RLIT0000470



Infected Blood Inquiry

The Report

Overview and Recommendations

- Summary
- Overview
- Lessons to be Learned
- Recommendations
- List of Chapters

1 of 7

20 May 2024
HC 569-I

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Infected Blood Inquiry

The Report

Presented to Parliament pursuant to section 26 of the Inquiries Act 2005.

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1.1 Summary

Patients have received blood or blood products from the NHS since it began in 1948. Many of those treated with them, particularly between 1970 and 1998, died or suffered miserably, and many continue to suffer. This was not as a direct result of the underlying condition or illness that took them to the NHS in the first place, but as a result of the treatment itself. This would be catastrophic enough if they were the only victims. But the treatment has caused others to suffer too – partners, family, children, friends – some by being themselves infected, some by having to watch loved ones die, some by having to give their lives to caring; and almost every one of them, infected and affected, suffering in almost every aspect of their lives.

I have to report a catalogue of failures which caused this to happen. Each on its own is serious. Taken together they are a calamity. Lord Winston famously called these events "*the worst treatment disaster in the history of the NHS*". I have to report that it could largely, though not entirely, have been avoided. And I have to report that it should have been.

I have also to report systemic, collective and individual failures to deal ethically, appropriately, and quickly, with the risk of infections being transmitted in blood, with the infections when the risk materialised, and with the consequences for thousands of families.

There were around 4,000 to 6,000 people with bleeding disorders in the UK at any one time. Around 1,250 were infected with HIV. The best estimate is that this included 380 children. Almost all infected with HIV were also infected with Hepatitis C and some with Hepatitis B and Hepatitis D as well. Three quarters of these 1,250 adults and children have died. A larger number still (between 2,400 and 5,000 people with bleeding disorders) who were not infected by HIV received blood products infected with one or more hepatitis viruses, and developed chronic Hepatitis C.

People who were infected by transfusions, rather than by blood products, were infected in even greater numbers. Between 80 and 100 were infected with HIV after a blood transfusion. Approximately 26,800 were infected with Hepatitis C after a blood transfusion, often linked with childbirth or surgery, but also from transfusions to treat thalassemia, sickle disease, or leukaemia, or tissue transfer. It has not been possible to estimate the number of people infected with chronic Hepatitis B due to limited data.

A significant number of people who received blood products and some who received blood transfusions have since been told that they are at an increased risk of vCJD, and should alert their medical practitioner or dentist prior to treatment. This in turn has compromised their access to that treatment.

The scale of what happened is horrifying. The most accurate estimate is that more than 3,000 deaths are attributable to infected blood, blood products and tissue.

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To understand the failings, it is necessary to set out the reasoning behind my conclusions in some detail. They need to be explained and set in context. That will follow in the chapters of this Report.

What follows makes for hard reading. For now, though, the headline points are these:

The principal infections considered by the Inquiry are Hepatitis (B and C) and HIV. The transmission of vCJD is also considered.

It was well known from at least the early 1940s, and became clear beyond doubt in the mid-1940s, that blood transfusions or the use of plasma could transmit "serum hepatitis". It was known that this could be fatal, or lead to serious long-term disease, liver failure, cirrhosis and cancer. The virus responsible for Hepatitis B was identified by the early 1970s. The virus responsible for Hepatitis C was not identified until 1988, but it was apparent at least from the mid 1970s that non-A non-B Hepatitis (as it was known prior to 1988) was responsible for the majority of post-transfusion hepatitis cases and that just as Hepatitis B could have serious long-term consequences, so too might non-A non-B Hepatitis.

Awareness of AIDS began in 1981, and it was apparent by mid 1982 that whatever was causing AIDS might be transmissible by blood and blood products.

What follows is **not** intended as a comprehensive account; for that the Report should be read in full. Set out below are some of the key failings.

Infections, leading to deaths, illness and suffering were caused needlessly to **people with bleeding disorders** by:

- Failures in the licensing regime – in particular (but not only) by allowing the importation and distribution from 1973 of blood products (Factor 8 concentrates) made in the US or Austria which carried a high risk of causing hepatitis, and were understood to be less safe than current domestic treatments for bleeding disorders.
- A failure to ensure a sufficient supply of Factor 8 concentrates from the plasma of UK donors to meet reasonable foreseeable demand without the need to import any products from abroad (ie failure to achieve "self-sufficiency"). In part this arose from the inept, fragmented system by which the blood services of England and Wales operated; and in larger part because (a) the fractionation facilities in England ("BPL") were in great need of redevelopment, but this was badly delayed; and (b) new fractionation facilities in Scotland ("PFC") which had been designed and funded to produce blood products for the North of England as well as Scotland were not utilised for that purpose.
- Increasing the size of the pools used to manufacture factor concentrates (both 8 and 9) in the UK, although it was well known that this would markedly increase the risks of viral transmission.
- Whilst presiding over this increase, failing to encourage and finance research into methods of viral inactivation of factor concentrates (both 8 and 9).

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- By failing to do so, failing to achieve the total or at least partial viral inactivation of hepatitis viruses (in domestic production) by around 1980/1981 which would probably have resulted from such research if it had been pursued earlier (no new technology was needed). Viral inactivation could have prevented many infections (hepatitis and later HIV) and deaths.
- Also, by failing to do so, failing to provide factor concentrates which would with rare exceptions have been free of active HIV virus.
- Failing to ensure sufficiently careful and rigorous donor selection and screening (and allowing continued collection of blood from prisons).
- Adopting an attitude of denial towards the risks of treatment with factor concentrates.
- Treating people with ever increasing volumes of concentrates despite the increased risks of viral transmission.
- Failing to respond to serious risks of infection by making adjustments to treatment regimes to make them safer: such adjustments might have included greater use of cryoprecipitate (and, on a temporary basis, fresh frozen plasma) and of DDAVP, taking a more conservative approach to treatment, reducing the amount of home treatment, avoiding prophylactic treatment, adopting batch dedication policies, and deferring elective or non-urgent surgery.
- Treating children at Treloar's with multiple, riskier, commercial concentrates, prophylactically and as objects for research.
- Treating children unnecessarily with concentrates (especially commercial ones) rather than choosing safer treatments.
- Failing to provide advice, guidance and information to clinicians to ensure that safer treatment practices were adopted.
- Adopting the wrong approach by looking for conclusive proof of what was the cause of AIDS rather than asking if there was a real risk that blood might transmit it.
- Falsely reassuring the public and patients – that blood did not carry AIDS; that the risk of AIDS for people with bleeding disorders was small; and that non-A non-B Hepatitis (Hepatitis C) was relatively mild and inconsequential.
- Taking a decision in July 1983 not to suspend the continued importation of commercially produced blood products.
- Having made that decision, failing to keep it under review.
- Failing to tell people of the risks of treatment and of available alternative treatments, thus treating them without their informed consent.

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- Conducting research on people without, in many cases, telling them (or in the case of children, their parents) beforehand, or informing them of the risks and whether the research would enhance their treatment or primarily benefit others, and without obtaining properly informed consent.
- In some cases, failing to tell people that they were infected and thereby denying them the opportunity to control the progression of their own illness more effectively and to prevent the spread of infection to others close to them.

Infections, leading to deaths, illness and suffering were caused needlessly to **people who received blood transfusions** by:

- Failing to ensure sufficiently careful and rigorous donor selection and screening (and allowing continued collection of blood from prisons).
- Failing to take all reasonable steps to deter high risk donors, in particular by delay in the production of AIDS donor leaflets and failing to ensure their effective distribution and wording.
- Missing the opportunity to screen out some high risk donors by surrogate testing as a response to the risk of HIV transmission.
- Failing to introduce surrogate testing for anti-HBC and ALT when it could and should reasonably have been introduced to reduce transmission of non – A non – B Hepatitis (Hepatitis C).
- Delaying universal screening of blood donations for the presence of HTLV-3 (HIV) despite it being urgent (it was a public emergency) to begin this.
- Delaying universal screening of blood donations for the presence of Hepatitis C.
- In particular, delaying screening for HIV and or Hepatitis C by unreasonably requiring, or if required delaying, an evaluation of different tests (which would have been reasonably effective) to see which was best (making the best the enemy of the merely good).
- Failing to warn patients of the risks of transfusion at least in situations where they reasonably had a choice.
- Giving too many transfusions when they were not clinically needed, or when less would have sufficed, or over-riding a patient's wish not to be transfused.
- Failing to make maximum use of alternatives to transfusion.
- Failing to take sufficient and timely steps to ensure the better use of blood by hospitals and clinicians.
- Failures of record keeping to enable each unit of blood to be traced from donation to use in treatment.

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- Failing to carry out any lookback at the time universal screening of donations for Hepatitis C was introduced.
- Delaying telling patients they had Hepatitis C, or should be tested for it, thereby preventing the individual from controlling its worst effects, seeking timely treatment, and limiting the spread to others.

So far as **both people with bleeding disorders and people receiving transfusions** were concerned, clinicians and the health service in particular failed them[1] by:

- Being complacent about the risks of non-A non-B Hepatitis (Hepatitis C) and being slow to respond to the risks of AIDS.
- Being too slow to establish an expert advisory committee on AIDS and too slow to establish an overarching body with responsibility for blood safety.
- Failing to tell people of the risks of treatment or transfusions, and failing to seek their consent on a properly informed basis.
- Failing to offer people reasonable alternatives to treatment or transfusions.
- In far too many cases, using insensitive and inappropriate means to tell people of their infections.
- Testing samples (which in most cases patients did not know were to be retained for the purpose) without their knowledge or consent.
- Delaying informing people of their infections by weeks, months and sometimes years.
- Too often compromising patient confidentiality and adding to stigma by prominent indications that these patients were a high risk to others.
- Failures of record-keeping, such that many people's medical records have been destroyed or lost or are materially incomplete.

So far as **all the people who were infected and affected were (and are) concerned**, the harms done to them were compounded by:

- Repeated and ongoing failures to acknowledge that they should not have been infected.
- The absence of any meaningful apology and redress.
- Repeated use of inaccurate, misleading and defensive lines to take which cruelly told people that they had received the best treatment available.

1 I acknowledge that many clinicians devoted a life to serving medicine, and there may have been a range of reasons why people allowed these failings to happen or caused them by their own actions. This sadly does not diminish the appalling nature of what occurred.

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- A lack of openness, transparency and candour, shown by the NHS and government, such that the truth has been hidden for decades.
- Deliberate destruction of some documents and the loss of others.
- Failing to provide psychological support and counselling to people who had been infected and their families.
- Difficulties and delays in accessing appropriate specialist treatment and monitoring for Hepatitis C.
- Failures of palliative care for those dying in consequence of infection with HIV or hepatitis.
- Refusal to provide compensation (on the ground there had been no fault).
- Long delays in agreeing to provide even ex gratia financial support.
- Establishing ex gratia payment schemes which were underfunded and did not function in the best interests of those infected and affected.
- Failing to reform those ex gratia schemes promptly and failing to ensure that the national schemes which replaced them offered parity of support across the UK.
- Responding to calls for a public inquiry by producing flawed, incomplete and unfair internal reports.
- Failing, until 2017, to decide to establish a public inquiry.
- Failing as yet to respond to many of the recommendations of Sir Robert Francis KC, and those of this Inquiry in its second interim report.

The chapters that follow make clear who is responsible for each of these failings, though in general I can say that responsibility for much lies with successive governments, even though others may share some of it.

It will be astonishing to anyone who reads this Report that these events could have happened in the UK. It may also be surprising that the questions why so many deaths and infections occurred have not had answers before now. Those answers cannot be as complete as they might have been thirty years ago, and I acknowledge that despite the vast number of pages of documents which the Inquiry has examined, some questions must remain unanswered. Any errors, any omissions, any shortcomings are mine alone.

I have no doubt however that, despite the difficulties of time and scale, the conclusion that wrongs were done on individual, collective and systemic levels is fully justified by the pages that follow; that a level of suffering which it is difficult to comprehend, still less understand, has been caused to so many, and that this harm has, for those who survived long enough to face it and for those who, infected and affected, are now able to read this, been compounded by the reaction of the government, NHS bodies, other public bodies, the medical professions and others as described in the Report.

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1.3 Overview

Introduction

The scope of this Inquiry has been exceptionally wide in four particular ways:

(1) the **scale** of the harm: the number of those infected amounts to tens of thousands, many of whom have died (and continue to die);

(2) the **geographical scope**, encompassing as it does all four nations within the United Kingdom;

(3) the **timeframe**: since the NHS began, exploring over five decades of decision-making, action and inaction;

(4) the **remit**, which has been to examine not only the events which caused or contributed to the infection of so many people ("*what happened and why*"?) but also the response of government, the NHS and others in the decades following the transmission of infection, and how that response has compounded the harms already inflicted.

I shall say a little more in this Introduction about each of these aspects.

As to **scale**, more than 3,000 deaths are attributable to infected blood and blood products. Around 380 children with bleeding disorders were infected with HIV, a third of the 1,250 people with bleeding disorders infected with HIV, with the majority also being coinfected with Hepatitis C and some with Hepatitis B and other infections as well. Three quarters of those with bleeding disorders who were infected with HIV have died. Between 80 and possibly up to about 100 people were infected with HIV through transfusions. About 85% of those have died.

Around 26,800 people were infected with Hepatitis C through blood transfusions between 1970 and 1991, of whom about 22,000 were chronically infected beyond the initial six months, with 2,700 surviving to the end of 2019. Between 2,400 and 5,000 people with bleeding disorders were infected with Hepatitis C without being infected with HIV, but sometimes with Hepatitis B and other infections as well. There is insufficient evidence to estimate the numbers of people infected with Hepatitis B through blood and blood products. There were five recorded cases of confirmed or probable blood-borne variant Creutzfeldt-Jakob disease ("vCJD") infections. Three were symptomatic and all have died.[2]

It is important not to lose sight of the fact that behind those statistics are individuals, each with a story of suffering and loss that is personal to them. People infected and affected

2 See Statistics Expert Panel Transcript 9 November 2022 pp32-197 INQY1000258, the Expert Reports to the Infected Blood Inquiry: Statistics Group EXPG0000049 and EXPG0000132, and Note by Counsel to the Inquiry on the number of children with bleeding disorders who were infected with HIV INQY0000387

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have told powerful stories of pain, sickness and loss, of lives damaged and destroyed, unrecognisable from before their infection and unrecognisable from all their hopes and dreams for their lives. Each person who has felt able to give evidence and each person who has supported them and continues to provide support and solidarity through the ongoing suffering and loss deserves respect. This account builds on their accounts, taken together with the evidence and input of all others who have participated in this Inquiry: participants not only in name but in a collective endeavour.

As to **geographical remit**, this Inquiry has sought to examine, as far as possible, relevant decision-making in England, Scotland, Wales and Northern Ireland. It is right to note, however, that many of the decisions and actions which this Report examines were taken in Westminster, by the UK government. The available evidence suggests that for the most part, and certainly in the period prior to legislative and executive devolution, Wales and Northern Ireland (and to a lesser extent Scotland) followed the path charted by the Department of Health.[3] That is inevitably reflected in the focus of some of the chapters in this Report.

The **timeframe** examined by this Report is extensive, covering over five decades of decision-making.[4] That has brought with it additional challenges, as has the fact that an inquiry did not take place at a much earlier stage.[5] Documents that existed years ago no longer exist.[6] There are individuals, from government, from the medical profession, from pharmaceutical companies and elsewhere, who played an important part in events, from whom the Inquiry has been unable to hear, either because they are dead or because of impairments of health or age. Some of those who did give evidence had little independent memory of events, save to the extent that they were prompted by contemporaneous documents. Notwithstanding these challenges it has been possible in this Report to reach conclusions on the central questions raised by the Inquiry's Terms of Reference.

The broad **remit** of the Inquiry is reflected in the structure of this Report. The Report begins with an examination of impact, through a narrative of the experiences of people who were infected and affected,[7] and with an analysis of events at Treloar's, which both illustrates and highlights the nature of, and many of the reasons for, the national treatment disaster which was infected blood.[8] The Report then looks at the question of "What happened and why?"

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3 The Department was the Department of Health and Social Security ("DHSS") until July 1988, at which point it became the Department of Health, before being renamed the Department of Health and Social Care ("DHSC") in 2018.

4 Whilst the primary focus of the Inquiry has been events from 1970 onwards, there are some areas where it has been important to consider earlier events (see for example the chapters on *Knowledge of Risk Before 1970* and *Self-Sufficiency*). That is entirely consistent with the Inquiry's Terms of Reference: the phrase "*in particular since 1970*" makes clear that events prior to 1970 can and should be examined where relevant.

5 The failure to hold an inquiry earlier is addressed in the chapter on *Delay in Holding a Public Inquiry*.

6 The circumstances in which some of those documents have disappeared are considered in the chapter on *Document Destruction*.

7 See the chapter on *People's Experiences*.

8 See the chapter on *Treloar's*.

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through an examination of the actions and inactions of governments,[9] the blood transfusion services,[10] haemophilia centres and their directors,[11] and pharmaceutical companies,[12] and an examination of transfusion practices.[13] It considers specific areas where opportunities to reduce risk were missed, such as the failure to achieve self-sufficiency in England and Wales,[14] the failure to introduce surrogate screening for either HIV or Hepatitis C,[15] and the delays in introducing screening for HIV and for Hepatitis C.[16]

The Report then turns to consider how governments, the NHS and others responded to the infections of so many people. Amongst other matters it looks at the refusal over decades to provide compensation and the decision-making that led (after delays) to agreements in principle to establish ex gratia payment schemes;[17] the ways in which those schemes (the Alliance House Organisations) operated and their replacement with national support schemes;[18] difficulties in accessing appropriate treatment and care;[19] problems created by missing or incomplete or inaccurate medical records;[20] and the defensiveness of government, through its publication of a self-sufficiency chronology, its repeated use of indefensible lines to take and its refusal over decades to hold a public inquiry.[21]

The picture that emerges overall from the findings in this Report is one in which people have been failed, not once but repeatedly, by their doctors, by the bodies (NHS and other) responsible for the safety of their treatment, and by their governments. Six particular themes are prominent.

The first is the failure to make patient safety the paramount focus of decision-making and of action – whether it be decisions by individual clinicians, haemophilia centres or hospitals, or decisions taken at a regional level by transfusion centres, or decisions taken at a national level by governments.

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9 See for example the chapters on *Regulation of Commercial Factor Concentrates* and *Role of Government: Response to Risk*, although the role of government (in particular the role of the Department of Health and Social Security/Department of Health) appears in most chapters in some form or another.

10 See the chapters on *Blood Services*.

11 See the chapter on *Haemophilia Centres: Policies and Practice*.

12 See the chapter on *Pharmaceutical Companies*.

13 See the chapter on *Blood Transfusion: Clinical Practice*.

14 See the chapter on *Self-Sufficiency*.

15 See the chapters on *Hepatitis C Surrogate Screening* and *HIV Surrogate Screening*.

16 See the chapters on *HIV Screening* and *Hepatitis C Screening*.

17 See the chapters on *The Initial Government Response 1985-1988, Government Response to HIV Infections through Blood or Tissue Transfer, Government Response to Hepatitis C Infections* and *Government Response to the Archer Inquiry*, as well as *The Government's Response to Calls for Compensation 2020-2024*.

18 See the chapters on *Macfarlane Trust*, *Eileen Trust*, *Skipton Fund*, *Caxton Foundation* and *National Support Schemes*.

19 See the chapter on *Access to Treatment*.

20 See the chapter on *Medical Records*.

21 See the chapters on *Self-Sufficiency Report*, *Lines to Take*, *Delay in Holding a Public Inquiry*, and *Accountability in the Absence of a Public Inquiry* as well as *Commentary on the Government Response*.

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The second theme is the slow and protracted nature of much of the decision-making examined in this Report: by way of example, the length of time taken for haemophilia centres to adapt treatment policies and practices, or the length of time taken by clinicians and NHS organisations to recognise the need for better transfusion practice, or the delays with regard to AIDS donor leaflets, or the delayed decision-making by government regarding the introduction of Hepatitis C screening of blood donations and the delay in deciding to undertake a lookback.

The third is the profoundly unethical lack of respect for individual patient autonomy, which will be most starkly apparent to readers from the chapters on *People's Experiences* and *Treloar's* and from parts of the chapters on *Haemophilia Centres: Policies and Practice* and *Blood Transfusion: Clinical Practice.*

The fourth theme, closely related to the third, speaks of the dangers of clinical freedom. Clinical freedom is the idea that doctors should be free to do what they believe to be right for an individual patient. But the danger of clinical freedom in the context of infected blood and blood products is that it allowed doctors to follow unsafe treatment policies and practices (such as administering commercial factor concentrates to young children, or giving unnecessary transfusions to postpartum women), and it meant that others (in particular the health departments and Chief Medical Officers) held back from providing advice, guidance or information in the misguided belief that this would interfere with clinical freedom.

The fifth theme is that of institutional defensiveness, from the NHS and in particular from government, compounded by groupthink amongst civil servants and ministers, and a lack of transparency and candour. These factors drove the response of government over the decades.

The institutional defensiveness identified above is damaging to the public interest. But the sixth principal theme that emerges from this Report is the damage that was done by that defensiveness and the accompanying lack of transparency and candour to the very people whose lives had been destroyed by infection. The harms already done to them were compounded by the refusal to accept responsibility and offer accountability, the refusal to give the answers that people fervently sought, the refusal to provide compensation, leaving people struggling and in desperate circumstances, the thoughtless repetition of unjustified and misleading lines to take, and the lack of any real recognition and of any meaningful apology.

The purpose of this Overview is to provide a chapter-by-chapter summary to help readers navigate the Report.[22] Some chapters lend themselves relatively easily to a neat summary; others tell a more multifactorial story, sometimes spanning decades, and are harder to compress. The summaries below are not intended as a substitute for reading the individual chapters, but will perhaps help readers to identify the chapters that are of the most

22 The summaries in the Overview contain some direct quotations from documents, statements and transcripts. Readers will find the references for each such quotation in the main chapters of the Report, rather than in the summaries below.

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importance or relevance to them. Where conclusions are expressed in a chapter they may be more nuanced than appears from the short summary given here, and the context against which they are drawn should be read if the conclusions are to be fully appreciated.

In the course of some of the *Overview*, abbreviations or acronyms are used: such as UKHCDO (UK Haemophilia Centre Directors' Organisation) or ACVSB (Advisory Committee on the Virological Safety of Blood). They are explained when they first appear in the text and used for brevity thereafter – but a glossary and brief chronology come at the end, for ease of reference.

Volume 2

2.1 People's Experiences

This chapter considers the impact of infected blood and blood products on people who have been infected and affected.

The Inquiry received over four thousand statements, each of which has been read carefully. The stories shared so powerfully in each statement and in the two intermediaries' reports were amplified, illustrated and confirmed by the oral evidence which the Inquiry heard. Although it is not possible to refer to each and every statement or transcript, every individual story has made a valuable contribution to the findings, conclusions and recommendations of this Report.

For many people this was the first time they had spoken about their ordeal, and I pay tribute to all those who felt able to do so – in a written statement; in private to an intermediary; in the hearing room; or by video link. From so many different perspectives and backgrounds they have painted such a compelling overall picture that, taken together, some conclusions have become overwhelmingly obvious.

