening of donated blood for HIV virtually ended the transmission of HIV by blood transfusion from 1985; there remained isolated cases of transmission by blood from donors who carried the virus but had not yet produced antibodies – the problem of donation in the so-called 'window period'. Prevention of infection in the window period relies on donor selection criteria.

The heat treatment of NHS factor IX introduced in Scotland in 1985 also rendered it safe against the Hepatitis C virus. More severe heat treatment of factor VIII introduced in 1987 inactivated the Hepatitis C virus. The introduction of screening of donated blood for the Hepatitis C virus in September 1991 virtually ended its transmission by blood transfusion; as with HIV, there remains a small risk if donors who have been infected donate during the 'window period'.

Blood transfusion continues today. The services publicise their donor selection criteria and are alert to new risks. The treatment of haemophilia is, however, different from that described in the Report; clotting factors are now artificially synthesised to produce drugs that do not carry a risk of viral transmission.

The legacy of the period when viral transmission via blood and blood products was occurring continues to be severe for many people, whether due to ill-health or the loss of a loved one. There is one respect in which the Inquiry can recommend action to prevent suffering from being greater than necessary – the detection of those whose transfusion transmitted infection is still undiagnosed.

The Inquiry therefore recommends:

> That the Scottish Government takes all reasonable steps to offer a Hepatitis C test to everyone in Scotland who had a blood transfusion before September 1991 and who has not been tested for Hepatitis C.

That concludes my remarks on the substance of the Final Report. It remains for me to place on record my gratitude to all those who assisted in the work of the Inquiry.

It would not have been possible to carry out the work of the Inquiry without the assistance of experts, some of whom provided background tuition on the science of the viruses and on the different therapies in the early phase of the Inquiry's work. Others gave evidence at hearings, sometimes bringing expertise from other countries to assist in evaluating the actions of those in Scotland. The Inquiry is grateful to all who assisted in this way. Those who were involved in the care of patients in the NHS in Scotland also assisted the Inquiry. In several instances, witnesses were required to give evidence on multiple occasions. The Inquiry was conscious of the strain placed on these individuals and is appreciative of the efforts they made to assist.

I also wish to express my thanks to everyone in the Inquiry team for their work; the names of all members of that team are set out in the Report. I wish to thank particularly Professor Oliver James, medical assessor to the Inquiry, whose support in exploring and understanding medical matters was of great value. I also wish to mention the core participants and their lawyers, whose cooperation in the running of the hearings permitted the evidence to be led in an efficient and effective manner.

I thank you for your attention this morning. Lord Penrose commends his Final Report to you.

25 March 2015