The chapter explores people's experiences through the following themes:

- communication of risk
- communication of diagnosis with HIV, Hepatitis C and/or Hepatitis B
- the effects of infection with HIV
  - the physical effects
  - the mental health effects
  - the impact of treatment
- the effects of infection with Hepatitis C
  - the physical effects
  - the mental health effects

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  - the impact of treatment
- the effects of infection with Hepatitis B
  - the physical effects
  - the mental health effects
- vCJD notifications
- other infections
- the impact of lack of accountability
- bereavement
  - the deaths of partners
  - the deaths of parents
  - the deaths of children
  - the deaths of siblings
  - burial arrangements
  - the impact of stigma
  - lack of support
  - permanence of loss
  - misplaced feelings of guilt
  - family breakdown
  - families with bleeding disorders
- the impact on family and social life
- the impact of caring
- marriage and relationships
- family, childbirth and being unable to have children
- fear of infecting others
- stigma associated with HIV
- stigma associated with hepatitis
- wider impacts:
  - impact on education

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  - impact on work
  - finance
  - housing
  - travel
  - former blood donors
- wider impacts on medical treatment
  - dental care
  - loss of trust in the medical profession
  - counselling and psychological support
- consent and communication.

This chapter is, however, no substitute for reading the written statements and intermediaries' reports or for watching and listening to the oral evidence from people who are infected or affected. Doing so now brings with it an additional poignancy, because some of those who gave such powerful written and oral testimony to the Inquiry have since died.

2.2 Treloar's

The focus of this chapter is the tragedy that was Treloar's. The Inquiry understands that only around 30 of the 122 pupils with haemophilia who attended the school between 1970 and 1987 survive. What happened at Treloar's both illustrates and highlights the nature of, and many of the reasons for, the national treatment disaster which was infected blood.

Research was a fundamental part of the activities of the haemophilia centre at Alton, beginning in the 1960s and continuing into the late 1970s – when the haemophilia centre relocated to the school – and the 1980s. The reasons for an intense focus on research are not difficult to understand. Dr Rosemary Biggs, a central figure in haemophilia care at the time, observed in December 1970 that "*the collection of 49 haemophilic patients at the Alton School makes this a unique opportunity to study the disease.*" Each year a number of studies were in progress: research was conducted at Treloar's to an extent which appears unparalleled elsewhere.

Of particular note were three sets of research at Treloar's: prophylactic therapy; hepatitis; and appropriate dosage regimes for different target joints. Three prophylaxis trials, involving injections of increasing frequency, are described in the chapter. The incidence of hepatitis was studied from 1970, with a prospective study in 1975 of hepatitis associated with the use of factor concentrates. The dosage trial involved some pupils being given lower doses than would otherwise have been thought appropriate for their treatment, which risked those doses being ineffective.

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The few surviving former pupils who had been among the research subjects in the trials gave a consistent account that there had been no meaningful consultation with their parents, or with them. The risks of hepatitis from treatment, and the increased risks from the use of commercial concentrates and from treatment on a prophylactic basis, were not explained.

The approach to treatment at Treloar's involved a deliberately heavy use of concentrates, in which different products – mainly commercial – was used indiscriminately (except when it was thought necessary for some research study to focus upon a particular type of concentrate). Most individual patients received multiple types of concentrate and by 1978 cryoprecipitate use had declined almost to nil. Dr Anthony Aronstam, the director of the haemophilia centre from 1977, recognised that the usage at Treloar's was high: in 1978 he referred to the routine use of prophylaxis "*in many clinical situations*" and described having secured "*all the material we need for our admittedly enthusiastic programme*"; later he said expressly that his policy was that bleeds should be "*treated vigorously*" where they involved adolescents. There was neither consistency as to the source or brand of the concentrate used, nor the adoption of any approach which sought to minimise the exposure of the pupil to the risk of receiving an infected dose. It was not until after 1984 (when it had become clear that many people with haemophilia had been infected with HIV, and potentially with AIDS, in consequence of repeated treatment with blood products) that the amount of Factor 8 given per transfusion reduced "*significantly*".

There is no doubt that the risks of viruses, in particular hepatitis, being transmitted through blood or blood products were well known to Treloar's clinicians. Moreover, practice at Treloar's shows that the clinical staff were well aware that their heavy use of commercial concentrate risked causing AIDS. From as early as February 1983, individual records show that pupils were examined for any signs of the "stigmata of AIDS". The records showed results thought possibly significant in relation to AIDS. Yet neither this, nor the recommendations of the UKHCDO following a meeting of reference centre directors in May 1983, nor the knowledge in later 1983 that people who had had commercial concentrate had contracted AIDS and that at least one had died, led to **any** change in treatment, or approach. Save for switching to heat-treated commercial concentrate in November 1984 (although unheat-treated NHS concentrate continued to be used) Dr Aronstam did little to reduce the risk of AIDS. He did not even tell others about the risk until it became inescapable. When Professor Arthur Bloom informed him that one of the pupils had received some of the same batch as the Cardiff patient who had developed AIDS, he identified that the boy was one of fifteen boys who had reversed T-cell ratios. This was an indicator of possible problems with their immune system. But this knowledge does not seem to have caused him noticeably to adjust his treatment policies. The prophylaxis programme continued – indeed, as late as December 1984, a pupil had been on prophylaxis "*almost the whole length of this term*", using unheated concentrates until that November, and it was proposed that during the Christmas holidays this intensive use of concentrate be continued.

There was no general system or process for telling parents of the risks of viral infection. Nor were pupils told of those risks. Parents were not given details, or even core information,

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about their children's treatment at Treloar's for haemophilia. Little truly informative was said to pupils and Dr Aronstam played down the risks both of hepatitis and AIDS. None of the boys were told that they were being tested for HIV (when the tests became available) nor that before that they had been checked to see whether they had any signs that they were developing AIDS. When it emerged in late 1984 that there were infections, Treloar's clinicians told the boys that it had been an unavoidable accident.

There was no consistent practice in telling individuals that they had been infected with HIV. Some were never told by the school and only found out from their home doctor. Others were told in groups: "*the staff went around the room saying 'YES, NO, YES, NO' to indicate whether they were HIV positive.*" Neither the headmaster nor the housemaster was involved in telling any pupil of his infection. If and when pupils were first told at the school that they had tested positive, they had no supporting presence. Their parents were not present. Nor was there any structured facility for giving support after that.

A large percentage (probably about 70%) of those pupils with haemophilia who attended Treloar's School died in consequence of their infection; of those who were pupils in the early 1980s, a great majority were infected with HIV; and very few, whether suffering from HIV or not, avoided being infected with hepatitis.

What occurred was not an inevitable course of events. It was not a tragic accident, in the sense of something that was unavoidable. It was not the result of an unknown against which steps could not be taken effectively.

In summary, as regards the treatment of pupils at Treloar's:

- The pupils were often regarded as objects for research, rather than first and foremost as children whose treatment should be firmly focused on their individual best interests alone. This was unethical and wrong.
- There were multiple research projects during the 1970s to early 1980s where informed consent for participation was neither sought nor given. This was unethical and wrong.
- The risks of treatment, including viral risks, were well known to the clinicians involved in decision-making regarding haemophilia treatment at Treloar's. Those risks were not explained to parents or to pupils, such that pupils were treated in the absence of informed consent. This was unethical and wrong.
- Those responsible for treatment adopted treatment policies and practices (including the widespread use of commercial concentrates, prophylaxis and treating individual boys with multiple different products and batches) which had the effect of increasing the risks of viral infection. This was wrong.
- Those responsible for treatment failed to respond to the risk of AIDS by making any significant changes to the treatment regimes. This was wrong.

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- Tests were undertaken on pupils, both in relation to liver function and, in 1984-85, in relation to HIV, without the knowledge or consent of pupils or parents. This was unethical and wrong.
- Some pupils and parents were never informed by Treloar's that they had tested positive for HIV. This was unconscionable.
- The way in which other pupils were informed of the fact that they had tested positive was unsupportive, insensitive and wrong.
- Insufficient support was provided to pupils after diagnosis. This too was wrong.

The outcome at Treloar's of this combination of events, for these reasons, demonstrates in microcosm much of what went wrong in the way in which many haemophilia clinicians treated their patients across the UK.

Volume 3 What happened and why?

This volume begins with five chapters about basic concepts:[23]

3.1 Risk

3.2 Consent

3.3 Blood and Transfusion

3.4 Nature of the Diseases

3.5 Treatment of Bleeding Disorders

3.6 – 3.8 Knowledge

These three chapters examine what was, or should have been, known about the risks of hepatitis and HIV at the time of the events under examination.[24] Set out below is a selection of the materials which are referred to in the chapters.

3.6 Knowledge of Risk Before 1970

Well before the inception of the NHS in 1948, scientists, state authorities and medical practitioners in the field knew that after any transfusion of blood or plasma there was a risk that hepatitis would develop. Knowledge of this "post-transfusion hepatitis" became well established during the Second World War at the latest, in particular after an epidemic of hepatitis amongst US and Allied troops inoculated against yellow fever.

23 These chapters on basic concepts are not summarised in this Overview.

24 This is an important point. These chapters on knowledge look at the information that was available **at the time** to clinicians, civil servants and ministers, pharmaceutical companies, NHS bodies and others with a role in ensuring the safety of treatment.

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At least by the time the NHS was established in 1948 it was known that:

- transfusions carried a risk of post-transfusion hepatitis
- this was often a delayed complication
- hepatitis was transmitted by a virus
- it could be fatal
- people transfused with plasma from a large pool of donations (up to 500 at that time) experienced higher rates of jaundice than people receiving single donations of whole blood.

Although serum hepatitis (as post-transfusion hepatitis was often called) was known to be caused by a viral infection, the viruses which caused it were not identified for many years. But it was not necessary to know the precise microbiological configuration of the viruses to understand that post-transfusion hepatitis could have serious consequences. This was well understood, whether the transfusion was of whole blood or plasma. In 1946 Dr William d'A Maycock noted that users of plasma "*must be told that it is a potentially lethal fluid which should be used with discretion.*"

Though in many cases the effects of serum hepatitis might appear short-lived, it was known both by scientists and in government that in other cases chronic infection – and possibly fatal liver failure or cancer – would follow. A Scottish Home and Health Department ("SHHD") memo in December 1964 said that "*All blood for transfusion must be regarded as potentially contaminated … The most important transmissible disease in this country is homologous serum hepatitis … No transfusion should be undertaken unless the benefits outweigh the risk of hepatitis.*"

In 1952, the World Health Organization ("WHO") reported serum hepatitis as a serious problem and suggested five measures to reduce the risks: selection of donors, control of pool size, treatment of plasma, the maintenance of proper records, and reporting. If these measures had been taken in relation to the supply of blood and blood products in the UK, it is reasonable to believe that a significant part of the harm on which this Inquiry is focused could have been prevented.

In 1965, researchers identified an antigen which was associated with serum hepatitis. This led to a virus being isolated in 1967, termed Hepatitis B. By around 1970, there was finally a test to screen blood for the presence of Hepatitis B, although it was not sensitive enough to identify every case of infection in the blood. Testing of donations was introduced in regional transfusion centres during 1971 and 1972; testing of plasma for fractionation was introduced in late 1971.

In Germany, from 1965 onwards, all blood donated for possible transfusion was tested to see if it contained abnormally high levels of a liver enzyme, alanine transaminase ("ALT"). Italy also introduced ALT testing of donations with effect from 1970. This increased the protection

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against infections which might cause hepatitis but which Hepatitis B testing, particularly in its early forms, failed to spot. The UK never adopted ALT screening.

3.7 Hepatitis Risks 1970 and After

In February 1970, Professor Richard Titmuss published *The Gift Relationship*. Professor Titmuss drew attention to a series of studies demonstrating the risk of hepatitis incurred by those who received transfusions of whole blood or blood products, to support his case that a system relying on voluntary non-remunerated donations was very much safer not only in theory but in reality. Shortly afterwards Professor Garrott Allen of Stanford University confirmed that same message (one which he had drawn attention to publicly since 1959): the hepatitis risk from blood commercially sourced was markedly higher than the risk from blood and plasma sourced from truly voluntary donors. Professor Garrot Allen also emphasised the seriousness of transfusion hepatitis.

It began to be apparent as soon as 1972 that despite the introduction of testing for Hepatitis B there was still a significant risk of post-transfusion hepatitis. It was increasingly reported that hepatitis was occurring after transfusion, yet when tested the patient was suffering neither from Hepatitis A nor Hepatitis B. Of particular note was the report by Dr Alfred Prince and others in *The Lancet* in August 1974 that an agent other than Hepatitis B (which became known as non-A non-B Hepatitis ("NANBH")) was the cause of 71% of cases of post-transfusion hepatitis; this article warned of the possibility that "*non-B hepatitis may play a role in the aetiology of some forms of chronic liver disease.*" *The Lancet* was one of the most widely-read journals by clinicians in the UK: no clinician dealing with transfusions had any reason to be unaware of this conclusion.

In January 1975, Professor Garrott Allen wrote to Dr Maycock to try to persuade him against the continued import of factor concentrates from the US. He said that one commercial product – which "*as you know*" was sourced "*100 percent from Skid-row derelicts*" – was extraordinarily hazardous: a 50-90% rate of hepatitis developed from its use. In May 1975 the WHO advised self-sufficiency for all nations and the use of voluntary non-remunerated blood donations. A 1974 outbreak of hepatitis at the haemophilia centre in Bournemouth after the administration of Hemofil, a commercial factor concentrate, was the subject of a report in *The Lancet* in August 1975. Later that year another significant warning was given: the memorable World in Action *Blood Money* programmes in December 1975 reported the high risk of hepatitis in blood products sourced from prisons and "skid row" paid donors.

For some time a number of doctors held the view that NANBH was a mild or benign disease. The view that the disease was mild rested centrally on assertion and/or wishful thinking rather than evidence and was reached by a comparison with Hepatitis B in the acute phase rather than on epidemiological studies. This represented a serious and collective failure of judgement amongst the many who asserted it. Unless there was good evidence to show that Hepatitis B on its own had caused almost all the serious effects previously attributed globally to "serum hepatitis", NANBH viruses simply could not be assumed to be any less harmful. The observed effects of serum hepatitis might just as well have been caused by the major

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viral component of serum hepatitis (NANBH) as by what now seemed the lesser (Hepatitis B). There could have been no proper confidence that NANBH would not have serious long-term consequences; those consequences would emerge only after an extended period of chronicity. Publications in the mid 1970s by eminent clinicians (such as Dr Harvey Alter, who was later to be awarded the Nobel Prize for his work in this area) rightly observed that "*chronic non-A, non-B hepatitis is not necessarily a benign infection and may be the cause of a significant proportion of chronic hepatitis not identifiable as type B disease*".

By 1978 there were a number of reports showing that NANBH was linked to persistent liver damage. Amongst them was a paper published in September 1978 in *The Lancet*, authored by Dr Eric Preston and colleagues in Sheffield. In his oral evidence to the Inquiry, Dr Mark Winter said that this paper "*blew out of the water instantly the idea that this* [NANB hepatitis] *was nothing to worry about because their study showed, as did other studies, that most of these patients had very significant chronic liver disease*". He thought doctors had been unwilling to think that NANBH might be a problem, because factor concentrate had brought "*such spectacular benefits*": it was this reluctance to face the facts described in scientific journals that had prevented earlier acceptance of the seriousness of the problem.

By February 1979 the Medical Research Council ("MRC") had been told by the chief scientist of the Department for Health and Social Security ("DHSS") that non-A non-B Hepatitis was "*being given high priority by the Department*". At the end of April 1979 Dr Peter Kernoff, the co-director of the haemophilia reference centre at the Royal Free Hospital, described NANBH as "*a serious disease with long-term consequences*". In May 1979 the North East Thames Regional Association of Haematologists Haemophilia Working Party recognised that "*Despite the generally mild nature of acute non-A non-B hepatitis it seems very possible that there may be serious long-term sequelae and the acute disease may sometimes be fatal.*"

During an international symposium into "*Unresolved problems in Haemophilia*" held in Glasgow in September 1980, attended by many haemophilia clinicians, Dr Howard Thomas and Dr David Triger (both hepatologists) explained that "*we are just building up trouble*" and "*it is in 10 years time that we shall see the problems. Bearing in mind the proportion of the patients that are infected, or have persistent abnormal liver function tests, anything from 60 to 80 per cent, it will be an enormous problem when it happens.*"

And by September 1980 Dr Diana Walford of the DHSS was confident enough to write a memo saying: "*I must emphasise that 90% of all post-transfusion (and blood-product infusion) hepatitis in the USA and elsewhere is caused by non-A non-B hepatitis viruses which (unlike hepatitis B) cannot, at present, be detected by testing donor blood. This form of hepatitis can be rapidly fatal … or can lead to progressive liver damage. It can also result in a chronic carrier state, thus increasing the 'pool' of these viruses in the community.*"

By the very start of the 1980s, therefore, it was clear that hepatitis caused by a blood transfusion, or treatment with a blood product, carried with it a serious risk of long-term consequences, and it was known that this could not be linked simply to Hepatitis B infection. Yet the view that NANBH was relatively benign and non-progressive remained difficult to

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shift in the early 1980s. It has been described to the Inquiry as the generally held view but this does not fit very closely with the contemporaneous evidence.

3.8 Knowledge of the Risks of AIDS

In June 1981 the Centers for Disease Control and Prevention ("CDC") in the US reported a cluster of five cases of people suffering from a failure of their immune systems, allowing a form of pneumonia (pneumocystis carinii pneumonia ("PCP")) to develop; the cluster was in the gay community. By July the CDC was reporting in the *Morbidity and Mortality Weekly Report* ("MMWR") that it had found approximately 10 more such cases, again amongst gay men, and in addition 26 cases of gay men who had developed Kaposi's sarcoma ("KS"), a skin lesion, which had been diagnosed within the previous two and a half years. By August 1981, an additional 70 cases of PCP and KS amongst gay men were reported; and by December 1981 the same failure of the immune system which gave rise to these characteristic opportunistic infections was seen in intravenous drug users. By March 1982 the possibility that the cause of AIDS was an infectious agent had been developed as a leading hypothesis in the US.

By now, the context was that there was growing concern about AIDS throughout the world. In the UK the first patient known to have AIDS had been identified in late 1981. By mid summer 1982 Terrence Higgins had died and what was initially called the Terry Higgins Trust was being formed by his friends. It was a growing illness, and already known that people who suffered from it were highly likely to die, after a wasting sickness.

In June 1982 the Second International Symposium on Infections in the Immunocompromised Host was held in Stirling, Scotland. Few haematologists attended, though Dr Ian Hann and (he thought) at least one representative of the Scottish National Blood Transfusion Service ("SNBTS") did. Dr Hann left the conference realising that developing information about AIDS might be relevant to haemophilia patients, and later commented that what he heard was "*a bombshell*" in terms of the severity of the new disease. He described this as "*part of the burgeoning knowledge that began to explode at that time.*"

On 9 July 1982 the Assistant Surgeon-General of the US wrote to all haemophilia centres in the US to alert them to the spread of AIDS to people with haemophilia. On 14 July the National Hemophilia Foundation in the US alerted its members that there was a risk to people with haemophilia. Dr Harold Gunson, consultant adviser on blood transfusion to the Chief Medical Officer ("CMO") and thereby the DHSS, was alerted to this development very shortly thereafter.

Then, in the MMWR of 16 July 1982, the CDC reported three cases which had been confirmed in people with haemophilia who had developed AIDS.

An internal DHSS memo on 16 July 1982 alerted the Medicines Division to possible adverse publicity about the risks of US Factor 8 concentrates and that the licences of certain manufacturers of imported blood products might have to be revoked. In August 1982, the

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Communicable Disease Surveillance Centre ("CDSC") took steps to introduce national surveillance for AIDS in the UK, and the journal *Science* carried an article headed "*New Disease Baffles Medical Community*" which described how more than 470 people in the US had AIDS, that almost half had died, and that an infectious agent appeared likeliest to be the cause. Ominously, it noted that the signpost "*opportunistic*" infections were first noticed in mid 1979 – ominous, because it suggested that if the cause was an infectious agent it had a long incubation period.

On 3 October 1982 the US National Hemophilia Foundation urged pharmaceutical companies to stop using plasma collected from gay men, intravenous drug users and people who had recently been in Haiti as a "*precautionary measure*".

On 5 November 1982 Dr John Craske of the Public Health Laboratory Service ("PHLS") produced a report which identified an infectious agent as the most likely of the possible causes of AIDS.

Given this history, there can be little doubt that possibly by March 1982, and certainly from July 1982 onward, it was known in the UK to both some clinicians and some within government that there was a real risk that blood, and blood products in particular, might transmit the cause of AIDS.

In November 1982 *The Observer* reported that people with haemophilia in the US were suffering from AIDS and that there was a "*major speculation*" that the AIDS virus was "*carried in the blood*". Though there was no certainty as yet, the risk that this was the case was clear. Then, in December 1982, the MMWR reported the case of a baby who had received multiple transfusions shortly after birth and had contracted the symptoms of AIDS. This – the San Francisco baby case, as it has often been referred to – was powerful evidence in support of the infectious agent theory and of transmission by blood. The same MMWR disclosed that the three individuals whose cases had been reported in the 16 July 1982 MMWR had since died, and that four additional cases of AIDS in haemophilia patients had been identified, together with a further "*highly suspect*" case of a 7-year-old child with severe haemophilia. All had received Factor 8 concentrates and two of the five had died.

By the end of 1982, Dr Joseph Smith, the director of the National Institute for Biological Standards and Control, had formed the view that the cause of AIDS was almost certainly a virus, and haemophilia centre directors (according to Dr Charles Rizza, the director of the Oxford Haemophilia Reference Centre) knew there was a real risk that AIDS could be transmitted by an infectious agent carried by blood products. In the Netherlands, the Central Laboratory of the Blood Transfusion Services was convinced by the end of 1982 that people with bleeding disorders were at risk and started to coordinate a response with the Netherlands Haemophilia Society, haemophilia clinicians and the Netherlands National Institute for Public Health and Environmental Protection.

On 7 January 1983 the MMWR reported that two female sexual partners of males with AIDS and four female sexual partners of intravenous drug users had developed either AIDS, or PCP, or opportunistic infections typical of AIDS, indicating that the cause was highly likely

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to be viral, transmissible by sex as well as blood, and similar to Hepatitis B. On the same day Alpha Pharmaceutical, a US company which produced blood products, issued a press release about people with haemophilia who had been infected: "*The evidence suggests, although it does not absolutely prove, that a virus or other disease agent was transmitted to them in the Factor VIII concentrate, derived from pooled human plasma.*"

The prestigious and widely read *New England Journal of Medicine* stated in its 13 January 1983 editorial that "*The fact that haemophiliacs are at risk from AIDS is becoming clear. If the use of cryoprecipitate will minimize this risk the current home-infusion program needs to be revised.*" This article, and the cases that had been reported in the MMWRs, were discussed at a meeting of UKHCDO's Hepatitis Working Party on 19 January 1983.

On 24 January 1983 at a meeting at Heathrow those attending, which included 21 haemophilia doctors, were told by Dr Craske that the disease was "*intractable*", that by December 1982 45% of people infected had died, that ten people with haemophilia in the US had been affected, of whom five had died, and that the disease appeared to have an incubation period of between six months and two years.

The Lancet of 29 January 1983 concluded that a blood-borne agent was likely to be the cause of AIDS and the *New Scientist* of 3 February 1983 reported that the "*prime suspect*" was a blood-borne virus.

On 7 March 1983 Dr Bruce Evatt of the CDC wrote in a letter to Professor Bloom that the AIDS epidemic was evolving "*with a frightening pace*". There were now 13 confirmed AIDS cases in the US among people with haemophilia, and a further 5 highly suspect cases under investigation; all had received factor concentrates. Preliminary data suggested that half of people with haemophilia in the US had T-cell abnormalities, with 13% markedly abnormal, as in AIDS patients. There is no evidence that Professor Bloom circulated this letter at the time.

Around this time some haemophilia doctors in the UK began to check patients for signs of AIDS as a routine measure: doing this shows they must already have recognised that receiving factor concentrate therapy carried a real risk of leading to AIDS.

Concern about AIDS became more widespread when the BBC screened a *Horizon* programme which identified "*the 4 Hs*" in the major risk groups – "*Homosexual males, IV Drug (Heroin) users, Haitians and Haemophiliacs*" on 25 April 1983. There were also reports in the mainstream press at the start of May 1983, notably an article by Susan Douglas in *The Mail on Sunday* on 1 May, with the banner headline "*Hospitals using killer blood*". She reported an epidemiologist as saying "*It seems madness that our blood supplies are coming from a country suffering from an epidemic*".

Despite this, and despite having reported to the CDSC on 26 April a probable case of AIDS in a young man with haemophilia treated at the Cardiff Haemophilia Centre, on 4 May 1983 a statement from Professor Bloom was sent to Haemophilia Society members saying that the "*cause of AIDS is quite unknown and it has not been proven to result from transmission of a specific infective agent in blood products*", that the number of AIDS cases was small,

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and that "*in spite of inaccurate statements in the press*" he was unaware of any proven case in "*our own haemophilic population*". Professor Bloom advised no change to therapy with factor concentrates.

Saying that the number of AIDS cases was small was a surprising thing to write without any qualification: it may have been true that the number of people with haemophilia known (so far) to have developed AIDS was small, but the popular press were already reflecting a considerable concern that a deadly unidentified disease was growing amongst the general population in epidemic form. Further, reports of two German patients with haemophilia developing AIDS became known during 1983, by late April. Professor Bloom ought to have realised that the number of cases in which the infection had become sufficiently developed to show themselves as cases of AIDS were potentially only the tip of a very much larger iceberg: *The Observer* had made this very point in terms clearly understandable by a layman let alone a scientist.

Professor Bloom may have been saying one thing for public consumption, whilst advocating a different tack within his own haemophilia centre. Only two weeks after his letter to the Haemophilia Society, *Haemophilia Treatment Policy Guidelines* for use in Cardiff were issued. They advised using DDAVP, cryoprecipitate and **only** NHS factor concentrates for children and those with mild haemophilia, and even when it came to those with severe haemophilia advised using only NHS concentrate for those who had never received commercial concentrate "*where possible*" and cryoprecipitate for in-patient treatment "*where feasible*". This can only have been on the basis that imported factor concentrates created such a risk of AIDS that they should not be used unless there was no alternative.

If what Professor Bloom had said had been faithful to the facts, and he had advised the Haemophilia Society that there was a real risk that taking factor concentrates risked contracting AIDS, and that the likelihood of the risk becoming a certainty appeared to be growing stronger by the month, it is not difficult to see that the events that followed might have taken a different turn.

On 9 May 1983 Dr Spence Galbraith (in his capacity as director of the CDSC, which had the role of identifying threats to public health from communicable diseases) wrote a paper entitled "*Action on AIDS*" which he sent to the DHSS, stating: "*I have reviewed the literature and come to the conclusion that all blood products made from blood donated in the USA after 1978 should be withdrawn from use until the risk of AIDS transmission by these products has been clarified.*"

A special meeting of UKHCDO reference centre directors on 13 May 1983 considered it "*circumspect*" to use only NHS materials to treat young children and people with mild haemophilia, but the minutes stated that there was "*as yet, insufficient evidence to warrant restriction of the use of imported concentrates in other patients in view of the immense benefits of therapy. The situation shall be kept under constant review.*" Dr Walford (DHSS) attended the meeting. On the same day she recorded Dr Galbraith's recommendation as

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"*premature in relation to the evidence and unbalanced in that it does not take into account the risks to haemophiliacs of withdrawing a major source of their FVIII supplies*".

Also in May, the Council of Europe Committee of Experts on Blood Transfusion and Immunohaematology concluded that although "*Absolute proof that AIDS is caused by a transmissible infectious agent is not yet available*" nonetheless "*it should be regarded as such and that a recommendation should be made to the Council of Ministers at the meeting in June to take necessary steps to minimise the transmission of AIDS by the transfusion of blood products.*" The Council of Europe accepted the recommendations in June 1983.

On 20 May 1983 the isolation of a viral particle (then called "LAV") by Dr Luc Montagnier and his team in Paris did not attract significant attention at the time, but was later said to have made it clear scientifically that the cause of AIDS was indeed a virus.

By July, *Transfusion International*, a journal directed to transfusionists, observed in an editorial by an eminent physician that "*There is relatively strong evidence indicating that* [AIDS] *may be transmitted by blood.*"

August 1983 saw the first known UK death from AIDS of a person with haemophilia. Nonetheless, when UKHCDO held its annual general meeting on 17 October, Professor Bloom dismissed a suggestion that patients should revert to cryoprecipitate, saying "*he felt that there was no need for patients to stop using the commercial concentrates because at present there was no proof that commercial concentrates were the cause of AIDS.*"

On 12 January 1984 *The New England Journal of Medicine* published a report of a study of 18 suspected cases of AIDS associated with transfusion. None of the recipients possessed any risk factor other than being the receipt of blood components. The conclusion of *The New England Journal of Medicine* was that blood components could transmit AIDS, that exposure to one infected unit might result in transmission, and that symptomless donors could be infectious

By March 1984 all blood products manufacturers in the US were warning of the risk of contracting AIDS from using their products.

On 23 April 1984 it was announced at a press conference in the US that Dr Robert Gallo had found the virus which caused AIDS, terming it "*HTLVIII*"; Dr Gallo had identified exactly that which Dr Montagnier had called LAV. From now on the overwhelming consensus was that the cause of AIDS was infection with HTLV-3 (LAV) which was later renamed HIV.

The risk that blood transfusion or factor concentrates could cause AIDS was apparent in mid 1982. Everyone involved in treating patients with blood or blood products (or involved in decision-making regarding the use of blood or blood products) either knew, or should have known, of the risk by the end of 1982. It became increasingly apparent as a serious risk until it came to be regarded as a near certainty in April 1984. This risk had to be addressed when it first became recognised as a real risk, by the end of 1982 or January 1983 at the latest; all the more so since the context was a developing epidemic.

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3.9 – 3.11 Blood Services

These next three chapters evaluate the organisation and role of the blood transfusion services in England, Wales, Scotland and Northern Ireland up to the early 1990s, and how they responded to the risks of viral transmission through blood. What is set out below will provide an indication of the issues explored within the chapters, but for a comprehensive narrative readers are referred to the chapters themselves.

3.9 Organisation of the Blood Services

This chapter explores the organisation of the blood services in the UK. The blood services in England and Wales were an amalgamation of autonomous regional services. There were divergences in practice between regional transfusion centres ("RTCs"), and efforts to standardise the medical selection of donors and other functions were only ever partially successful as there was no obligation on regional transfusion directors ("RTDs") to adopt national policy, particularly where it came into conflict with regional priorities. At their head from the Second World War until 1978 – though with only a role of advising and persuading – was Dr Maycock. His formal role was as Consultant Advisor on Blood Transfusion to the CMO, and the CMO headed the medical hierarchy in the DHSS. Until 1978 Dr Maycock also had a role as director of the Blood Products Laboratory ("BPL") which despite the term "Laboratory" was principally a unit which was responsible for producing blood products from plasma supplied by the regions, though itself being under separate control from them.

At a special meeting between RTDs and DHSS representatives, held in 1970 to consider a green paper on the future structure of the NHS, the RTDs advanced a case for the reintroduction of a national service. They complained that the existing structure of independent RTCs was leading to fragmented administration. A strong recommendation by RTDs in 1973 that the service be reorganised around "*a unified system of central administration*" was rejected when the NHS was reorganised. Instead the centres remained under local management by regional health authorities. No national executive was established to control blood services policy or management.

RTDs remained sceptical about the effectiveness of this structure. An ad hoc committee was set up to consider their concerns, and whether any change should be made in the organisation of the blood transfusion services in England and Wales. This committee, though recognising the force of many reasons for centralising administration of the national blood services, was unconvinced that responsibility for administration and providing services should be taken away from regional health authorities, although a Central Committee for the National Blood Transfusion Service ("NBTS") was created in 1975 to keep under review the operation of the blood service in England and Wales, and to advise the DHSS on the development of the blood service.

In 1977 RTDs proposed to the Royal Commission on the NHS that the blood transfusion service had assumed an increasingly national role which had suffered from constraints arising from regional development, inadequate central coordination and financing, and a

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poor integration of the activities of regional transfusion centres. The current structure of the transfusion service was described as a "*loose confederation of 14 Regional Transfusion Centres, independently financed, each providing services which vary considerably from Region to Region, and three central laboratories financed by the DHSS.*"

The structure of the blood services across the UK was linked to the supply to the fractionation centres in England and in Scotland of sufficient plasma to enable them to utilise production facilities to the full. Regional health authorities had little incentive to provide plasma for fractionation if those health authorities were not themselves going to see a benefit for patients within their own region, the BPL itself was suffering from an extended period of underinvestment, and there was an accompanying lack of funds and incentive for research to be conducted into producing safer products.

An Advisory Committee on the NBTS was established in 1981 to advise the DHSS and the Welsh Office on the coordination of the development and work of RTCs. Difficulties in establishing national standardisation nonetheless persisted: Dr Harold Gunson, who had succeeded Dr Maycock in his role relating to transfusion (though not his role in respect of BPL) was later to highlight that the inconsistent and inadequate supply of plasma to BPL, and the difficulties in implementing HIV testing were examples of problems caused by a lack of an effective national policy for decision-making.

By the start of 1983 the UK service was still one in which there were a number of autonomous parts: regional transfusion centres, organised in England and Wales into three districts but still consisting of individual RTCs, each under the financial and administrative control of their respective regions, and the services in Scotland and Northern Ireland. The Advisory Committee on the NBTS was advisory only and remained unable to exercise executive control over the service as a whole.

The directors of all the RTCs in England and Wales repeatedly noted that if plasma supply to BPL were to be sufficient to support the goal of self-sufficiency, this required national management. The DHSS was aware too that research and development were duplicated unnecessarily across regional transfusion centres, BPL, and the Protein Fractionation Centre ("PFC") due to a lack of central coordination.

A National Directorate, intended formally to co-ordinate the blood transfusion services in England and Wales, was set up as from July 1988 but lacked executive authority, which remained with the RTCs and their regional health authorities. It was not until April 1993 that a single body with executive authority, the National Blood Authority, was established in England.

The position in Scotland was different. The SNBTS was set up in 1940 and comprised five regional transfusion centres. From 1974 responsibility for the service rested with the Common Services Agency. Its funding was received centrally, rather than from regional budgets as in England and Wales. Northern Ireland had a single regional transfusion centre.

Problems of a lack of coordination and the lack of any one person or body exercising executive authority contributed to the failure of the UK as a whole to achieve the goal of

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self-sufficiency in blood products. A lack of coordination between England, Wales, Northern Ireland and Scotland from the early to mid 1970s onwards added to this. The lack of centralised funding led to research being a poor orphan of the service so far as funding and resources were concerned.

The fragmented nature of the blood services also contributed to a failure to achieve as much plasmapheresis as would probably have resulted had there been one national point of executive control, and made it more difficult to mount an effective coordinated national approach to achieving a greater use of packed red blood cells, and to introduce measures to help minimise the use of transfusions where possible. When it came to a need to pass information on to donors (through measures such as the donor leaflets produced in response to the HIV epidemic), to screen donors consistently, and to facilitate the screening of donations, a nationally coordinated response would likely have achieved more than was done: it was difficult to achieve it under the system as it stood.

3.10 Regional Transfusion Centres

This next chapter considers in more detail the role and functions of the RTCs. Again what follows below is a summary of some of the main points only.

Throughout the 1970s and 1980s each RTC served its own region. In England and Wales each RTC's activities were shaped by the services required by the hospitals they served, and the adequacy of the funding provided by the regional health authority. Many of the RTCs were in old, cramped, inadequate buildings, which curtailed what they could do. Some were inadequately staffed.

A common arrangement in England and Wales was one where hospitals within the region had their own blood banks, which were supplied by the RTC. This could lead to a disconnect between those using the blood (at the hospital) and those who were concerned with securing future blood supplies (the RTC), which may in part be responsible for what was a sluggish change of practice from the over-enthusiastic use of whole blood for transfusion to both the more general use of concentrated red blood cells and a more sparing approach to giving transfusions. In Scotland, by contrast, four out of the five Scottish RTCs carried out blood banking for the hospitals in which they were based. All five of the RTCs were centrally funded. Despite this, the national SNBTS director, Professor John Cash, did not have any power to compel the RTCs to adopt any particular policy and so any decisions that were to be implemented nationally had to be reached by consensus. The Scottish RTCs also suffered from poor facilities and inadequate staffing which in some instances limited what they could offer.

Most of the RTCs in England and Wales provided plasma to BPL for fractionation, then received back and distributed the fractionated products. Some RTCs were involved in the purchase of commercial Factor 8. There was no formal national system for RTCs which collected more than they needed to help RTCs with shortages caused by the donor population not necessarily matching the demand. Professor Cash noted the need for a national system,

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when he observed that when private hospitals in London could not secure blood from the RTC, they obtained blood supplies from Europe and occasionally this was passed to NHS hospitals. This is the only evidence the Inquiry has found that the UK received blood (as opposed to blood products) to use in the NHS which did not come from voluntary non-remunerated donors living in the UK.

The system of national plasma targets for BPL with regional funding was fundamentally flawed and ultimately unsuccessful. Until 1981 the system was that the overall target would be divided between RTCs on the basis of population size, but product would be delivered back in proportion to the numbers who had been treated in the previous year. In April 1981 the pro rata system was introduced but it still had a number of flaws: the targets set for each RTC were not based on the amount of concentrate a region needed by on its population; the pro rata system did not provide the RTCs with certainty as to the amount of factor products they would receive back from BPL in any given year; and some RTCs pushed back against the targets set by BPL because they did not agree that they were set at the right level.

Finally in April 1989 an improved cross-charging system was introduced with RTCs selling their plasma to BPL, buying back the fractionated products and selling these to hospitals in their region.

The drive to provide more plasma to BPL led to two changes in RTC practices: discouraging hospitals from using whole blood for transfusions where the patient needed only the red blood cells (as the remaining plasma could be sent to BPL); and adding a solution called SAG-M to blood to make red cell concentrate easier to administer. Almost all the RTCs had some form of plasmapheresis programme by the end of the 1980s or beginning of the 1990s.

The Scottish transfusion centres did not experience difficulties of supply. In fact, the centre in Edinburgh would sometimes send its surplus red cells to an English RTC to address their shortages. As in England and Wales, SNBTS encouraged the use of red cell concentrates over whole blood, using SAG-M, and adopting plasmapheresis.

Prior to 1982 the transfusion centre in Belfast sent only time-expired liquid plasma to BPL for fractionation and received only a small amount of Factor 8 from BPL in return. From the end of 1982 all Northern Irish plasma was sent to PFC in Edinburgh.

The fact that the system was regionally funded and regionally controlled in England and Wales led to problems, and tensions within the service. So far as blood was concerned, there was a tension between the supply of it, and the clinicians' demand for it. This rarely caused problems on its own, but when demand for plasma for fractionation rose, this demand, together with those of the clinicians, had to be balanced against the available supply.

The system was inefficient when it used whole blood for transfusion where only red blood cells were required, wasting the plasma, and also when whole blood was used as the source of plasma for fractionation or cryoprecipitate, wasting the red blood cell component. Efforts were made to persuade clinicians to change their prescribing habits, and to adopt the use of SAG-M to enable the red blood cell component to be more easily used. Education and

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persuasion were ultimately reasonably successful. But this success could and should have been achieved more quickly than it was.

3.11 Response to Risk by the Blood Services

The process of selecting a donor involves choosing whom to approach to give blood, screening those who answer the call, and testing donations. This chapter examines the approaches of the blood services to the first two of these, and whether they effectively reduced risk as far as they reasonably could and should have done. The testing of donations is examined in later chapters.

Prisons were regarded as a valuable source of blood donations from the 1950s until the 1970s. Following the introduction of screening for Hepatitis B in the early 1970s, it became clear that there was a markedly higher incidence of Hepatitis B amongst prisoners. The American Red Cross stopped collecting blood from prisons in the US in July 1971 because the incidence of hepatitis was ten times greater among prisoners than among voluntary unpaid donors. Despite this, it was still Home Office policy in the early 1980s to encourage prisoners to become donors as it was believed to help with rehabilitation. The collection of blood from closed prisons and borstals in England and Wales only finally stopped at the end of 1984 and from the last open prison in 1986. In Scotland the practice finally stopped from March 1984 and in Northern Ireland from October 1983. The blood services should have resisted earlier and more effectively: prison donations continued for much too long.

The armed forces were another source of blood donors throughout the 1970s and 1980s for some RTCs, despite this cohort of donors giving rise to risks not far removed from those seen in the prison population, because of the difficulty in disclosing personal risk factors in front of fellow members of the armed forces.

Workplace sessions were an important source of donations and although there was no evidence to suggest higher levels of blood-borne viruses in such donors, there was a risk that employees might feel pressured to donate and unable to admit to risk factors in conditions where workmates might become aware of them.

Screening by assessing donor health was primarily a matter for the donors themselves who were said to be "*the best judge*". The blood services relied on donors answering their questions truthfully. There was little privacy at donor centres and questions about the donor having an infectious disease might easily be overheard. This problem became particularly acute when the blood service introduced leaflets setting out eligibility criteria for donors in response to the threat of HIV and AIDS. The North London Blood Transfusion Centre developed a system which allowed donors who felt under pressure to donate (if they had come with work colleagues for instance) to declare their health conditions privately.

It would not necessarily have been easy to introduce direct confidential questioning about the private lives of donors: but it is regrettable that it was not done, at least in some form, when AIDS first emerged.

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Prior to 1976 any donor with a history of jaundice was, or should have been, excluded but this was relaxed following the issue of circulars in 1977, and the Memorandum on the Selection, Medical Examination and Care of Donors was amended in 1977 to allow people with a history of jaundice or hepatitis to donate as long as they had not suffered from jaundice or hepatitis in the preceding 12 months and as long as their blood tested negative for Hepatitis B. Scotland followed a similar approach from 1980. This approach should have been reconsidered much earlier than it was. In 1989 the blood services of the UK published the first edition of the "Red Book" transfusion guidelines. The criteria with respect to hepatitis and jaundice were that a donor should be allowed to donate 12 months after recovery. That was unwise, since chronic infection could persist. It was not until the second edition of the Red Book in 1993, that the guidelines explicitly ruled out potential donors infected with Hepatitis C.

Although from 1977 those who were suspected of or admitted to illicit drug-taking were in theory debarred from donating, it is unclear how such individuals would be identified or even what attempts were made to identify them. The form which donors were asked to sign made no reference to this and there were no specific measures in place to prevent those with a history of intravenous drug abuse from giving blood.

In 1982 the DHSS published a report making recommendations as to the role of RTCs in promoting good practice in blood transfusion, including "*economies in blood usage*". A circular issued by the DHSS in 1983 recommended regular meetings between RTCs and hospital consultants to consider such matters. Similar recommendations were produced by SNBTS. In practice the extent to which individual RTDs played a role in educating clinical colleagues on the use of blood varied from centre to centre and over time. One of the obvious steps that treating clinicians could (and should) have taken once it was understood that HIV was a blood-borne infection, was to reduce all patients' exposure to blood and blood products as far as reasonably practicable. However, RTDs did not, on the whole, consider that they had a role in trying to influence treating clinicians to prescribe one product over another on the grounds of safety. The principal reason for this was respect for the clinical freedom of doctors.

All RTC directors (for England, Wales and Northern Ireland) who were in post in the years 1982-1984 before blood products were heat treated against HIV gave evidence that if they had been asked to increase their production of cryoprecipitate (a much lower-risk product) during the mid 1980s, they would have been able to do so, and quickly. They were all clear that no such request was made of them by treating clinicians and so no steps were taken to achieve this. In Scotland Professor Cash emphasised the role of cryoprecipitate and raised concerns about the purchase of commercial products and Dr Brian McClelland produced a paper which suggested reassessing the role of single-donor or small pool cryoprecipitate. However the extent to which these actions influenced the prescribing practices of haemophilia clinicians in Scotland is doubtful.

AIDS was first discussed at the regular meeting of RTDs on 18 May 1983, some ten months after the MMWR had reported three cases of suspected AIDS in people with haemophilia

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in the US. Four options were identified for consideration: questioning donors at sessions, discontinuing sessions in areas of high-risk donors, pamphlets explaining AIDS to donors, and information in newspapers. In Scotland, although there was passing reference to AIDS at meetings in January 1983 and March 1983, it was not until 24 May 1983 that there was a discussion about the implications of AIDS for blood donation. The blood services were too slow to react to the threat of AIDS. On 16 July 1982 (at the latest) the blood services in England and Wales and the Government became aware that its cause might well be blood borne. The only immediately available defence was careful donor selection and screening. The failure on the part of the blood services to give any kind of collective consideration to what could be done prior to May 1983 was wrong. Few centres took proactive steps in advance of receipt of the first AIDS leaflet for donors, which were not in general use until September 1983, and there were variable means of distributing such leaflets. A much more active approach to distribution of the leaflets should have been adopted from the outset.

Doing more, more quickly, would have prevented some infections. Deterring or preventing people in high-risk groups from donating should have been a priority. Acting swiftly was not just the responsibility of ministers, and officials. It was also the responsibility of the blood services. Although some within the services did more than others, this was not true overall: in general the blood services did too little, too late.

3.12 – 3.15 Blood Products and Addressing Risk

The next four chapters look at the particular risks posed by certain blood products, and examine the way in which the known risks described in earlier chapters were dealt with by government, ministers, civil servants, the blood services and fractionation centres, and influenced by clinicians who set out their needs and preferences.

3.12 Regulation describes how the Licensing Authority (technically, composed of ministers of state covering the UK, and in practice operated by them through the DHSS) regulated the importation, licensing, and distribution of blood products under the Medicines Act 1968.

3.13 Self-Sufficiency looks at how the government policy of UK "self-sufficiency" in blood products was approached.

3.14 Viral Inactivation examines how steps were taken to eliminate or reduce the harmful effects of viruses such as hepatitis and HIV contained in blood products.

3.15 Pool sizes looks at the way in which pools from which batches of blood product were made became larger and larger, increasing the risks that any treatments taken from those batches might infect the recipients, and considers the extent to which the pool sizes used in the UK departed from what had been regarded as an upper safe limit for roughly 20 years before 1970.

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3.12 Regulation of Commercial Factor Concentrates

The principal issues explored in this chapter are the system for the grant of licences granted for the importation of factor concentrates; whether the decisions to grant licences in the 1970s were wrong; and whether actions should have been taken in 1983 to stop the importation of factor concentrates.

The chapter concludes, on the limited information now available to the Inquiry, that in 1973 the Licensing Authority should not have permitted the importation into the UK of concentrates manufactured in the US and in Austria where the Licensing Authority was informed of the large pool sizes from which it was made, and that the plasma came from "*donors who do not inspire confidence*" who were selling their plasma to the company concerned. It decides that the decision not to suspend imports of commercial concentrates in July 1983 was wrong. It explores whether more should have been done to control the distribution in the UK of products which were made from plasma collected in the US before March 1983.

The chapter also considers the approach to the licensing of heat-treated concentrates and the Licensing Authority's role in gathering and communicating information regarding risks: these matters have not been summarised below but can be found in the latter part of the chapter.

The Licensing Authority

The Committee on Safety of Medicines ("CSM") was a group of independent experts appointed by ministers on the advice of the Medicines Commission. The CSM's role was to advise the Licensing Authority (i.e. the relevant ministers through their officials) on the safety, quality and efficacy of medicines. When an application was made for a licence to distribute pharmaceutical products, it was considered in the first instance by the Medicines Division of the DHSS. Where their reports related to blood products, these were usually submitted to the Sub-Committee on Biological Products ("CSM(B)"). The reports summarised any risks and expressed the view of the assessors. The CSM(B) would consider the report and agree a recommendation for the CSM, usually accepting the assessors' recommendations, perhaps with some additional conditions.

The proceedings of the CSM (and its sub-committees) were confidential and the available information about the details of discussions is incomplete. The Inquiry's view of the quality of decisions to permit the importation of blood products in the 1970s and 1980s is necessarily based on the limited evidence available.

The Medicines Act 1968 required the Licensing Authority to consider the product's safety, efficacy and quality. It allowed the Licensing Authority, in deciding whether to recommend the grant of a licence, to consider whether another product might be safer.

Professor Sir Michael Rawlins (member of the CSM from 1980 and CSM chair 1993-1998) told the Inquiry, "*if you're treating some lethal condition, then you're prepared to put up with*

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more adverse reactions, perhaps, than something relatively mild. So it was a judgment of balancing safety and efficacy."

Licensing in the 1970s

The first licensing applications for Factor 8 concentrates were submitted in 1972 and were for Kryobulin and Hemofil.

In October 1972 Dr Duncan Thomas (a medical assessor within the Medicines Division) inspected Hyland Laboratories and a blood bank in California in relation to the application for a licence to sell Hemofil in the UK. Dr Thomas noted the hepatitis risk associated with Hyland products: that they were made from "*very large plasma pools*", and the donors "*do not inspire confidence*". He added that: "*no attempt is made to disguise the risk of hepatitis, and it may be considered that the decision to use this material could be left to the individual clinician who can balance the potential hazard against the anticipated therapeutic benefit to the patient*". He recommended the grant of a licence. The CSM(B) accepted his advice and recommended a product licence for Hemofil in January 1973. The minutes do not indicate any discussion about hepatitis risks. The CSM(B)'s recommendation was in turn accepted by the CSM; again no discussion regarding hepatitis risks was recorded in the minutes.

In respect of the Kryobulin application, Dr Thomas reported that it was prepared from pools of 1,000 donors, with all donors tested at each donation and permanently excluded for any evidence of hepatitis. Nonetheless, he commented that "*the risk of transmission of serum hepatitis can only be diminished and not completely eliminated.*" The information provided was that donors came from Austria and Germany; there was no suggestion that they were volunteers. Dr Thomas advised that CSM(B) might consider requesting the Austrian authorities to carry out an inspection. Whilst the CSM(B) minutes record that "*the manufacturer of Kryobulin PL/0215/0003 had not been visited recently, but the licensing authority intended to ask the Austrian authorities to carry out an inspection on its behalf*" it is unclear why the CSM(B) recommended the grant of a licence without waiting for the inspection and considering its findings.

There were growing concerns at this time about the blood and plasma from which commercial products were made. It was understood that the risk of causing hepatitis from blood taken from paid donors was markedly higher than from volunteer donors. If the CSM and CSM(B) had wished to consider whether another, safer product might be readily available to treat patients, Dr Rosemary Biggs and Dr Katharine Dormandy had publicly reported that patients with haemophilia could be adequately treated with the use of cryoprecipitate. NHS concentrates were also understood to be safer.

Once the decisions to licence Hemofil and Kryobulin had been made in 1973, the grant of a licence for Profilate in 1975 was inevitable.

In 1976 licences were granted in respect of Koate and Factorate. In relation to Koate, Dr Andrews (medical assessor) noted in his assessment report of Koate that the plasma for the product was supplied by 54 firms under different ownership (including US state

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prisons). He pointed out that in the past the CSM had recommended conditions regarding donations and donors. In early 1976, the CSM(B) and CSM recommended the grant of a licence but subject to conditions, including information about the reasons for, and rate of, donor rejection on a centre-by-centre basis. Although there was then correspondence between the Licensing Authority and the pharmaceutical company on other issues, that correspondence did not address further the question of donor rejection rate or provide the information requested. In due course the product licence was issued with no condition regarding the provision of ongoing data about donor rejections.

Dr Andrew's report on the Factorate application noted the hepatitis risk associated with Factorate when Armour applied for a licence, and the CSM(B) recommended the grant of a licence with conditions that included information about donor sources and donor rejection. The importance of the proposed condition on the rate of rejection of donors or donations was emphasised at a DHSS meeting the day after the broadcast of part two of *Blood Money*: "*What was needed was to strengthen the requirements in the product licence, and to insist on returns from each collecting centre including the rate of rejection of donors or donations.*"

The *Blood Money* programme led also to a meeting with the Minister of State, Dr (later Lord) David Owen, followed by a submission which noted that "*seems best to assume that all blood products of this nature coming from the USA may be obtained from plasma taken under the worst circumstances and any protective measures should be achieved by other means.*"

The information provided by Armour in response to the proposed conditions was limited and there is no evidence that the Licensing Authority took any further steps to clarify these matters. If, as the evidence suggests, they did not press Armour further, then given the knowledge that collection of plasma in the US invited rather than limited risks of infection, this was a failure of regulation.

When licences were given to Hemofil and Kryobulin in 1973 they did essentially the same job – increasing Factor 8 levels – as NHS concentrates and locally produced cryoprecipitates. Why, then, was the safety of recipients put at risk by permitting a more widespread distribution of commercial concentrates than when imported on a named person basis? One of the reasons may have been to satisfy a desire of clinicians in the UK to use a product with the advantages of factor concentrates.

Once a product is licensed practitioners are likely to consider that an indication of its safety, quality and efficacy. They know that regulatory authorities whose primary concern is safety have authorised its marketing and distribution. Summarising what one clinician ruefully said to the Inquiry, surely, if it was licensed it was safe?

Given the belief in 1973 that commercially manufactured blood products sourced from paid donors and manufactured in large pools were less safe than either NHS concentrate or cryoprecipitate, and given the absence of any evidence that failure to import factor concentrates put patient safety at risk, the chapter concludes that the decisions to license Hemofil and Kryobulin were wrong. They led to the decisions about Profilate, Koate and

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Factorate. The evidence available to the Inquiry suggests that safety was not put first – as it should have been.

The CSM(B) and CSM meetings in July 1983

In late March 1983, Dr Joseph Smith, the chair of the CSM(B) proposed a meeting to consider AIDS in relation to licensed blood products. The meeting did not take place until 13 July 1983 and was attended by nine members of the CSM(B) together with invited experts including Professor Bloom, Dr Craske, Dr Galbraith and Dr Gunson. Officials from the Medical Division also attended. The upshot of the meeting was that no action was taken in response to the risks from imported factor concentrates. The CSM(B) considered only two papers at that meeting: a paper from Dr Keith Fowler and an annotated agenda prepared by Dr Smith. An important letter that had been sent to the DHSS by Dr Galbraith on 9 May 1983 was not circulated, nor any other paper from the CDSC. At its meeting on 21-22 July 1983 the CSM endorsed the recommendations of its Biologicals Sub-Committee. There appears to have been little by way of discussion, if any.

The decision of the CSM(B) and the adequacy of the information which it considered are examined in detail in the chapter. The conclusions reached by the Inquiry are in summary:

- The meeting was unusual in having suggested conclusions on the very issues to be discussed, which probably led the discussion towards drawing conclusions of that sort.
- The chair probably discussed these suggested conclusions beforehand with Dr Fowler, Professor Bloom and Dr Richard Lane; each of whom had their own distinctive views. Neither Dr Fowler's nor Professor Bloom's stands up to logical analysis; Dr Lane's inevitably reflected his perspective as a director of BPL, manufacturing blood products, and thus concerned with future supplies of plasma if much of it was diverted to local production of cryoprecipitate.
- The CSM(B)'s approach to risk conflated incidence with risk.
- It regarded US factor concentrates as "life-saving" (true, in some cases – but so also were cryoprecipitate and NHS concentrates, and this was not acknowledged as a balanced view required).
- It did not recognise what the Inquiry knows, that it would not have been difficult to ensure adequate supplies of cryoprecipitate from regional transfusion centres for treatment. Nor did it take adequate steps to investigate the potential level of supply (despite the minutes reading that "supply" was a – indeed, was the – critical factor).
- As Dr Walford acknowledged in her evidence, there were two non-sequiturs in its reasoning.
- The chair had a misguided view of the likelihood of self-sufficiency being achieved in the very near future.

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- The meeting did not have a number of important documents before it: Dr Galbraith's letter of 9 May; the Council of Europe recommendations; Dr Evatt's letter to Professor Bloom – it only had Dr Fowler's report, and an agenda with suggested conclusions.
- It seems likely that Professor Bloom's views were overly influential.
- The CSM(B) appear to have relied on the assertion (presumably by Professor Bloom) that UKHCDO had adopted a policy for use of commercial Factor 8 "*in order to minimise risks as far as possible*". There is no evidence that the CSM(B) actually saw, or asked to see, the policy itself, and such a policy could not be described on any view as minimising risks as far as possible. Insofar as the CSM(B) assumed that in practice clinicians had a treatment policy that minimised risks as far as was possible, that assumption was simply fallacious.

The chapter concludes that the decision was flawed in the way in which it was taken and in the reasoning that was advanced. There is no doubt – not only in retrospect – that it was wrong. If paramount consideration were to be given to patient safety as it should have been, it should have resulted in a stay on further imports of commercial concentrate, coupled with an increase in local supplies of cryoprecipitate, whilst reserving NHS concentrates for those occasions when their use was truly life-saving, appropriate to provide cover for elective surgery, or used for patients only after careful consideration between clinician and patient as to the balance of risk and remedy.

The CSM(B) recognised that its view of the risk at the meeting of 13 July 1983 might evolve and should be reviewed. The Inquiry has not been able to find any evidence of such a review. That was a further failure of regulation.

"Dumping" of riskier products in the UK

The Food and Drug Administration ("FDA") had formally recommended in March 1983 that pharmaceutical companies should not fractionate plasma collected from "*the four Hs*". The logical corollary of that recommendation is that products made from "pre-March plasma" should not be used, as supplying them would give rise to an increased risk of AIDS. The chapter next considers the steps that were taken in the UK in respect of pre-March products. These are not repeated here, but in summary:

- There was a marked change in the approach of those responsible for regulating the importation of blood products between the end of March 1983 and the end of August. Within five months the approach had changed from, in effect, "There shall be no dumping here" to "There shall be no restriction on dumping here".
- The reason for not wanting dumping was the worry that pre-March products would pose a greater risk of AIDS to the patient receiving them than post-March products. It is obvious that the recommendations of the FDA that firms should not accept donations of plasma from those in groups at high risk of AIDS compared to others

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were designed to reduce the risk of AIDS as far as practicable by aiming to make the sources of plasma safer.

- It is thus equally obvious that to impose no restriction on the continued import of products made from such plasma sources put the British public at some additional risk.
- Why, then, was there a U-turn? The reasons given for it relate to a textual interpretation of Dr Joseph Smith's draft on the minutes of the CSM(B) but there is no record of his having been asked if, when he recommended that the use of pre-March plasma be avoided, he was actually countenancing that its supply should continue for as long as there were stockpiles of previously manufactured products. If he had been asked, as he should have been, there might have been a clearer answer. From what he has subsequently said – that he expected self-sufficiency within a few months – it is difficult to think he would have said this, for there would then be no need to use commercial products, whenever produced.
- The grounds were simply that supply would be insufficient without reliance on the riskier product. The Inquiry has found no convincing evidence that this was the case; nor that there was detailed consideration of how much "post-March" plasma was available to augment the mix of NHS concentrate and cryoprecipitate which was available for treatment; nor any step "in between" which could have led to discussions between clinician and patient, such as obliging pharmaceutical companies to label, clearly, the date of the collection of the source plasma. It was however noted that (when looking at August stock levels) all of Miles' pre-March 1983 stock and around 70% of the Alpha and Armour stock had been "*collected in accordance with companies' special precautions*". These "*special precautions*" were individual companies' practices to meet the possibility that factor concentrates transmitted the cause of AIDS which each of the major firms had adopted prior to 24 March 1983 when the FDA made its recommendations.
- Even if the importation of all commercial blood products should not have been suspended for a period, the decision to allow continued importation of pre-March 1983 plasma products is difficult to justify on the evidence available to the Inquiry.
- Although the increased risk posed by "pre-March" plasma products was appreciated, nothing was done to try to reduce this risk or help clinicians and patients to identify the additional risk to which they might be exposed. The possibility of imposing a requirement to state the date of collection of the source plasma was contemplated by the DHSS but this remained only a suggestion. It did not result in the DHSS doing anything.
- If the DHSS was not going to take action to prevent the importation of pre-24 March products, the least it could do was to take steps to mitigate the additional risk which it was permitting by going down the route of a labelling requirement; and/or making clear to haemophilia centre directors/UKHCDO the fact that pre-March

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1983 products would continue to be available on the market for a further period, thus enabling haemophilia centre directors to take informed decisions about whether to use such products or not and/or to provide information to patients and the Haemophilia Society.

3.13 Self-Sufficiency

Despite being the policy of governments since the end of 1974 to achieve self-sufficiency in the production of blood products to treat haemophilia throughout the UK, this was not achieved in England and Wales until after 1990. This chapter examines the causes of this, looking at each factor individually, except for finance which is a theme present throughout. The story of the efforts to achieve self-sufficiency is a complicated one: whilst the summary below identifies some key points, readers are likely to need to read the entire chapter to understand the reasoning behind the conclusion that self-sufficiency could and should have been achieved significantly earlier than it was.

A simple definition of self-sufficiency in blood products is producing from a country's own resources enough factor concentrate to meet clinical need without having to import any. Clinical need is not easy to identify objectively, for example, three treating clinicians may all have different approaches to treatment as to what the patient's clinical need is. This question is made more difficult if the hospital administrator, who is seeking to save costs to make the most of limited resources, is asked. In the context of organising the supply of blood and blood products the "needs" of the population as a whole had to be determined.

When the NHS began operating on 5 July 1948 the supply of blood was almost entirely from domestic sources. The supply of blood products to patients however could be traced through both domestic and commercial routes. Domestic supply can be traced back to the start of the Second World War, and to arrangements which were inherited when the NHS first began. Commercial supply involved the importation of blood products (mainly clotting factor concentrates) for use for those who required them. "Self-sufficiency" relates principally to Factor 8, since there was generally enough Factor 9 and cryoprecipitate (and more of the latter could have been produced if requested).

There were three blood product manufacturing units in the UK: the Blood Products Laboratory ("BPL") in Elstree, the Plasma Fractionation Laboratory ("PFL") in Oxford, and the Protein Fractionation Centre ("PFC") in Edinburgh/Liberton.

By April 1967 it was being said in *The British Medical Journal* (based on a paper presented in September 1966) that cryoprecipitate was an "*extremely valuable therapeutic material*" and that from "*many points of view it is the therapeutic material of choice.*" Blood product usage now focussed upon cryoprecipitate: and thus, so did production. Cryoprecipitate was the major therapeutic material used for "on demand" treatment of bleeds. It could be made regionally at transfusion centres with relative ease. Centralised production facilities were largely unnecessary to provide it.

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By 1973 the manufacturing facilities at BPL were inadequate, out of date, and struggling, as they had not been designed to manufacture factor concentrates. It was expected that new, more efficient facilities at Liberton would provide approaching half the needs of mainland UK. But it had not been recognised that BPL would need to be either extended or completely redeveloped.

In January 1973 Dr Maycock urged the DHSS to "*have constantly in mind the need to develop our own sources in the UK transfusion services.*" This was a plea for the Government to expand the capability of the UK to produce its own product.

In March 1973 the new Expert Group on the Treatment of Haemophilia agreed that 400,000 units of concentrate and cryoprecipitate would be needed annually (300,000 donor units were anticipated for that year's treatment). Dr Biggs pressed the case for higher figures through the MRC's Blood Transfusion Working Party. Her paper noted that calculations based on pupils at Treloar's indicated that between 547,540 and 750,000 blood donations a year would be required to treat everyone with haemophilia in the UK.

Between 1974 and 1975, for the first time, the use of commercial concentrate exceeded the use of NHS concentrate so far as the consumption of concentrates was concerned: but two thirds of the total product used for factor replacement was still cryoprecipitate.

Between October 1974 and the end of the year, the policy on self-sufficiency evolved internally. In December 1974 a letter to regional administrative officers set it out. The DHSS recognised that there was an immediate need to provide antihaemophilic globulin ("AHG") concentrate, equivalent (now) to some 275,000 blood donor units. The DHSS regarded it "*as of the greatest importance… that the NHS should become self-sufficient as soon as practicable in the production of PPF and other blood products.*" This was due to the cost of commercial alternatives, and the potential threat to the voluntary donor system, should commercial firms consider establishing panels of paid donors in the UK.

On 22 January 1975 the Minister of State, Dr Owen answered a written parliamentary question: "*I believe it is vitally important that the National Health Service should become self-sufficient as soon as practicable in the production of Factor VIII including AHG concentrate. This will stop us being dependent on imports and make the best-known treatment more readily available to people suffering from haemophilia. I have, therefore, authorised the allocation of special finance to boost our own production with the objective of becoming self-sufficient over the next few years.*"

On 25 and 26 February 1975 he again pointed in Parliament to the £500,000 of special financing which was "*to increase the existing production of Factor VIII*". In evidence to the Inquiry, Lord Owen explained that he was motivated by the safety of people with haemophilia in view of the dangers of hepatitis, and the increased risks from the pool sizes used by commercial companies.

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By July 1975 the DHSS had set targets for 1977 of plasma from 337,000 blood donations. "*This is some 20% more than the total of 275,000 recommended by the Expert Group on Haemophilia but that figure must be regarded as the minimum.*"

In January 1976 Dr Ethel Bidwell, director of the PFL, calculated that the need for plasma would be for between 970,920 and 1,213,650 donations and that the DHSS target (which would be met 18 months later) would produce only around a third of what was needed.

Roland Moyle, then Minister of Health, reported to Parliament in 1978 that the DHSS goal of 340,000 donations had been met by the middle of 1977 but recognised that the commitment to self-sufficiency had "*not yet*" been achieved.

The next year there was again an upward shift in estimates of future needs. Current demand for Factor 8 was probably in the region of 60 million international units though it might well approach the 100 million international units per annum mark in the near to medium future. Those figures helped inform planning for the capacity which would be necessary at a redeveloped BPL. In 1979 Dr Lane considered that a redeveloped BPL could be commissioned to increase its production capacity to 90 million international units between 1985 and 1990, as an intermediate stage, and then might need to scale up production to 120 million units for the years that followed.

By 1982, planning was eventually under way for a new building to constitute BPL at Elstree. The approval given by the Treasury in November 1982 for the reconstructed BPL was for a plant capable of fractionating 400,000 kilograms per annum.

The therapies thought desirable for the treatment of people with bleeding disorders during the 1970s required larger and larger amounts of factor concentrate. Home therapy was a significant driver in increasing demand, as well as the improved lifespan and more active lifestyles of people with bleeding disorders. Operations requiring factor concentrate also became more common. Unfortunately, the figures used as a basis for Dr Owen's agreed expenditure of £500,000 were outdated even before the policy was announced. The DHSS understood that production facilities needed to be improved and expanded alongside more plasma being collected.

There needed to be an effective, coordinated approach to achieve self-sufficiency.

This centrally depended on both there being sufficient plasma collected from the regions to enable sufficient product to be made to meet the growing demands, and the capability of BPL, given sufficient plasma, to make it into product.

There were a number of ways of achieving an increase in the amount of plasma collected:

- more donations, whether whole blood or plasma from plasmapheresis
- avoiding unnecessary transfusions
- reducing the number of units transfused

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- increasing the use of concentrated red blood cells
- single plasma packs, which improved the quantity and quality of plasma collected
- using a solution (SAG-M) to recover one and a half times as much plasma from a donation

The chapter examines the problems there were in obtaining a reliable and sufficient supply of plasma. It concludes that these measures, taken together, would have helped to secure close to the amount of plasma which BPL on its own could handle when re-developed.[25] Single plasma packs and SAG-M were introduced swiftly once operationally feasible. But the other measures could and should have been adopted from at least the early 1970s. It seems that this did not happen because of a misplaced fear that clinicians might view this as restricting their clinical freedoms.

The principal reason why self-sufficiency was not achieved in England and Wales until the end of the 1980s was not these difficulties in obtaining a sufficient supply of plasma. It was that the redeveloped BPL only became fully functional at that point. Until then it lacked the manufacturing capacity necessary. BPL and PFL could not deliver what was needed because they had not been designed as production units. It is plain from what Dr Maycock and others were saying in the first half of the 1970s that a substantial redevelopment was necessary at BPL. It was on too small a site, and was ill equipped. It was expected that if and when the Medicines Inspectorate inspected BPL's premises they would be highly critical – in fact, when they did so (later than at first expected) in 1979 they effectively condemned it, only allowing it to continue with the then limited production because it was necessary for national supplies of concentrate for it to do so. However, this necessitated remedial work which diverted funds, and caused some delay to the process of starting redevelopment. Government did not give sufficient thought to planning to meet the future needs of haemophilia therapy in England, Wales and Northern Ireland (this did happen in Scotland).

The delays between 1978 when planning began towards a redeveloped BPL and 1982 when a decision in principle was made to do it was some four years; and that between April 1979, when the Medicines Inspectorate condemned the BPL premises as unsuitable for a pharmaceutical company, and the middle of May 1983, when construction began, was just over four years. Dr Walford was right to describe the delays as "*unconscionable*". A decision to plan in earnest for redevelopment should have been made no later than the end of 1976, when it was already known that the BPL premises simply could not produce enough products to meet the government's, clinicians' and patients' requirements. A full account of these delays is set out in the chapter.

The failure to make full use of the PFC in Edinburgh to meet UK problems in achieving self-sufficiency contributed significantly to the problems with supply.

25 ie when its manufacturing capacity allowed it to cope with greater supplies of plasma.

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Immediately after the Second World War it had been decided that there should be two production units in the UK – one in the south, and one in the north (Edinburgh) – to provide sufficient production of blood products for the whole country. Factor concentrates were not then in contemplation.

Over time, it became clear that these units (and PFL) would need to develop capacity for making factor concentrates, along with immunoglubulins and albumin as they had before. They were ill suited for this.

In Scotland, Dr Robert Cummings advocated forward planning. As a result, in 1965 the Ministry of Health agreed with the SHHD that PFC would fractionate what was needed for Scotland, and would supply at least one third of England's needs as well, using plasma collected by Newcastle, Leeds, Manchester and Liverpool to do so.

In December 1968, in light of the financial pressures, the SHHD sought a contribution from the DHSS for the capital cost of a new Edinburgh plant The DHSS eventually invested £400,000 towards the capital costs of PFC, which would amount to somewhere between a quarter and a third of the costs as then estimated.

In March 1969, in line with the approach thus far, Dr Maycock indicated that he expected one third of the plasma from England would be processed at Liberton.

Construction began in 1971. It continued until 1974. PFC then progressively, though slowly, came on stream.

The financial commitment from the DHSS showed the intent that BPL, PFC and PFL together should supply the blood products needed for the whole UK. Throughout the early 1970s it was said repeatedly at meetings of various committees that PFC and BPL should together serve the whole UK. The commercial viability of PFC, as designed in accord with this plan, depended to some extent on fractionating plasma from England, and a small amount of English plasma was supplied to it. Despite this, the position changed when Dr Lane took over from Dr Maycock as director of BPL in 1979, having been director designate in 1977. From then, the BPL and PFC were seen as primarily serving England and Scotland separately, rather than the joint interests of both. Dr Lane saw PFC as a rival, bidding for funds that were needed to renew BPL, rather than as a partner in an enterprise to ensure UK-wide self-sufficiency. He was sceptical about the abilities of PFC to manufacture products in the quantities claimed. Though some attempts were made in 1980 and 1981 to see whether Scotland could (as it was said in Scotland that it could) still make a contribution, in the event the plans which had been developed, and funded, in the mid 1960s envisaging two equal units of production were no longer pursued.

The delays in taking a decision to rebuild BPL were indeed "*unconscionable*" – and allowing that delay during the years from 1978 until 1982, all the while offering more risky commercial products, was a disgrace. The consequences of the missed opportunities was that commercial concentrates carrying HIV virus, as well as non-A non-B Hepatitis, were supplied in greater quantities to patients in England, Wales and Northern Ireland than would

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otherwise have been the case. This lasted until the late 1980s (in relation to Hepatitis C) as the UK, with the exception of Scotland, was still not self-sufficient.

It is highly likely that if self-sufficiency had been achieved significantly earlier there would have been less infection, in particular with HIV.

Overall, the DHSS bears a greater part of responsibility for the failures to achieve self-sufficiency. Ministerial indecision contributed to delay in the late 1970s and early 1980s, but (so far as can now be determined given that many of the submissions to ministers are no longer available) ministers may have been inadequately briefed. The documents that have survived suggest that ministers were not consulted about the decision to abandon the UK-wide approach. However, ministers also bear some responsibility for the systems that contributed to the delays.

3.14 Viral Inactivation

This chapter's primary focus is on the question of whether viral inactivation could have been achieved earlier than it was. It decides that this could reasonably have been achieved: if research had been encouraged and funded adequately by central government no later than the mid 1970s, as should have happened, it is reasonable to conclude that a heat-treated product likely to reduce the risk of hepatitis would have been available no later than 1980/81, and quite possibly earlier. It also considers other issues relevant to viral inactivation, including the events which led to the withdrawal of Armour's heat-treated Factorate in October 1986.

Before 1970, it was known that hepatitis transmitted by blood or blood products was caused by a virus, and that that virus (or those viruses) might be inactivated by one of a number of means. Among those means was the possibility that heat might inactivate the virus, another possibility was that solvent detergents could be used to destroy the lipid coating and render such a virus inactive. It was known that some possibilities could be discounted: in 1950 attempts to inactivate serum hepatitis by irradiation with UV light had failed. Throughout the 1970s a number of attempts were made to inactivate hepatitis. Not all involved heat.

There is no evidence that research into viral inactivation or removal occurred at the BPL or PFL in the early to mid 1970s. Conversely, Dr Peter Foster was appointed as head of the R&D Department at the PFC in April 1974 where he found that research was underway there to find a means of physically removing Hepatitis B virus from factor products.

By 1978 three companies (Behringwerke, Hyland, and Cutter) were actively engaged in what was seen as promising research into heat treating factor products to inactivate hepatitis viruses. Whereas Behringwerke used a "wet heat" approach, akin to pasteurisation, Cutter and Hyland both used dry heat, applying the heat to a product which had already been freeze-dried. Behringwerke presented its process to the medical public at the International Haemophilia Conference in Bonn. Dr Cash returned from that conference and told Dr Foster who had previously thought it "*inconceivable*" that heat could be used to inactivate a virus in Factor 8 or Factor 9 due to the vulnerability of the proteins. Dr Foster, and other fractionators,

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believed those proteins so vulnerable to heat that their coagulation activity could not be preserved. Yet within about three years, PFC had also developed a method of heat treating factor concentrate.

By the early 1980s, other major pharmaceutical companies had begun to prepare both wet and dry heated factor concentrates for active marketing. Dr Lane, director of BPL, recorded that no work to research heat treatment was done by BPL during 1981. On 27 February 1981 Dr James Smith proposed to Dr Lane some first outline proposals for programmes to research tackling the transmission of viruses by coagulation factor concentrates. Dr Lane reported to the Scientific and Technical Committee of the Central Blood Laboratories Authority ("CBLA") during the next month that "*a research project into the development of coagulation factor concentrates with reduced risk of hepatitis transmission, was an appropriate case for central funding.*" BPL's work on heat treatment only really started in 1982, and was in relation to Factor 9 only.

From mid 1982 onwards the risk that people with haemophilia treated with blood products might suffer AIDS (in addition to the risks they had of contracting hepatitis) became more apparent. There was some encouragement for the potential of heat treatment in Factor 8 in the journal *Transfusion* in late 1982, though this was focused on hepatitis, not on the suspected viral cause of AIDS.

At the end of 1982, Dr Walford wrote a minute flagging that Travenol (Hyland) were planning a symposium in early 1983 to launch a reduced hepatitis risk product. A handwritten note from Stanley Godfrey of the DHSS indicates there was concern as to whether doctors might insist on using such a "hepatitis-free" product at great cost and would "*turn away from the BPL product*". He also expressed his concern that should BPL obtain the technology on licence the yield would reduce and "*Goodness knows what size factory we'd need!*"

BPL began working on heat-treated Factor 8 at the start of 1983. In July 1984 BPL started intensive development of what was to become 8Y and by autumn it was shown that heat treatment appeared to inactivate the HTLV-3 virus which had by then been identified as the cause of AIDS. The purpose of introducing heat treatment was to eliminate or reduce hepatitis, although it was recognised that the heat might destroy other viruses too. It was speculated that heat treatment might reduce or eliminate AIDS if the cause was viral. Some haemophilia centre clinicians had started to use heat-treated concentrates for their patients by mid 1984 in this hope.

In September 1984 *The Lancet* published an article which in its summary said that the findings reported in it "*support the possible role of retroviruses in AIDS, and indicate that factor VIII concentrates must be heated to inactivate these infectious viruses.*" In early November, it was reported to the annual symposium about blood transfusion in Groningen that heating at 68ºC for 24 hours inactivated HIV. Internationally, there was a move to abandon the use of factor concentrate products which had not been heat treated.

Dr Lane had written to Dr Edmund Harris at the DHSS to notify him of his plan to dry heat all the Factor 8 to be produced "*on the empirical basis that it has a satisfactory process efficacy*

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for inactivation of HTLV-III". Dr Harris did not agree immediately and responded by asking Dr Lane to refer his plan to an advisory group to consider if the evidence for inactivation of HTLV-3 by heat was "*sufficient to warrant*" taking such a step, "*particularly if a screening test can be made available.*" Dr Lane did not wait for the meeting to which Dr Harris had referred the issue. Although on 13 November 1984 his team gave him a "*very provisional*" date of 1 April 1985 for the implementation of heat treatment, and said it was "*impossible to judge its feasibility*", by 19 November the CBLA was announcing that they planned to heat all Factor 8 manufactured at BPL/PFL from April 1985.

Later that November the NBTS Working Group on AIDS met. Scotland had started to heat Factor 8 stocks to inactivate HTLV-3. Considering heat treatment more broadly, the meeting report said: "*although there is not yet the evidence to guarantee that this is satisfactory; the view was nevertheless unanimous that it should be done. This should be in addition to using a screening test when available … Some expressed the view that we should stop the import of Factor VIII not heat treated.*"

By the start of 1985 Scotland was self-sufficient in heat-treated Factor 8 product. It had been tested successfully in Edinburgh, and a continuous supply would be provided in sufficient quantities to enable non heat-treated product to be recalled. Scotland was later described as the first country to be self-sufficient in Factor 8 heated to eliminate a risk of AIDS, and only heat-treated product capable of eliminating HTLV-3/HIV was issued from 10 December 1984. This product did not, however, prevent the transmission of hepatitis (that took over another two years).

By early May 1985 all Factor 8 concentrate issued by BPL had been heat treated. There was no recall of unheated stocks of domestic product in England and Wales, as had been done in Scotland. One reason may be that BPL in 1984 was not in a position to produce heat-treated product more quickly. Dr Terence Snape also commented that "*At the time, the unheated UK product was still considered to be 'a product of choice' by many physicians and the product was not withdrawn … Some UK haemophilia specialists took the decision to continue to use unheated NHS concentrate, in preference to heated (US) commercial concentrate, until such time as 8Y was readily available.*" It was not until Dr Harris wrote to all haemophilia centre directors on 15 August 1985 to confirm availability of heated Factor 8 concentrates from various sources and advised "*There would thus appear to be no longer any need to use un-heat-treated Factor VIII concentrate*" that there was a definitive DHSS response to the threat to patient safety from the use of unheated product.

Some clinicians were reluctant to embrace commercial heat-treated products. There was as yet little direct evidence of how reliable the claims about commercial heat-treated products were in practice. Although there was no evidence of side-effects after a year of use in the US, heat-treated commercial products were not licensed for use in the UK until early in 1985. It is not difficult to see why clinicians may have preferred to wait for domestic product rather than change their treatment practices. Further, commercial products were believed to be more likely to carry hepatitis than domestic ones. Understandable though this reluctance may have been, it did not excuse continued use of unheated products beyond a short period

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into 1985. Nor was it, ethically, the clinician's choice. Patients should have been alerted to the balance of risks and advantages, and given information about other treatment options to make that decision. Yet the evidence is clear that, in the main, this did not happen.

The failure to recall stocks of unheated Factor 8 product, at least by the start of the next financial year (after 31 March 1985) cannot be justified. By that time commercial heat-treated product was licensed, and it was obvious that supplying unheated product was taking an unjustified risk with the safety of any patient.

The UK was self-sufficient in Factor 9 for the treatment of Haemophilia B. Heat-treated Factor 9 was issued routinely from the beginning of October 1985, and any stocks of the unheated DEFIX (Scotland) and Factor 9 (England) were recalled and destroyed.

Could and should heat-treated products have come sooner in the UK? The answer the chapter gives is "yes". Pharmaceutical companies, working independently of one another, all began actively to develop heat treatment to inactivate viruses at about the same time in the late 1970s, when there was more pressure to improve market share. Research into viral inactivation to protect recipients of blood products should have been encouraged, and funded adequately, by government no later than the mid 1970s. If this had happened, it is reasonable to conclude that a heat-treated product likely to reduce the risk of hepatitis would have been available no later than 1980/81, and quite possibly earlier. And if this had happened – albeit by chance – the risk that any recipient would have suffered HIV infection would have been reduced almost to extinction.

Factorate

The chapter considers the handling by Armour Pharmaceutical Company Limited ("Armour") and by the Licensing Authority of developing concerns regarding the safety of heat-treated Factorate. The full chronology of events is not repeated here. In summary, however, the behaviour of Armour gives rise to a number of concerns. Armour did not report the possible seroconversion in Lewisham to the DHSS until February 1986, despite being aware of it since July 1985. Its letter of 3 October 1985 to the DHSS was potentially misleading in its omission of reference to that case. Armour did not, as far as the contemporaneous documentation suggests, bring Dr Prince's concerns about the effectiveness of its heat treatment process to the attention of the DHSS: it could have communicated those concerns whilst also drawing attention to the conflicting results obtained by others. Armour confirmed to the DHSS that all product now being supplied to the UK was from donors who had been individually tested, but there remained in stock product from unscreened donors that Armour was apparently open to supplying. Armour did not voluntarily withdraw all such material, as it should have done in the interests of ensuring patient safety. The letter sent by Armour to haemophilia centre directors in March 1986 was misleading by omission in the absence of any reference to the Lewisham patient. When in July 1986 Armour finally wrote to directors recommending the return of all non-donor tested Factorate, it did so having effectively had its hand forced by the decisions of its parent company in the US. The contemporaneous

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documentation supports an inference that patient safety was not accorded the weight that it should have had during this sequence of events.

The conduct of the regulatory authority from February 1986 was also wanting. It did not take any regulatory step to ban or secure the withdrawal of the product until October 1986 when it did belatedly achieve a withdrawal by Armour. It is surprising, and disappointing, that Armour were not asked to recall all the stocks which had been distributed and came from untested source plasma. Although the issue came promptly to the attention of the CSM(B), its decision, subsequently endorsed by the CSM, that there was insufficient evidence for action to be taken failed to place safety at the centre of decision-making. The Expert Advisory Group on AIDS ("EAGA")'s agreed statement in March 1986 went even further, concluding that there was "*no evidence*" that HIV had been transmitted in heat-treated concentrates and thus ignoring the Lewisham case. It took the report from Dr Hill in Birmingham of further seroconversions for the DHSS to act. Whilst action then was prompt, it should not have taken that report to push the licensing authority into action. It is further surprising and disappointing to note that the CMO's immediate response to Dr Peter Jones' actions in February 1986 (when he broadcast his concerns about seroconversions at a conference on AIDS) was to condemn them, at a point in time when the CMO could not have known whether Dr Jones' claims were capable of substantiation or not, and that a DHSS spokeswoman felt able to say that the Netherlands case could be discounted, when the DHSS could not have known at that time whether or not the Netherlands case was one of seroconversion caused by Factorate. These responses, and those of the CSM(B), CSM and EAGA, are unhappily redolent of the "*no conclusive proof*" line that had been erroneously adopted by the DHSS in 1983.

3.15 Pool Sizes

This chapter looks at one of the two most significant matters which determine whether plasma or a blood product made from plasma may transmit infection: the number of donors whose donations have contributed to the pool from which it is drawn. The chapter shows that – alarmingly – those responsible for the administration of blood products in the UK knew the risks, took little notice, and presided over an increase in the risk to levels which were more than 300 times higher than they had been at the start of the 1970s.

The need for caution with regard to pool sizes, and the importance of restricting their size, was recognised in the 1940s in the UK, and by 1951 the use of large pool plasma had been abandoned. In 1952 the WHO's Expert Committee on Hepatitis recommended control of pool size amongst other methods of reducing the spread of serum hepatitis.

In 1967 pressure grew for an increase in pool sizes. Dr Rosemary Biggs wrote to the MRC referring to a conversation with Dr Maycock, to say that he "*also thought that we should probably consider the question of serum hepatitis and, in view of the American activities, whether or not it would be reasonable to increase the pool size for fractionation.*" By contrast, in early 1968 Dr Cumming at Edinburgh briefed Dr Maycock that the expanded blood products unit would use a pool of 8 litres, equivalent to approximately 40 donors.

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At the end of the 1960s and start of the 1970s Factor 8 and Factor 9 were being made at the PFL in Oxford. In 1971 the mean pool size for Factor 8 was 192 donations. Larger pools were used for Factor 9, with 300 donations in 1971. Thus, at the start of the 1970s, so far as NHS plasma was concerned, pool sizes were larger than had been accepted in and since the early 1950s, but were still relatively small in scale compared to what was yet to come, and compared to those in use in the US.

In March 1973 PFC began planning to produce high purity Factor 8 concentrates, with a planned production capacity of one pool of 200 litres per week, and by June 1973 BPL had plans to move to a pool size of 250 litres (around 1,250 donations). There was no discussion in advance about the increased viral risks from increasing pool sizes but those risks were nonetheless widely appreciated.

In 1975 Dr John Craske reported on the Bournemouth hepatitis outbreak, and the risk of using large pool concentrates: "*The risk is greatly increased with factor-VIII concentrates prepared from pools of more than a thousand donations*." By 1977 the pools used to make NHS concentrates at BPL contained 2,000 donations. That increased to 5,000 donations by September 1980, 7,500 donations by 1983, and it was 10,000 in March 1985. It follows that the pools used to manufacture Factor 8 concentrate in 1983 could be almost 40 times as large as the number of donations used to treat patients at Oxford in 1971. Whilst these calculations are estimates based on the available data, and cannot be relied on for precise accuracy, the true figure will be close to the estimate.

There is no evidence of high level discussions in the DHSS about the size of pools or that ministers, or the CMO, were alerted to the dramatic increase. It is unlikely that this was not known to the CMO's consultant advisers on blood transfusion (Dr Maycock, succeeded by Dr Tovey, and then by Dr Gunson), and they should have alerted the CMO.

In 1980, at an international symposium on hepatitis from blood products, Professor Manucci pointed out that strict adherence to the "*small pool concept*" in Sweden had given rise to "*a very low incidence*" of post-transfusion hepatitis in people with Haemophilia B. He suggested that the adoption of this concept would be "*a significant step forward in the prevention of posttransfusion hepatitis and liver disease in hemophiliacs.*" The Council of Europe's Committee of Ministers recommended in April 1980 that blood collection agencies and pharmaceutical companies should provide detailed information about blood and blood related products, including the nature of the donor pool from which the products were made.

The evidence establishes that Dr Lane, and Dr Maycock before him, were aware that increasing the pool size increased the risk of hepatitis transmission but decided to do so nonetheless. It establishes that clinicians too knew of the increasing risk with increasing pool sizes. But it does not show clear evidence, despite these various events, that the DHSS saw the issue of pool sizes as one on which it should take some action.

There is less data available to determine pool sizes in Scotland but contemporaneous documents suggest pool sizes ranging from a minimum of 800 donations to 2,200. This had

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increased by 1984: 4,000 donors appear to have contributed to the implicated batch of PFC product identified as having infected Edinburgh patients with HTLV-3.

Pool sizes mattered. Some claims have been made that they did not matter much, because people with bleeding disorders required frequent treatment, and so – whether cryoprecipitate or factor concentrates were used – they would suffer in any event. Non-A non-B Hepatitis could not be screened out until 1989: so there was simply no way of knowing for sure if any treatment was or was not infective so far as that was concerned.

This argument ignores a number of points. First, it does not apply to people who were infrequently treated. Second, people receiving frequent treatment would be exposed to a much greater extent to multiple viruses, some of which might not yet be identifiable but were nonetheless potentially threatening. Third, it significantly increased the risk of new viruses taking a hold (as was shown with HIV). Fourth, single donor cryoprecipitate was recommended for children and the newly diagnosed to avoid the risks of hepatitis, precisely to avoid the risks of infection. Fifth, the claim of inevitable infection would suggest that commercial concentrates were no worse than NHS concentrates or cryoprecipitate: yet the weight of the evidence shows that this is not so.

If there is an acknowledged risk that treating a patient with a single donation product might transmit hepatitis, why should that risk then be increased multiple times on every occasion the patient needs treatment? If cryoprecipitate or small pool fractions had been more widely available, it is probable that the same extent of infection would not have occurred.

Product labels used at PFL and BPL contained statements as to the maximum pool size (eg "*Less than 7,500 plasma donations were used in the preparation of this batch*"), and some indication as to risk ("*The preparation is of human origin and cannot be assumed to be free of hepatitis virus*"). There was no warning as to the risk specifically of AIDS until late 1985, and then on vials of 8Y, a product which was heat-treated. By 1987 the reference to donor numbers had been removed from the label.

In Scotland in 1978 there was a warning for Factor 8 that "*Product may carry the risks of transmitting serum hepatitis*"; and for Factor 9 that "*none of these tests are of sufficient sensitivity to eliminate the possibility of transmitting hepatitis ... the risk of transmission cannot be disregarded.*" In 1984 the vial labels stated that "*This preparation is of human origin and cannot be assumed free of hepatitis virus*" (for unheated Factor 8 concentrate); and the same wording was used for unheated Factor 9 concentrate. By 1985 it was "*The freeze dried product has been heat treated but cannot be assumed to be non-infective*" (for heat-treated Factor 8 concentrate with the label dated 1985). Nothing was said about AIDS or HIV specifically.

The purpose of warnings is to communicate that there is a risk to those who need to know of it. A proper approach by manufacturers to risk – that is, they should alert professional users and patients to risks of which they are aware once there is enough material to show that there is such a risk – is one aspect of a system which has three points at which notice of a risk may be given: by the manufacturer, by the regulator, by the prescribing clinician. The

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system should ensure that the patient is properly informed of the risk. It cannot achieve this if the manufacturer does not say sufficient about the risk but leaves that to the regulator or clinician, if the regulator in turn does not require a full account of the risks or prevents the manufacturer from talking of risk because it looks for certainty, and if the clinician leaves it to the manufacturer (or regulator) to reveal the risk. What could be a "triple fail-safe" in effect becomes instead a system in which each part leaves the matter to the other. In the case of BPL/PFC the same failings of product labelling were evident as they were in respect of the labelling and product warnings given in respect of commercial concentrates.

Volume 4 What happened and why?

This volume has four chapters, which at 4.1 considers the response of the government to risk; at 4.2 examines haemophilia centres, their policies and practice (those interested in Treloar's should look at chapter 2.2); at 4.3 looks at pharmaceutical companies; and at 4.4 the Haemophilia Society.

4.1 Role of Government: Response to Risk

It was the responsibility of the DHSS, and of the Secretary of State for Health, and of those in positions of equivalent responsibility in Scotland, Wales and Northern Ireland, to ensure, as much as possible, that treatment given through the NHS was safe. This chapter examines in detail the extent to which this responsibility was satisfactorily discharged and concludes that government failed to discharge its fundamental duty to ensure the safety of the public so far as recipients of blood and blood products were concerned. What is set out below is no more than a summary of the key facts and issues which are examined in greater depth in the chapter.

Knowledge of risk of infection from blood and blood products

By the early 1970s it was well known among the responsible government officials that treatment with blood and blood products carried a risk of transmission of viral hepatitis. The seriousness of Hepatitis B was well understood. Nobody who received the minute from Dr Walford in September 1980 stating that NANBH could potentially lead to severe chronic disease could have been under any illusion about that. However, the DHSS did nothing to ensure that the serious nature of this condition was also properly understood by doctors, representative bodies (such as the Haemophilia Society) or the public.

Collection of blood from prisons

Both the DHSS and the SHHD knew from the early 1970s that the collection of blood from prisons and similar institutions led to an increased risk of transmission of Hepatitis B. Despite this indication that prison donation might not be safe, blood collection from prisons was a common practice in the UK throughout the 1970s and early 1980s.

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In May 1975 a "Dear Doctor" letter from the CMO, Sir Henry Yellowlees, advised that collections could continue, despite the higher risk of Hepatitis B. This letter, which relied on the fact that there were other high risk groups such as drug users as a reason to continue to collect from prisons, contained deeply flawed logic and effectively endorsed and encouraged this practice. The hands off approach of the DHSS and SHHD, leaving blood safety entirely to the judgement of local RTDs, was wholly unacceptable. It should have been taken seriously by government and was not. It was also wrong not to bring the issue of prison donation to the attention of ministers. It was not raised with a Scottish minister until May 1983; it was never raised with ministers in the DHSS.

Response to AIDS July 1982-April 1983

On 16 July 1982 – the same date as the MMWR carried a report of AIDS in three haemophilia patients in the US – the possibility of AIDS being transmitted through blood was explicitly drawn to the attention of civil servants within the DHSS by Dr Harold Gunson. This led to an exchange of memos by civil servants in July. Beyond this, however, there is no evidence of there being, over the next few months, within the DHSS, any documented discussions or planning or any consideration of what steps might need to be taken with regard to the safety of blood or blood products in light of this grave new threat. Indeed, other than this exchange of memos, there is no record of discussions about AIDS and blood within the DHSS between 16 July 1982 and the end of 1982.

It would have been clear from a paper prepared by Dr Craske in November 1982, which was copied to Dr Mary Sibellas of the DHSS, that he considered an infectious agent to be the most likely cause of AIDS.

At the CBLA's first meeting in December 1982, attended by the Deputy CMO and civil servants from the DHSS, there was no discussion about AIDS. Nor was there any such discussion at the meeting of the Advisory Committee on the NBTS which met at the DHSS under the chairmanship of the Deputy CMO on 10 January 1983, or at the CBLA's meeting on 26 January 1983. There was a brief discussion about AIDS at the CBLA's meetings on 23 March and 27 April but with no action identified for the DHSS to take.

Dr Walford told the Inquiry that by the beginning of 1983 she understood it was likely that AIDS was transmissible through blood and blood products. She thought that the San Francisco baby case was "*a sort of watershed*" and "*rang all sorts of alarm bells.*" She thought that gradually the feeling within the DHSS was that it was "*looking more and more likely that blood and blood products are certainly capable of transmitting this agent*".

Dr Walford believed at the time, as did others in the DHSS, that the hazards of transmission were unproven and that people with severe haemophilia desperately needed factor concentrates. This was wrong – and not just with hindsight. The hazards of AIDS may have been "*unproven*", and the extent of the risk at that stage unclear, but it was clear that there was a risk and that the consequences of infection were grave and this should have weighed more heavily in the balance. As for the desperate need for concentrates, the DHSS did not

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sufficiently understand the availability of alternative treatment strategies, and over-inflated the risks to people with bleeding disorders of not having factor concentrates available to them for treatment.

There is no evidence, in the period up to May 1983, of any issues relating to AIDS and blood being brought to the attention of the Secretary of State or other ministers.

May-June 1983

It was not until May 1983 that there was within the DHSS any real focus on how best to respond to the risks of AIDS from blood or blood products and that was as a response to press reporting, which led to a briefing note and line to take being prepared for the Prime Minister.

On 6 May 1983 Dr Spence Galbraith of CDSC telephoned Dr Sibellas at the DHSS to report that the Cardiff patient had the right symptoms and signs for a diagnosis of AIDS, and to flag up the three cases in Spain. He asked that the DHSS "*consider the matter as a priority – and asks that any top level meeting should include CDSC*". On 9 May he wrote to Dr Ian Field at the DHSS. He referred to the Cardiff patient and probable cases of AIDS in people with haemophilia in Spain and the US, attached a paper outlining his reasoning, and said: "*I have reviewed the literature and come to the conclusion that all blood products made from blood donated in the USA after 1978 should be withdrawn from use until the risk of AIDS transmission by those products has been clarified.*"

Dr Galbraith's reasoning was impeccable. His views deserved to be given great weight and circulated widely. Unfortunately, that did not happen. His paper was the subject of internal comment by Dr Walford but was not acted on or shared more widely. The DHSS did not share the letter with CSM(B) or the CSM, as it should have. It was not circulated to haemophilia centre directors or to RTDs, to allow a fully informed and comprehensive debate and discussion. It was not brought to the attention of ministers, or to the CMO. The DHSS's response to it was inadequate.

In dismissing, or at least ignoring, Dr Galbraith's position, the whole issue of concentrate use was seen as an all or nothing scenario of either continuing with the status quo or providing people with haemophilia with no treatment at all. That was the wrong way to look at it: there were other ways in which people with haemophilia could receive treatment which were not considered.

An internal DHSS meeting to consider AIDS took place on 3 June 1983, at which there was no discussion whatsoever of Dr Galbraith's letter and paper, nor any discussion about any different approaches to the treatment of bleeding disorders. This reflected the departmental position that, having regard to the principle of clinical freedom, it was not the role of the DHSS to provide guidance or advice to clinicians. This was a short-sighted position for the DHSS to adopt and ultimately a dereliction of its responsibility to patients.

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Council of Europe recommendations

In June 1983, the Council of Europe's Committee of Ministers published a resolution which was addressed to the governments of member states. Its overarching recommendation was "*to take all necessary steps and measures with respect to*" AIDS. The first detailed recommendation was "*to avoid wherever possible the use of coagulation factor products prepared from large plasma pools; this is especially important for those countries where self-sufficiency in the production of such products has not yet been achieved*". The government took no steps in response to this recommendation.

The second recommendation was to tell clinicians and patients about the risks of treatment with blood and blood products and the possibilities of minimising the risks. The UK government took no steps in response to this recommendation. Dr Walford's explanation was that this would not be a usual course of action for the DHSS. But this was a situation in which there was a very real risk that the very treatment being provided by the NHS – for which the DHSS bore ultimate responsibility – would directly transmit to patients a fatal, untreatable and new viral disease. Whatever the normal approach of the DHSS, this was a different situation, and one in which there was a culpable failure to act.

The last specific recommendation was "*to provide all blood donors with information on the Acquired Immune Deficiency Syndrome so that those in risk groups will refrain from donating*". Action was taken on this, with leaflets being produced for donors, although too slowly.

Reversion to cryoprecipitate, alternative approaches to treatment and guidance to doctors and patients

The DHSS did not seriously consider alternatives to treatment with imported concentrates, such as a temporary increase in use of cryoprecipitate. It relied on Dr Gunson, who said this was not feasible, and Dr Lane who said it was not possible to produce small pool freeze dried cryoprecipitate. The issue was not, however, explored with the RTCs. The DHSS did not regard it as its role to issue any kind of advice or guidance or steer to clinicians advising, or even simply encouraging, them to consider alternative approaches to treatment. It was a failing on the part of the DHSS not to take such measures, particularly as they did so in other cases. In September 1982 the Secretary of State for Health, Norman Fowler, issued a statement about whooping cough. That statement gave information about the numbers of cases; the importance of immunisation; the risks of the disease and the benefits of vaccination in reducing that risk. The DHSS believed this campaign saved lives.

In September 1983 it was known to the DHSS that a patient with haemophilia had died from AIDS. It was also known that some of the commercial Factor 8 concentrate from the batches administered to the patient in Bristol who had died had found their way to hospitals which were not haemophilia centres. This fact should have – but did not (or, if it did, no action was taken) – alerted the DHSS to the fact that, given that some people with haemophilia were treated elsewhere than at haemophilia centres, those treating them might have a limited understanding of the risks of treatment. Neither the CMO nor the DHSS could have made any assumptions about the state of knowledge of those hospitals. This risk should have

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been an impetus to the dissemination of information, whether by the CMO or the DHSS directly, but did not lead to any action.

No conclusive proof

Press coverage early in May 1983 led to officials providing briefing for Prime Minister's Questions on AIDS. The first use of "*no conclusive proof*" appears in a line to take drafted for the Prime Minister: "*It is important to put this in perspective: there is as yet no conclusive proof that AIDS has been transmitted from American blood products.*" The accompanying briefing note included the sentence: "*As yet there is no conclusive proof that AIDS is transmitted by blood as well as by homosexual contact but the evidence is suggestive that this is likely to be the case.*"

The line was used on 31 May 1983 in a letter from Lord David Trefgarne to Nicholas Baker MP which stated: "*I can well appreciate the anxiety, particularly amongst haemophiliacs and their families, which recent press reports on AIDS may have caused and would first of all like to put matters into perspective: the cause of AIDS is as yet unknown and there is no conclusive proof that the disease has been transmitted by American blood products.*" Lord Trefgarne did not know why the caveat in the briefing note ("*but the evidence is suggestive that this is likely to be the case*") had been omitted from the letter drafted for him by officials.

On 1 July 1983 a paper sent to Lord Simon Glenarthur referred to "*increasing evidence that AIDS may be transmitted by the transfusion of blood … Blood products … may also transmit AIDS and haemophiliacs are at particular risk ... It is believed that there may be under-reporting of cases … Although there is no conclusive evidence, it seems very likely that AIDS is caused by an as yet unidentified virus.*"

On 14 July 1983 the "*no conclusive proof*" line was used in Parliament: Lord Glenarthur stated that "*Although there is no conclusive evidence that AIDS is transmitted by blood or blood products, the department is considering the publication of a leaflet indicating the circumstances in which blood donations should be avoided.*"[26] In the course of the debate, Baroness Susan Masham posed a question to which Lord Glenarthur said he would "*find out and let her know.*" Dr Walford's proposed draft response to Baroness Masham included the following: "*There is no conclusive proof that AIDS can be transmitted by blood, cryoprecipitate or Factor VIII concentrates but the assumption is that such transmission may be possible.*" The letter then sent to Baroness Masham stated that "*There is, in fact, no conclusive proof that AIDS can be transmitted by blood, cryoprecipitate or Factor VIII concentrates.*" The qualifying phrase ("*but the assumption is that such transmission may be possible*") in Dr Walford's original draft had been dropped.

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26 It is an essential part of the narrative of the Report to describe, where relevant, statements made in Parliament: see, by way of further example, the chapter on *Lines to Take*. If (which has not been authoritatively determined) parliamentary privilege as set out in Article 9 of the Bill of Rights applies to the proceedings of the Inquiry (see further Note from Counsel to the Inquiry on Parliamentary Privilege 11 January 2023 INQY0000432) it does not breach parliamentary privilege for the Report to describe what was said to Parliament as part of its account of, and findings about, decision-making and policy-making.

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On 25 August 1983 Lord Glenarthur wrote to Nicholas Baker, providing information about the monitoring of AIDS cases by CDSC; his letter ended "*Finally, I would like to stress that there is as yet no proof that AIDS is transmitted by blood or blood products.*"

On 26 August 1983 Lord Glenarthur wrote to Clive Jenkins, the general secretary of the Association of Scientific Technical and Managerial Staffs. His letter read: "*I think that I should emphasise, firstly, that there is no conclusive evidence that AIDS is transmitted through blood products.*" It continued "*Nevertheless we are taking all practicable measures to reduce any possible risks to recipients of blood and blood products.*"

On 1 September 1983 the publication of the AIDS donor leaflet was announced with a press release in which Kenneth Clarke said "*It has been suggested that AIDS may be transmitted in blood or blood products. There is no conclusive proof that this is so.*" This line was picked up and repeated in press reports.

At the 17 October 1983 meeting of the Advisory Committee on the NBTS the minutes record a contribution from Dr Walford that "*Although there was as yet no conclusive proof of a link between AIDS and blood products the Department had, in conjunction with RTDs produced a leaflet aimed at reducing the risk of transmission of AIDS by blood donation.*"

A newspaper report of the death of the patient in Bristol prompted a civil servant to ask Dr Walford on 23 November "*is it Ok for me to continue to say 'there is no conclusive proof that the disease has been transmitted by American blood products'*", to which Dr Walford replied "*Yes it is ok*".

On 14 November 1983 Kenneth Clarke told Parliament that "*There is no conclusive evidence that acquired immune deficiency syndrome (AIDS) is transmitted by blood products.*"

On 16 November 1983 Lord Glenarthur wrote to Jerry Wiggin MP. The letter read "*I can well appreciate the anxiety, particularly amongst haemophiliacs and their families which recent press reports on AIDS may have caused and would first of all like to put matters into perspective: the cause of AIDS is as yet unknown and there is no conclusive proof that the disease has been transmitted by American blood products.*" Forwarding the letter to his constituent, Jerry Wiggin expressed the hope that "*Lord Glenarthur's reply will reassure you on the Government's stand on this issue*". The same line appeared in a letter dated 16 December 1983 from Lord Glenarthur to John Maples MP.

A handwritten note on 26 March 1984 stated that "*We dropped 'there is no conclusive proof that AIDS is transmitted through blood or blood products' from our standard line some time ago.*"

This line to take, whilst technically correct, was indefensible. It did not spell out the real risk. It gave false reassurance. It lacked candour and by not telling the whole truth was misleading. It was not an accurate reflection of the DHSS' actual understanding, which was that it was likely that AIDS was transmitted through blood and blood products. No minister challenged the "*no conclusive proof*" line. They should have done. Far from seeking to

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reassure those taking blood or blood products that doing so came without significant risk, the authorities ought to have been emphasising that there were indeed risks.

The AIDS leaflet

Until a screening test was available, the only way to reduce the risk of AIDS transmission in the domestic blood supply was to ensure, as far as possible, that donors most likely to transmit the virus did not donate. Given that the risk of transmission of AIDS through blood or blood products was known by the DHSS since mid 1982, it took far too long until the production of a leaflet was first discussed in May 1983. Though rightly described as urgent within the DHSS, it then took too long for the leaflet to be finalised and made available to regional transfusion centres at the beginning of September 1983. Further, although it should have been obvious that the issue of the leaflet with donor call-up cards was more likely to meet the public health objective of the exercise, it was decided that RTDs should be given the discretion to decide the most effective means of distribution in their own regions, which would be reviewed after three months. The decision to leave the method of distribution to RTDs rather than ensure from the outset that the leaflets reached donors to the greatest possible extent was wrong.

The wording of this first leaflet was problematic. First, those in the risk groups were merely requested not to give blood, rather than being instructed that they should not or must not give blood. Second, the request was contingent upon the donor thinking "*they may either have the disease or be at risk from it*", but the leaflet twice described the disease as rare, and in terms of the numbers of cases in the UK indicated that "*about a dozen cases have been reported, by the middle of 1983.*" Donors might, not unreasonably, have thought it unlikely that they themselves would be at risk of such a rare disease and thus thought that they did not need to self-exclude. Third, the risk group in relation to homosexual men was limited to those "*who have many different partners*": this was problematic both in terms of the present tense ("*have*") and in terms of the reference to "*many different partners*" – those who had only one partner or more than one (but not "*many*" – whatever that meant) would not think to self-exclude; nor would they have thought themselves excluded if they had had only one partner, but that partner had had several others before him. Fourth, the risk group in relation to IV drug use was limited to "*Drug addicts*": those who had previously engaged in IV drug use but no longer did so, or who had used drugs but did not consider themselves to be "addicts", would not necessarily think to self-exclude. Fifth, the risk group in relation to sexual contacts was limited to the sexual contacts of those suffering from AIDS, rather than sexual contacts of people at risk of AIDS.

Lord Glenarthur argued against six months as a trial period, insisting on three. Accordingly, the three month trial period for distribution of the first leaflet should have led to a review at the end of November or the beginning of December 1983. It did not. Instead, there was substantial delay in evaluating whether the content of the first leaflet was sufficient to achieve its purpose and whether there should be a changed approach to distribution of the leaflets. It was only in August 1984 that ministers were asked to agree more effective

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distribution and to a revision of the leaflet to include a stronger warning to high-risk groups not to donate. It then took until January 1985 for the revised leaflet to be finally approved, meaning that for the year from January 1984 – and as a result of multiple delays – a leaflet with wording agreed not to be sufficiently strong, which was not being distributed in the best way to deter high-risk donors, continued to be used.

The second leaflet was an improvement on the first, but two of the risk groups were still ambiguously and confusingly described. The first was described as "*Practising homosexual and bisexual men*". Whilst there was no longer the reference to "*many different partners*", the word "*practising*" was ambiguous and would exclude those who (perhaps because of fear of transmission of AIDS) might have stopped having sexual relations with men. Drug "*addicts*" had been replaced by "*Drug abusers*", but this was qualified by the phrase "*who inject drugs*": the present tense thus did not encompass those who had previously injected drugs but no longer did. By the time the second leaflet was issued, it had already been recognised that it needed further redrafting.

The AIDS leaflet was one of the few measures that could be taken to try to ensure that those donors most likely to transmit the virus did not donate. The safety of the blood supply should have been the central focus rather than a preoccupation with adverse publicity.

The potential consequences of the failure to act earlier and more decisively are starkly illustrated in the case of the Wessex donor. This donor was diagnosed with AIDS at Bournemouth Hospital in autumn 1984, and had previously donated blood, including in late March 1984. Transfusions had been given to three people all of whom were infected with HIV. The donor's plasma was also part of the source material for one batch of Factor 8 concentrate which was used in the treatment of 38 people with bleeding disorders in Wessex and South Wales, and transmitted HIV to a number of them.

Reliance upon Professor Bloom

Professor Arthur Bloom's views overly influenced the way the DHSS viewed the emergence of AIDS and the threat posed to people with bleeding disorders. He was the only haemophilia expert who participated in the meeting of the CSM(B) on 13 July 1983. He shaped the views of the Haemophilia Society, who in turn made representations to the DHSS about the correct response to AIDS. He was, amongst other roles, a member of the CBLA and its Committee on Research and Development in Blood Transfusion, the MRC Working Party on AIDS, the EAGA and the Working Group on AIDS of the Advisory Committee to the NBTS. There was an uncritical acceptance of his line of thinking and a failure to probe his advice.

Failure to establish the Expert Advisory Group on AIDS earlier

Allied with the over-reliance on a single haemophilia clinician was the failure to establish a body such as the EAGA until late 1984.

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It is not clear why a working group on AIDS was rejected by the DHSS in May 1983. This would have provided a multidisciplinary forum for discussion and might have led to more decisive and earlier action. The EAGA met for the first time in January 1985.

Lack of involvement of the Chief Medical Officer

The role of the Chief Medical Officer ("CMO") was to inform "*Ministers and the public of risks to Public Health and advising on policy measures to minimise these risks. He was also responsible for giving guidance to clinicians, health boards and patients where he thought it appropriate.*"

However, the CMO was conspicuous by his absence from discussions and decision-making relating to AIDS in the period from mid 1982 to late 1984. There is little evidence of involvement by Sir Henry Yellowlees. It took Dr (later Sir) Donald Acheson, his successor, too long to appreciate, and respond to, the gravity of the situation. It was not until late 1984 that there began to be any real involvement by the CMO, and by the Secretary of State, in the response to AIDS.

There is ample evidence of the CMO's active involvement from late 1984 onwards. What is unclear is why there was no such active engagement at an earlier stage, at least from mid 1982 onwards.

The role of ministers

The evidence available to the Inquiry demonstrates that officials failed to bring many important matters to the attention of ministers. There was no particular logic or consistency in what went to ministers and what did not. They were not told of the CSM/CSM(B) decision-making. They were not told of Dr Galbraith's recommendations. Lord Glenarthur was not told in late 1984 that a number of individuals in Scotland had been infected with HIV through NHS Factor 8 produced at the PFC.

It is not the fault of ministers if civil servants do not bring matters to their attention. It is, however, the responsibility of ministers to demonstrate a degree of proactivity and to challenge. Viewed overall ministers appeared to have lacked curiosity in the early period of the developing public health crisis. No minister, for example, asked officials to investigate what other steps could be taken to protect people short of stopping the importation of concentrates.

Committees and working groups

A number of different committees and groups were responsible for advising DHSS officials and ministers on blood safety during the 1970s and 1980s. There was no overarching advisory committee on blood safety until the establishment of the Advisory Committee on the Virological Safety of Blood ("ACVSB") in 1989. The repetition of advice from more than one committee covering the same subject may seem reassuring. However, given the small

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number of leading experts in haemophilia, fractionation plants, and the blood transfusion service the same people were often involved in different bodies. Instead of cultivating assurance through a range of advice, this masked the reality and perhaps discouraged ministers from asking whether there were other views. Decision-making on something so fundamental to the health of the nation as blood safety should have been better organised.

One of these committees was the Advisory Group on Hepatitis, set up in part to consider and advise on non-A non-B Hepatitis. Despite the need for the expert group having been identified in July 1979, it was not established until the autumn of 1980. The first meeting of this new Advisory Group on Hepatitis was on 3 October 1980: there was no discussion about NANBH. The second meeting was on 5 December 1980: again no discussion about NANBH. The third was on 11 May 1981: still no discussion of NANBH. The fourth meeting was in October 1981: again nothing on NANBH. A year then elapsed before the fifth meeting in October 1982: Hepatitis A and Hepatitis B were both considered, but not NANBH. The next meeting took place a year later, in October 1983: on this occasion AIDS was discussed as well as Hepatitis B, but not NANBH. Nor was NANBH considered at either of the Advisory Group's 1984 meetings, nor at its October 1985 meeting, nor its July 1987 meeting. The February 1989 meeting merely noted that there was a paper on "*NANB virus in blood for transfusion*" but there was no discussion about the issue. By this time the ACVSB was being set up. The December 1990 meeting of the Advisory Group on Hepatitis again contained no consideration of NANBH/Hepatitis C, other than recording that the blood transfusion service would be testing donations from 1991. This was symptomatic of a wider problem within government in the 1980s, namely the lack of attention paid to NANBH and its transmission through blood and blood products.

As for the establishment of the ACVSB, it is surprising, and disappointing, that – the need for such a committee having been identified in June 1988 (a need that should in any event have been identified long before) – it took until April 1989 for it to be in a position to meet. The delay was particularly concerning because the purpose of the group was to provide advice so that the DHSS could "*enable quick reactions to be made to new developments in screening techniques and new epidemiological information.*"

Northern Ireland

The Northern Ireland Department of Health and Social Services ("DHSSNI") played a very limited role in decision-making regarding blood safety in the 1970s and 1980s. This was in part due to the fact that direct rule from Westminster was introduced in March 1972 following the suspension of devolved government.

There is comparatively little contemporaneous documentation available, but it is clear that overall the DHSSNI followed the policy decisions made by the DHSS in London and that the DHSSNI had little observable influence on those decisions. Two particular factors contributed to that state of affairs. The first was that in reality security and political aspects "*took up a significant amount of ministerial time*". The second was that the responsibilities of the relatively small number of medical and administrative civil servants in Northern Ireland

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covered a broad range of matters, with less expertise and (in reality) less time devoted to matters of blood and blood products.

Wales

The role played by the Welsh Office was, on occasions, a little more active than the Northern Ireland Office, but with Wales still following the lead of the DHSS on matters of health policy regarding blood and blood products. There was no independent Welsh Office action concerning the risk of hepatitis from blood and blood products, although it was recognised as a hazard. There were some discussions within the Welsh Office regarding AIDS, independent of the decision-making being undertaken by the DHSS in the period 1983 to 1984 regarding AIDS. On 4 May 1983, for example, a meeting was convened involving the CMO for Wales and a number of medical officers, as well as Professor Bloom and the RTD for Cardiff, Dr Tony Napier. This meeting did not result in any action.

Scotland

Scotland had its own separate health and transfusion services, as well as a large degree of independence in matters of health policy and administration. Health was the responsibility of the SHHD.

The first recorded discussion concerning AIDS which included officials from the SHHD occurred at a meeting held between SNBTS and Scottish haemophilia centre directors on 21 January 1983. The minutes do not record that any action to minimise the risks in Scotland of AIDS was to be taken by SHHD (or anyone else). A briefing was sent to the minister in May 1983; no specific steps to be taken by the SHHD were identified, nor was the minister asked to make any decision or take any action. Just as with the DHSS, the reaction of the SHHD was to do too little and to do it too late. The SHHD wrongly adopted and used the "no conclusive proof" line.

The SHHD appears to have been content to sit back and let the DHSS take the lead in respect of decision-making on the AIDS leaflet. Too much faith was placed in the safety of the domestic blood supply in Scotland because of the voluntary donor system.

There is every reason to suppose that decision-makers in Scotland became aware of the risk of AIDS at broadly the same time as the DHSS in Westminster. It was thus unlikely to be long before it reached blood donors in Scotland, and thus transfused patients, and people with bleeding disorders, unless effective precautions were taken. Despite this, there is little sense of the need for urgent action.

4.2 Haemophilia Centres: Policies and Practice

This is a lengthy and detailed chapter examining the treatment policies and practices of haemophilia centres in the 1970s and 1980s. The chapter considers the following issues:

- the organisation of haemophilia centres

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- the shift from cryoprecipitate to factor concentrates, explored first through UKHCDO meetings and then through the treatment policies and practices at the reference centres (Newcastle, Cardiff, Manchester, St Thomas' Hospital, the Royal Free Hospital, Oxford, Edinburgh, Glasgow Royal Infirmary, Belfast, Sheffield) and at some of the larger non-reference centres (Birmingham, Royal London, Leeds)
- the Glasgow symposium in the autumn of 1980 and what it revealed about the risks of hepatitis
- the emergence of AIDS and the response of UKHCDO
- treatment practices and policies 1982-1984 (examining in particular Newcastle, Birmingham, Royal Free, Edinburgh, Glasgow Royal Infirmary, Belfast, Cardiff, Oxford, Bradford, St George's, Guy's Hospital, Margate, Royal London, Leeds, Liverpool, Sheffield, and Leicester)
- Haemophilia B
- von Willebrand disorder
- the use of PFC concentrates in Scotland 1985-1987
- relationships with pharmaceutical companies
- research
- the treatment of children, explored first through examination of the paediatric haemophilia centres (Alder Hey, Birmingham Children's Hospital, Royal Manchester Children's Hospital, Royal Belfast Hospital for Sick Children, Great Ormond Street Hospital, Royal Hospital for Sick Children (Yorkhill), Bristol Children's Hospital, Sheffield Children's Hospital) and then through examination of how children were treated at other haemophilia centres
- ethical failings: consent and testing

The chapter includes detailed data, drawn mainly from annual returns, showing product usage in the second half of the 1970s. That data is not replicated here but can be read in the chapter.

What follows below is a summary only of some of the central points: readers should refer to the full chapter for a proper understanding of the Inquiry's analysis and findings.

Treatment policies and practices in the 1970s: UKHCDO meetings

The 1970s saw a gradual shift from the almost exclusive use of cryoprecipitate, largely in hospitals, to the extensive use of factor concentrates, both in hospitals and in home treatment.

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Home treatment

Home treatment was discussed by haemophilia centre directors in October 1972: it was at a very early stage but had been discussed in some centres. Over the following years home treatment programmes became more widespread. At a directors' meeting in January 1974 it was recorded that some directors were buying commercial concentrates for use in home therapy. At the 1975 annual meeting of haemophilia centre directors, 25 centres were reported to be using home therapy: 20 of those centres were using commercial concentrates for some home treatment, 12 centres were using some cryoprecipitate. 1977 saw the establishment of UKHCDO's Home Treatment Working Party. At the reference centre directors' meeting in January 1978, it was unanimously agreed "*that freeze dried concentrates were the material of choice for home treatment and the Reference Centre Directors recommend that all patients on home treatment should have freeze dried concentrates.*" There was no discussion about the relative safety of cryoprecipitate versus concentrate, or of the increased risk of viral transmission in consequence of such a change.

Supply issues and the growth of concentrate use

Concerns about insufficient supplies of NHS Factor 8 were a feature of UKHCDO meetings throughout the 1970s. The October 1972 meeting recorded that many directors were pressing for permission to purchase the "*good commercial products*" manufactured overseas. At a joint meeting of directors of haemophilia centres and blood transfusion directors in January 1974 there was "*a wide ranging discussion about the relative merits of cryoprecipitate and freeze dried concentrates with regard to ease of manufacture, recovery from the original plasma, ease of administration and recovery of activity in the patients*". Notably, the discussion did not include relative safety. The minutes recorded the general feeling that "*larger supplies of concentrated preparations were required now and urgently*" and that none of those present would prefer cryoprecipitate if freeze-dried concentrates were freely available.

Hepatitis

Hepatitis was also a constant theme of discussion in the 1970s but increasing awareness of the risks of hepatitis, in particular those of non-A non-B Hepatitis, did not influence the approach to treatment. In December 1975 the World In Action documentary "*Blood Money*" was broadcast. The minutes of the meeting two months later indicate no discussion of the issues raised but note that taking part in TV programmes could "*distort the facts and present biased views which were embarrassing to doctors and could be alarming to patients*".

1977 saw the establishment of UKHCDO's Hepatitis Working Party. The very establishment of a working party to study "*knowledge of transfusion hepatitis in British haemophiliacs and its sequelae*" reinforces the conclusion that it was, rightly, understood that hepatitis (including NANBH) was something serious, requiring further investigation, rather than, as some clinicians have claimed, something believed at the time to be benign and mild. At the very least it shows that clinicians did not truly know what the consequences were, and that if they thought despite that lack of knowledge that the disease was benign, it was

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"*wishful thinking*". The 1978 report of the Hepatitis Working Party referred to studies carried out at Chapel Hill hospital in the US: "*They have carried out almost 100 liver biopsies on patients with chronically elevated serum transaminases in a collaborative survey, and nearly 50% of these have histological changes compatible with cirrhosis, chronic active or chronic persistent hepatitis. These patients have had up to ten years of treatment with freeze dried factor VIII concentrates of different brands.*"

The evidence is clear that haemophilia clinicians in the 1970s knew or ought to have known that hepatitis might well have serious long-term consequences, that there was still much to be learned, and it was a real threat. By 1975 there had been an epidemic in Bournemouth, it was recognised that cases not presenting as jaundice were a real problem, and that the pool sizes for commercial concentrates were more likely to cause infection. There is no point at which the minutes of the various meetings suggest that as a group the haemophilia centre directors reflected whether they should continue with ever more product from even larger donor pools of uncertain origin, or whether they should offer their patients alternatives. Safety was not the paramount consideration which it should have been.

Treatment policies and practices in the 1970s: the reference centres

Six features emerge from the treatment of patients with Haemophilia A in the 1970s:

(a) the increasing use of concentrates (particularly commercial)

(b) the insufficiency of NHS concentrates outside Scotland: many clinicians complained of a "*shortfall*" in what was available from BPL

(c) the decreasing use of cryoprecipitate

(d) the lack of express consideration given to safety

(e) the growth in use of greater quantities of Factor 8 therapies, especially for home treatment, but also for some prophylaxis

(f) the limited use of risk mitigation or reduction measures such as DDAVP and batch dedication policies

Underpinning the approach to treatment was an assumption that hepatitis was "*an inconvenience, but essentially harmless*": an assumption "*of the kind that doctors should not make.*" An elementary principle is that if a certain process or procedure carries risks with it then reasonable steps should be taken to eliminate those risks or, if they cannot be eliminated, to reduce them. Scant regard is paid to this principle if no attempt is made to take any such step.

Newcastle

This centre was an early proponent of home treatment and commercial concentrates were an established part of its treatment practices by or soon after 1973. Dr Jones' policy from

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the 1970s was to treat young children with "*locally produced*" cryoprecipitate rather than factor concentrates but from the age of six (or possibly younger), depending on their veins and parental expertise, home therapy could begin, and this involved factor concentrates including substantial amounts of commercial concentrates. Prophylaxis was also a feature of the treatment policy. The risks of hepatitis from use of concentrates (particularly commercial ones) were well known to Dr Jones. In a 1980 newsletter he said both that "*the dangers of viral disease transmission inherent in intensive transfusion are far from over, and that these dangers are compounded by the use of large plasma pools from commercial sources*", and that the risk of infection with non-A non-B Hepatitis "*is almost always a very mild one*". In Newcastle, as in so many other Centres, the knowledge of almost inevitable infection with non-A non-B Hepatitis and risk of chronic liver disease was not shared with patients as it should have been.

Cardiff

By 1976 a home treatment programme had been established in Cardiff. Over the following years there was a substantial increase in the amount of commercial concentrates used. As to hepatitis risks, Professor Bloom's approach is apparent from a letter he wrote in February 1975 to another clinician about a patient with haemophilia who had "*been selected for home treatment*" with Factor 8 concentrate, stating that: "*A small percentage of these freeze dried preparations contain, unavoidably, the virus of serum hepatitis and therefore potentially dangerous to the patient, his relatives etc.*" In a report for the HIV Haemophilia Litigation Professor Bloom wrote that most patients with haemophilia were infected with both Hepatitis B and non-A non-B Hepatitis. The impact of this recognition on his treatment practice was, however, marginal: "*The general recommendation however was that bleeding was still the main cause of morbidity and mortality and that treatment with concentrates should continue except perhaps that treatment with cryoprecipitate may have been more circumspect in general in young children and that DDAVP should be used, within its constraints, in mildly affected patients with haemophilia A.*"

Manchester

Manchester was slower than some other large centres to institute home treatment and appears to have used cryoprecipitate for home treatment at least until 1978. Dr Richard Wensley was described as a "*powerful advocate of cryoprecipitate*" whose "*thoughts were that yields of cryoprecipitate over those of concentrate are roughly 70% compared to 20%, and the risks of transfused virus are certainly less.*" He was described by a colleague as being "*very much alone on this point at one time.*" The annual returns in the second half of the 1970s reveal use of cryoprecipitate, NHS concentrate and commercial concentrates in significant quantities.

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St Thomas' Hospital

Professor Ilsley Ingram, the centre director until 1979, was an early advocate of home treatment and in 1974 wrote "*Until the N.H.S. provision is adequate, it is cruel not to make good the shortfall from the large supplies of good commercial material which … are now available.*" In his statement to the Archer Inquiry, his successor as centre director, Professor Geoffrey Savidge, wrote that:

> "*extra money when found was spent on the purchase of commercial imported factor VIII concentrate, usually from the US, in preference to the safer cryoprecipitate that was the recommend* [sic] *treatment of children and mild haemophilia patients (assuming failure with DDAVP) generally available (in some regions in excess). The US commercial concentrate was considered to be more user friendly, it could be stored at room temperature and was eminently more suitable for patients on home care programmes.*"

By 1978 commercial concentrates were the products most in use at St Thomas'.

The Royal Free Hospital

It was, prior to 1978, the policy of Dr Dormandy, the centre director, to use cryoprecipitate for home treatment. Following her death Dr Kernoff and Dr (later Professor) Edward Tuddenham "*came in in 1978 and very rapidly changed everybody to concentrate.*" Dr Kernoff was well aware of the risks from commercial concentrates. Writing in April 1979, he recorded non-A non-B Hepatitis being a "*serious disease with long-term consequences*" and that there were "*both clinical and moral reasons for preferring the N.H.S. material.*" The shortfall in NHS concentrates was "*met by buying commercial concentrate.*"

Oxford

NHS Factor 8 was (according to Dr Rizza, the centre director, writing in 1984) always in very short supply and reserved "*as far as possible*" for young children and adolescents: "*Ultimately most severely affected patients are changed from NHS to commercial factor VIII especially those who use larger amounts of factor VIII.*" By 1977 no cryoprecipitate was being used. Dr Rizza produced a report for the HIV Haemophilia Litigation suggesting that during the first half of the 1970s "*hepatitis was probably not perceived as a long term problem in haemophiliacs*" but that more detailed follow up of people with haemophilia during the late 1970s showed a significant number had persistently abnormal liver function tests and chronic liver disease.

Edinburgh

During the 1970s cryoprecipitate was the preferred treatment of Dr Davies, with no commercial concentrates being used even for the treatment of inhibitors. Dr Davies' preference for cryoprecipitate was because of the risks associated with hepatitis viruses and a reluctance to introduce new viruses to the local population.

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Glasgow Royal Infirmary

Commercial concentrates were in use in Glasgow in 1974 and 1975, although cryoprecipitate was the predominant product in both years, and the centre strongly advocated home treatment. From 1976, the use of concentrates (NHS and commercial) exceeded the use of cryoprecipitate. According to Professor Charles Forbes' evidence to the Penrose Inquiry, the December 1975 World In Action documentary "*was the talk of the haemophilia part of the hospital. Very much so.*" However, he suggested that "*at the end of the day the risk of dying of bleeding was always much greater and that was what drove all of us to use these products despite the possible downside.*"

Belfast

Concentrate was first used in Belfast in 1971. Thereafter Hemofil was the commercial concentrate used for the next three years. In the mid 1970s Dr Elizabeth Mayne instituted a home treatment programme using commercial concentrate. Her policy was that all home treatment patients would be treated with Kryobulin and all hospital treatment would be with Hemofil. Children would continue to be treated with cryoprecipitate. Little or no NHS concentrate was used in the second half of the 1970s. A pharmaceutical sales representative described in 1978 that

> "*Dr Mayne is not prepared to change her present policy concerning human factor VIII. She uses Hemofil for operations and Immuno for home treatment (22 patients). She realises this is an expensive policy, but feels that treatment changes are something best avoided with Haemophiliacs. She is very concerned about liver enzyme changes, but at least she knows what to expect with products which have been used for some years. There is also loyalty to Hemofil, because Baxter obviously gave her considerable financial help in the early days.*"

Sheffield (Royal Hallamshire)

From 1977 there was a substantial reduction in the use of cryoprecipitate, and by 1980 the mainstay of treatment was commercial concentrate. The limited use of cryoprecipitate at Sheffield may have reflected Dr Preston's view that cryoprecipitate was "*not an option for the treatment of severe haemophiliacs.*" Dr Preston also indicated that although the hepatitis risk from commercial products was substantially greater than from NHS products, "*there were insufficient NHS products for the treatment of Royal Hallamshire Hospital patients.*" Dr Preston's approach was to purchase a number of different commercial concentrates but to "*keep individual patients on the same concentrate, and the same 'batch' for as long as possible to minimise exposure to different blood donations.*"

Birmingham (Queen Elizabeth Hospital)

By the late 1970s there was little cryoprecipitate being used and substantial quantities of commercial concentrates were used. Professor Frank Hill told the Inquiry that he believed

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in the late 1970s that non-A non-B Hepatitis was a minor self-limiting condition with no serious long-term consequences. However, the minutes of the November 1976 West Midlands working party meeting show him concerned about "*the hepatitis risk in respect of freeze dried Factor VIII concentrate obtained from commercial sources*". He asked whether it might be advantageous to reserve the NHS Factor 8 for children, "*leaving the concentrate obtained from commercial sources, largely of foreign origin, for adults.*"

Royal London

By 1975 Dr Brian Colvin "*was aware that there was at least a possibility of chronic liver disease in haemophilia*". He described Dr Craske's August 1975 paper on the Bournemouth hepatitis outbreak as: "*a watershed moment, after which it was known that there was quite a significant problem for the future, at least in terms of numbers … We didn't know what was going to happen next but I think we knew that it was going to happen to a lot of people.*" By the late 1970s cryoprecipitate was seen as the past, used only for the treatment of very small children, and otherwise concentrate was the treatment of choice. No analysis of the relative risks of cryoprecipitate and factor concentrates was undertaken.

Leeds

By 1977 Leeds was using a substantial volume of commercial concentrates. By 1978 little cryoprecipitate was in use and the 1979 return recorded the use of no cryoprecipitate at all. There does not appear to have been any system of batch dedication, nor any other evidence of a risk reduction or minimisation strategy.

The Glasgow symposium in autumn 1980

In September 1980 a symposium "*Unresolved Problems in Haemophilia*" was held in Glasgow. It immediately followed the annual meeting of haemophilia centre directors and it is reasonable to assume that most directors attending the annual meeting would also have attended the symposium.

Dr Craske gave the first presentation. He stated that most cases of non-A non-B Hepatitis were mild illnesses, but he also observed that: "*About 40 patients have undergone biopsy in the UK and approximately 50% of these have histological evidence of chronic persistent hepatitis … Other patients showed evidence of chronic liver disease or cirrhosis … Most of the patients in this group are children or young adults, though the age range at Oxford is 6-70 years. It seems likely that some patients will develop severe chronic liver disease over the next 10 years.*"

Following a talk from Dr Thomas and colleagues at the Royal Free, the discussion included this further contribution from Dr Thomas:

> "*if we are to believe that this illness at the most has been going on since 1974 when the commercial concentrates were first introduced, then this period is short in the course of the disease. There are some indications that these patients may*

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> *have lesions which will turn to fibrosis or cirrhosis … It is really now a question of how long it takes. Just because we have not seen it in this six-year period, it does not mean that it will not happen. I think the thinking is that it takes ten or twenty years, or even thirty years for these lesions to progress. I think we have to realise that these are young patients, with many years ahead, when we are considering the significance of these lesions.*"

A talk by Dr Preston, Dr Triger and Dr Underwood (from Sheffield) stated that they had now examined liver biopsies from 19 patients with haemophilia, including 5 children (from 2 to 10), and one patient with von Willebrand disorder. "*The biopsy findings ranged from chronic persistent hepatitis, present in the majority of our cases, to severe chronic active (aggressive) hepatitis with evolving or established cirrhosis.*" Dr Thomas (Royal Free) observed that for patients with haemophilia "*The prediction is that it will be a more significant progressive illness, and I think they will develop fibrosis. Indeed, Dr Triger's studies have shown that a significant proportion have cirrhosis.*" Dr Triger emphasised that "*We are dealing with chronic liver disease, in which 5 to 7 years is a very short time – as we all know. 10 to 20 years may be a long time, but we have been looking at liver biopsies of children under the age of 10 years, and what we are concerned with is what is likely to happen to them when they should be fit, healthy 25 year olds … I think we are just building up trouble.*" Dr Thomas agreed: "*it is in 10 years time that we shall see the problems. Bearing in mind the proportion of the patients that are infected, or have persistent abnormal liver function tests, anything from 60 to 80 per cent, it will be an enormous problem when it happens.*"

Dr Mark Winter, in his oral evidence to the Inquiry, rightly described the 1978 Sheffield study as showing NANBH to be a "*really serious evolving clinical problem*" and as an "*absolutely key moment, where any haemophilia doctor should have switched from a viewpoint* [from] '*they have probably got a mild form of the virus' to 'I'm very concerned'*"; it was "*one of the great sea change moments*". But for any haemophilia clinician working in that capacity in 1980 who had not picked up on the significance of the Sheffield study, the Glasgow symposium in September 1980 was another "absolutely key moment" and should have driven home the message that NANBH could not be dismissed as "benign" or "mild" or as a risk that did not need to be taken seriously.

Yet treatment with factor concentrates continued unabated throughout the early 1980s. The Hepatitis Working Party continued to meet and discuss its various studies; the reference centre directors turned their attention to concerns about the new concentrates said to be hepatitis-free or hepatitis-reduced and noted that the annual returns for 1980 showed that the amount of Factor 8 concentrates used had again increased, especially commercial materials; the haemophilia centre directors met again in the autumn of 1981 and received Dr Craske's report on behalf of the Hepatitis Working Party for 1980-81 with its recommendations that the surveillance should continue, as should further studies. But for most centres little or nothing changed. The chapter summarises data from the annual returns for 1980 to 1982 for Newcastle, Royal Free, Cardiff, Belfast, Glasgow Royal Infirmary, Edinburgh, Sheffield, St Thomas' Hospital, Manchester Royal Infirmary, Oxford,

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Birmingham, Bristol, Leeds, Liverpool, Royal London, Lewisham, Cambridge, Coventry and Kent. The Glasgow symposium, and what ought on any view to have been understood to be the risks of transmission of NANBH and the potentially serious nature of NANBH, did not lead to any noticeable difference of approach to treatment, or even of any consideration of whether a changed approach was warranted. Nor was there any consideration or discussion about the position of patients and the information that should be provided to them about the risks of treatment.

UKHCDO response to the emergence of AIDS

Possibly by March 1982, and certainly from July 1982 onward, some clinicians and some in government knew that there was a real risk that blood, and blood products in particular, would transmit the cause of AIDS.

Yet by September 1982 the haemophilia centre directors were only beginning enquiries into this risk – when they commissioned Dr Craske to obtain more information about the reports from the US because there was "*a remote possibility that commercial blood products had been involved*." There was no sense of urgency, despite – on any reasonable view at that stage – the role of commercial blood products being more than a "remote possibility".

In December 1982, the Royal Free Hospital began to measure the ratio of T4 to T8 cells in patients with haemophilia. This was plainly a reaction to a perceived threat of AIDS, and implies a belief that AIDS might be transmissible by blood or blood products.

On 7 January 1983 Alpha pharmaceutical issued a press release: "*The evidence suggests, although it does not absolutely prove, that a virus or other disease agent was transmitted to* [patients with haemophilia who had contracted AIDS] *in the Factor VIII concentrate … AIDS has jumped from the seventh to the second most common cause of death in hemophiliacs within a year*"

On 11 January 1983 Professor Bloom and Dr Rizza issued a letter to all haemophilia centre directors which discussed the attempts by commercial companies to reduce the risk of hepatitis transmission through heat treatment and emphasised the importance of finding out "*by studies in human beings to what extent the infectivity of the various concentrates has been reduced.*" Professor Bloom and Dr Rizza suggested that "*The most clear cut way of doing this is by administering those concentrates to patients requiring treatment who have not been previously exposed to large pool concentrates,*" and encouraged directors to avoid the use of such concentrates on a named patient basis, because this "*might seriously hinder controlled studies in the future.*" This letter is important for three reasons: there is a complete absence of *any* reference to AIDS; it shows that UKHCDO *could* give advice and information to haemophilia centre directors where it thought this warranted; and the letter proposed giving large pool concentrates to patients who had not previously received them *at the very time* when the emergence of AIDS should have led clinicians to avoid that.

On 13 January 1983 the widely read *New England Journal of Medicine* published an editorial stating that "*The fact that haemophiliacs are at risk from AIDS is becoming clear*"

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and advocating a revised approach to treatment. At the Heathrow meeting later that month no one questioned that AIDS was likely to result from the transmission of an infectious agent, and Dr Craske informed those present that the disease was intractable, had a lengthy incubation period and a high mortality rate. No one present at that meeting could have been left in any doubt as to the seriousness of the position.

By May 1983, while treatment continued as normal, a young man with haemophilia in Wales had developed symptoms of AIDS. Kevin Slater was 20 years old when his AIDS symptoms were first identified and just 22 when he died in 1985. He was suspected of suffering from AIDS in March 1983, following a visit to University Hospital Wales. Professor Bloom was aware of his case and told the audience at a 22 April 1983 Haemophilia Society meeting that one of his patients "*may have a mild form*" of the syndrome. Around 6 May 1983, the CDSC published a weekly report identifying Kevin's case (without naming him) and observing that "*this is the first report of AIDS in a patient with haemophilia in the United Kingdom known to CDSC.*" Dr Spence Galbraith, director of the CDSC, notified the DHSS of this development on 6 May.

Dr Walford was invited to attend the special meeting of haemophilia reference centre directors on 13 May, which was chaired by Professor Bloom and attended by Dr Craske, Dr Peter Hamilton, Dr Kernoff, Dr Ludlam, Dr Savidge, Dr Preston, Dr Irvine Delamore and Dr Rizza. The minutes record that: "*It was agreed that there was insufficient information available from the U.S. to warrant changing the type of concentrate used in any particular patient.*" It was suggested that "*many directors have up until now reserved a supply of National Health Service concentrates for children and mildly affected haemophiliacs and it was considered that it would be circumspect to continue with that policy.*" There was no discussion about any measures such as: reverting to cryoprecipitate (even if only on a temporary basis); batch dedication; more conservative treatment including less prophylaxis; cancelling or postponing elective surgery.

The decisions in the meeting were taken in ignorance of the 9 May 1983 paper from Dr Galbraith to the DHSS advising against using imported factor concentrates, and Professor Bloom did not tell the meeting that Dr Evatt of the CDC had told him that "*the evolution of the epidemic is occurring with a frightening pace*" and that there were now 13 confirmed cases in people with haemophilia in the US, with five more highly suspect cases under investigation. Once again, there was no discussion about advising patients of the risks.

Following the May meeting, Professor Bloom and Dr Rizza wrote to all Haemophilia Centre Directors on 24 June. This letter was the only advice issued by the UKHCDO until December 1984. It suggested that treatment should continue as before, despite the risks of AIDS in addition to hepatitis. The complacency, and absence of any practical advice to reduce the risk, represent a failure of leadership and a missed opportunity.

At the October 1983 annual meeting of Haemophilia Centre Directors, by which time the first death of a patient with haemophilia with AIDS was known, Dr Morag Chisholm (Southampton) raised the question of patients refusing to take commercial Factor 8 concentrate because

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of the AIDS scare. She wondered whether directors could revert to using cryoprecipitate for home therapy. Professor Bloom replied that "*he felt that there was no need for patients to stop using the commercial concentrates because at present there was no proof that the commercial concentrates were the cause of AIDS*." After discussion it was "*agreed that patients should not be encouraged to go over to cryoprecipitate for home therapy but should continue to receive the NHS or commercial concentrates in their usual way.*"

It is astonishing that in October 1983 Professor Bloom felt able to say to Dr Chisholm that there was "*no proof*" that commercial concentrates were the cause of AIDS, and astonishing that the directors as a whole agreed that patients should not be encouraged to switch to a substantially safer treatment. It was an unsustainable and misleading position in the autumn of 1983. It was tantamount to telling clinicians that they did not need to do anything. It is surprising that Professor Bloom was not challenged on this by his peers at the meeting.

Thus the position as at the end of 1983 was that far too little had been done by UKHCDO or the reference centre directors in response to the emergence of AIDS. The focus was on surveillance and research rather than on taking urgent steps to reduce the risk of transmission. The only guidance that had been provided – the 24 June letter – was woefully inadequate. It amounted to "carry on as you are already probably doing". The reference centre directors were apparently unaware of key pieces of information – Dr Galbraith's paper and the Council of Europe recommendations – and thus their advice (such as it was) was issued in ignorance of them. The risks were assessed on the basis of the number of cases which had emerged, when the focus should have been on what might be already on the way. And the risks to people with bleeding disorders were consistently, and unjustifiably, downplayed.

During the following year, despite the increase in cases of AIDS, and despite being told that "*One-third of the Centres* [in Europe] *had changed their treatment regimes for patients following the onset of the AIDS problem*", there was no further thought to treatment policy, risk reduction or further advice. It was not until December 1984, some two or more years after the risks of transmission of AIDS should have been apparent to all centre directors, that the implications for treatment were finally addressed, with the product of an "*AIDS Advisory Document*".

It is difficult to understand why the UKHCDO and the reference centre directors were so dangerously slow to recognise and react to the risks of AIDS being transmitted to their patients. It was wrong.

Treatment practices and policies 1982-1984

Haemophilia centre directors knew or ought to have known no later than the end of 1982 (and probably earlier) of the risks of transmission of AIDS by blood and blood products. Put more colloquially by Dr Winter, "*however many alarm bells a human being has, they should all have been ringing at this stage.*" Yet it is clear that those alarm bells were not ringing for many, indeed most, haemophilia clinicians – or if they were, they did not lead to any substantial changes in treatment policies and practices.

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At Newcastle commercial concentrates continued to be the mainstay of treatment in 1983 and 1984 and there were no significant changes in approach to treatment until the introduction of heat treated concentrates in December 1984. In Birmingham Professor Ian Franklin's evidence was that "*I think … in Birmingham the feeling was to carry on, but probably to carry on in the hope that we would eventually get more NHS material*." There was no change in the Royal Free's treatment policies until heat-treated products became available at the end of 1984.

In Edinburgh Dr Ludlam had reversed his predecessor's policy of using cryoprecipitate and moved from cryoprecipitate to predominantly PFC Factor 8 concentrates. He substantially increased the number of patients on home treatment and the volume of product used. Dr Ludlam thought that he first became aware of cases of AIDS in people with haemophilia in August-October 1982. In his oral evidence to the Inquiry, he was at pains to emphasise "*the uncertainty that there was at the time about the cause of AIDS.*" There was no significant change of approach to treatment in 1983 and 1984 at Edinburgh because Professor Ludlam thought the PFC concentrates were reasonably safe: "*we felt it reasonable to go on with using cryoprecipitate in decreasing amounts and using local concentrate for treating the patients.*" In the autumn of 1984 Professor Ludlam sent a number of stored samples to Dr Tedder for testing without the knowledge or agreement of the patients involved. He was told the results in October. He did not tell patients then. It was not until in response to impending publication in the *Yorkshire Post* that a group meeting of people with haemophilia was called on 19 December 1984 and it was then left to people to make contact with the Centre to find out if they had been tested and what their test results were. It was not until 1985 that the process began of informing individual patients of their test results. Until then, some who were infected with HIV were not aware of the need to avoid infecting others; others continued to treat themselves with concentrates in the erroneous belief that PFC concentrates were entirely safe.

In Glasgow the usage of cryoprecipitate declined markedly in 1982, with NHS (PFC) concentrates as the mainstay of treatment. Dr Forbes told the Penrose Inquiry that by March 1983 "*already we were starting to look rather differently at our patients to see if they had any of the features that might be an early warning of AIDS.*" He also acknowledged that in 1983 there was a potential for contamination of blood products "*even from local, home-grown sources … that was always a concern, that HIV would come into the donor population of the UK.*" There is no evidence of any significant change of approach to treatment.

In Belfast in 1982-1984 patients continued to be extensively treated with commercial concentrates with no evidence of any risk reduction measures. In a report for the HIV Haemophilia Litigation, Dr Mayne suggested that some risk reduction measures would have denied "*the goal of haemophilia treatment, namely to minimise pain and disability and to prolong life.*" She objected to restriction of "*the choice of treatment available to the physicians in charge of the patient: the person in possession of all the information regarding the patient's needs.*" This characterisation of the physician as being "*in charge of*" the patient, "*in possession of all the information regarding the patient's needs*" is paternalism writ large.

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In Cardiff Professor Bloom materially downplayed the risks of transmission at this critical time. There can be no doubt that in early 1983 Professor Bloom had more information than other haemophilia clinicians. By April he also knew that one of his own patients had AIDS. Yet he continued to minimise the risk, as seen by the advice which he provided to the Haemophilia Society.

There is evidence to suggest that following the special meeting of reference centre directors on 13 May 1983, Cardiff produced written guidelines for haemophilia treatment. There are four observations to make regarding those guidelines: the first is that their production in May 1983 suggests that no steps were taken prior to that date in response to the risk of AIDS. The second is that the picture revealed by the annual returns is not consistent with the full implementation of those guidelines. The third is that the guidelines drew little distinction between the use of NHS concentrate and cryoprecipitate, yet the former was made from large donor pools and on any view carried a substantially greater risk of transmitting both NANBH and the agent causing AIDS. The fourth point is that the guidelines may relate only to treatment in hospital. Professor Bloom's view on home treatment was that there was no need for patients to stop using commercial concentrates and they should not switch to cryoprecipitate for home therapy but "*continue to receive the NHS or commercial concentrates in the same way.*" It is clear from both the returns and the statements from people treated in Cardiff that home treatment continued unabated.

In Oxford Dr Rizza knew by at least September 1982 that three US patients with haemophilia were reported to have AIDS. On 8 October 1982 he wrote to Dr Craske referring to the US: "*one very senior physician has withdrawn his factor VIII concentrates from the accident room and insists on vetting the patients himself before any dose was given.*" In November 1983 Dr Rizza was provided with a copy of Dr Craske's paper on AIDS, and he attended the Hepatitis Working Party and the Heathrow meetings in January 1983. Yet there is no evidence of any change in treatment. The 1983 and 1984 annual returns show that almost no cryoprecipitate was used for the treatment of Haemophilia A. Only in December 1984, when the Centre placed its first order for heat-treated concentrates, was there any significant change of approach.

This section of the chapter also considers the position in relation to the haemophilia centres in Bradford, St George's Hospital, Guy's Hospital, Margate, the Royal London, Leeds, Liverpool, Sheffield and Leicester. The latter is of particular note as one of the very few centres where there is evidence of positive steps being taken to attempt to reduce the risk of transmission (in particular by a greater use of cryoprecipitate than other centres).

The chapter concludes that clinicians should all have been alert to a risk of AIDS by the end of 1982, if not earlier, and that in light of this the steps that could and should have been taken by Haemophilia Centres (but generally were not taken) were:

- stop using commercial concentrates, as they carried the greatest risk
- take a conservative approach to treatment, using less concentrate (or cryoprecipitate), and treating only where strictly necessary

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- return to using cryoprecipitate in place of concentrates (commercial or NHS), or fresh frozen plasma for Haemophilia B
- suspend home treatment and stop prophylactic treatment
- avoid treating patients with multiple products and multiple batches: introduce batch dedication
- defer elective / non-essential surgery
- maximise the use of DDAVP and tranexamic acid
- provide advice and encouragement to individuals on reducing the risk of bleeds
- above all, discuss the risks and alternatives (and the gaps in knowledge) with each patient individually, as fully as reasonably possible, and be guided by their view of what mattered to them.

These failures lie with the Haemophilia Centres and their directors, particularly the more senior and experienced, who failed to provide guidance when it was required; they failed to adjust treatment policies as they should and failed to tell patients adequately of the risks to them as individuals.

Haemophilia B

This section of the chapter examines the approach to treatment of people with Haemophilia B. By the late 1970s, if not earlier, the potential for non-A non-B Hepatitis to have serious effects should have been appreciated in relation to Factor 9 concentrates just as for Factor 8. By the late 1970s pool sizes for Factor 9 were at least seven times, and often more, than at the start of the decade. The average use of Factor 9 per patient rose from 21,000 units in 1978 to just over 36,000 in 1984. The increased awareness of serious long-term consequences of hepatitis demonstrated in the Glasgow symposium had no obvious effect on practice. On the contrary, as the risk of long-term disease grew greater, so did the amount of Factor 9 prescribed.

As for the response to AIDS, although there was much less to be said in favour of fresh frozen plasma as a form of alternative treatment than there was to be said for considering cryoprecipitate as an alternative to Factor 8 concentrate (it had to be administered in large volumes to be effective, and that created its own risks), nonetheless in the guidelines circulated after 10 December 1984 FFP was recommended as the treatment of choice for mild cases of Haemophilia B, previously untreated patients, and children. There was plainly some role for it, even if relatively limited, and that role should have been spelt out to patients, so that they could assess risks for themselves and take their own decisions. A step that should have been taken, but was not, would have been to limit home treatment and suspend prophylaxis using unheated Factor 9 concentrates.

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Von Willebrand disorder

This next part of the chapter looks at the treatment of people with von Willebrand disorder. Cryoprecipitate, Factor 8 concentrates and DDAVP (as well as FFP) were all treatments that could be (and were in varying degrees) used for the treatment of von Willebrand. DDAVP in particular gave rise to no risk of viral transmission: it was not a biological product. It was one of a number of alternative treatments (available from 1977 onwards) which ethically should have been discussed with a patient in advance of treatment, together with the other possibilities. The meetings of haemophilia clinicians in 1980, 1982 and the advice given in June 1983 all show that haemophilia clinicians were alive to the risk that using concentrates, especially commercial concentrates, risked transmitting viral infection and should best be avoided if possible. Yet people with von Willebrand disorder were typically not given advice or information about the risks of treatment (insofar as those risks related to transmission of hepatitis or HIV) and were not given information about safer alternatives. The evidence available to the Inquiry indicates that DDAVP was not used to the extent that it should have been, given the risks of viral transmission; and that whilst cryoprecipitate was used, concentrates (including commercial concentrates) were used more frequently than they should have been for the treatment of people with von Willebrand disorder, particularly after the risks of AIDS had become apparent from mid 1982 onwards.

The use of PFC concentrates in Scotland 1985-1987

Heat-treated Factor 8 concentrate produced by PFC (known as NY) was available from December 1984. It was believed to (and did) inactivate HIV; it did not, however, prevent the transmission of non-A non-B Hepatitis. It was not until April 1987 that PFC produced a Factor 8 concentrate (Z8) that was effective against non-A non-B Hepatitis. By contrast the heat-treated concentrate produced by BPL (8Y) over the same period transmitted neither HIV nor non-A non-B Hepatitis. Thus there was in Scotland a continuing need for particular care to be taken by clinicians in relation to people with bleeding disorders who were untreated or minimally treated and who thus had not been, or were unlikely to have been, previously exposed. Haemophilia clinicians should have been alert to this, so as to avoid such patients receiving NY unless absolutely necessary. Appropriate systems should have been in place to address this. If such a patient were to be offered NY, they needed to be told in advance of their treatment what the options were (including the possibility of alternative treatment eg with DDAVP or cryoprecipitate), what the risks and benefits were, and in particular it should have been explained to them what by now was on any view abundantly clear – that non-A non-B Hepatitis was a serious illness which could cause long term (and potentially fatal) liver disease and that treatment with NY would in all probability infect them with it.

This part of the chapter concludes that such systems were lacking and that appropriate information and choices were not provided, leading to infection with Hepatitis C that was avoidable.

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Relationships with pharmaceutical companies

In the 1970s and 1980s there were regular, usually cordial, interactions between sales representatives of pharmaceutical companies and haemophilia centre clinicians. Sometimes gifts were provided, sometimes sponsorship or funding for research. More commonly funding was provided to cover the costs of attendance at international conferences and the close relationship between haemophilia centre directors and pharmaceutical companies is evidenced in contemporaneous documents. An internal Cutter memo in May 1985 describes how the author "*sought out and visited briefly with Prof. Bloom during the AIDS Conference in Atlanta. He asked if he could visit with Cutter the week following the San Diego meeting … He will need room reservations in the city for Saturday, Sunday and Monday, plane reservations from San Diego. He will be accompanied by his wife.*" Professor Tuddenham recalled hospitality from pharmaceutical companies that was: "*overwhelmingly lavish … at various stages … you would be going to the best – – to a conference on haemophilia, there would be the very best restaurants, the river cruises, the – – all the paraphernalia of marketing products.*" Asked why the companies were spending that money, the answer was "*Because they could gain influence with it.*" Professor Liakat Parapia described "*Extravagant hospitality*" being available "*for Centres using large amounts of their products*", adding that for attendance at scientific meetings support from pharmaceutical companies was the only way for clinical staff to attend: "*There was no money in the NHS*".

Professor Michael Rawlins, giving evidence in October 1984 to the Royal College of Physicians Working Party on the Ethics of the Relationship between Physicians and the Pharmaceutical Industry, described the "*fundamental ethical issue*" as being based on the fact that "*doctors spent very large sums of public money each year, and that the public could reasonably expect doctors to prescribe drugs with deference to their efficacy, safety and economy.*" He felt strongly that "*consultancies and their financial details*" should be disclosed, that money should "*not go to one person but to a department*", that the General Medical Council should give doctors "*positive advice concerning their relationships with the Industry*", and that hospitality should be "*totally divorced from promotion*".

In light of the above, it is not surprising that many core participants expressed in their submissions to the Inquiry serious concerns about the relationship between haemophilia centre directors and pharmaceutical companies. It is always difficult to ascertain the extent of bias – whether conscious or subconscious. At this distance of time, and where the clinicians most prominently associated with pharmaceutical companies (such as Professor Bloom, Dr Kernoff, Dr Aronstam, and Professor Savidge) are dead, it is no longer possible to determine what impact these relationships and these offers of funding had on clinical decision-making. But if clinicians accepted funding (whether for hospitality or attending conferences, or research) it was all the more incumbent on them to ensure that their clinical recommendations and the risks and benefits of treatment were fully explained to their patients. As this Report finds, the failure to do so was widespread and profound.

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Research

The organisation of haemophilia centres in the United Kingdom "*made it possible to carry out collaborative research which was not so easily done elsewhere.*" (Dr Biggs). The "*collection of 49 haemophilic patients at the Alton School makes this a unique opportunity to study the disease*." (also Dr Biggs). They – the "*almost unique group of haemophiliacs we have in Edinburgh because they have never received commercial concentrate*" – "*are, therefore … useful material for a variety of studies in relation to liver disease.*" (Dr Christopher Ludlam).

> "*Although initial production batches may have been tested for infectivity by injecting them into chimpanzees it is unlikely that the manufacturers will be able to guarantee this form of quality control for all future batches. It is therefore very important to find out by studies in human beings to what extent the infectivity of the various concentrates has been reduced. The most clear cut way of doing this, is by administering those concentrates to patients requiring treatment who have not been previously exposed to large pool concentrates.*" (Professor Bloom and Dr Rizza).

"*So what are we? Are we human beings or are we just material?*" That rhetorical question, posed by a campaigner in his oral evidence to the Inquiry, conveys the understandable – and in many respects well-founded – feelings of many people with bleeding disorders who were infected in consequence of their treatment with concentrates: that they were, often without their knowledge or consent, objects of research.

The requirement for informed consent to participation in research is fundamental. It was reflected in the terms of the Nuremberg Code in 1947, with the first principle that "*The voluntary consent of the human subject is absolutely essential.*" Similar stipulations were set out in the 1964 Declaration of Helsinki. Where there is a therapeutic benefit to the participant, the doctor should "*obtain the patient's freely given consent after the patient has been given a full explanation*"; where there is no therapeutic benefit, "*The nature, the purpose and the risk of clinical research must be explained to the subject by the doctor.*"

This section of the chapter examines: some of the research projects undertaken involving the Oxford Haemophilia Centre; Dr Craske's hepatitis studies; a hepatitis pilot study involving Treloar's, Newcastle and Oxford; a study of patients treated with concentrate for the first time ("PUPs" – previously untreated patients); the culture of research within haemophilia centres; a study undertaken at the Royal Free haemophilia centre; research in Edinburgh, in particular Dr Ludlam's "AIDS Study"; the immune studies undertaken in Glasgow; and the Liberate trials in the early 1990s. It also considers the question of post-mortem research.

These various studies differed in nature from one other and each gives rise to its own ethical considerations; this part of the chapter therefore requires to be read with care. However, a number of general considerations arise. The evidence before the Inquiry has shown that in the great majority of cases people were participating in research without full knowledge and consent. The research described in this chapter did not lead to patient benefit. It did not lead to safer treatment. Worse still, much was undertaken with no reasonable prospect

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of advancing the immediate personal treatment of the patient. It was often conducted in ways that were unacceptable. Patients were frequently viewed as research subjects rather than first and foremost as individuals with varying clinical needs whose informed consent should have been central to the studies that were undertaken. Patients were regularly monitored for the presence of diseases that might be transmitted by their treatment. Blood samples were taken from them repeatedly without any clear explanation of what they were for. Samples were retained, without the knowledge and consent of those whose blood it was. There is limited evidence of any kind of effective oversight by ethics committees in the 1970s and early 1980s.

There were four major failings in relation to research:

(a) Research was conducted when it exposed patients to a greater risk of harm than they should have faced, in the light of the best available medical knowledge at the time, without there being any commensurate benefit for them.

(b) This was done without (i) (in many cases) telling patients that research was being conducted, and (ii) (in most cases) giving the patient sufficient information on risks, benefits and alternatives to enable consent to be properly given. On occasion it is clear that it was imposed on the patient concerned, as where one clinician wrote to another to seek their permission to conduct the research on one of their patients, or to thank the other clinician for having given it with no record of the patient having been consulted.

(c) Patients were unaware that they were the subjects of studies and (in particular) of prospective research, such that:

(d) When results were received which showed that those patients had become infected, or had seriously compromised immune systems, they were not told. They did not know to ask, because they did not know they had been tested.

These failings were aggravated by the way in which previously untreated patients – in particular children – were sought out to become the subject of research, and in some cases to be given treatments which were unnecessary, or conferred no advantage but only additional risk. The ethics of this are clear. It was, and is, unacceptable.

The treatment of children

Around 380 children with bleeding disorders were infected with HIV. Many of those died in childhood or young adulthood, having endured a level of pain and fear that no child or young person should ever have to face. Some survived but have lived their lives under the shadow of HIV and AIDS, with an appalling toll on physical and mental health. All those children infected with HIV were also infected with Hepatitis C. Others escaped HIV infection only to learn later that they had been infected with Hepatitis C, sometimes with deadly consequences. Those who survive have suffered profound ill health and endured the horror of the early treatments with interferon. Some were also infected with Hepatitis B.

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This section of the chapter looks at the available evidence about treatment practices at seven paediatric haemophilia centres, and then at evidence of how children were treated at general haemophilia centres.

The way in which children were treated is so problematic that it is difficult to summarise; this section of the chapter requires to be read in full.

The seven paediatric centres whose policies and practices are examined are: Alder Hey; Birmingham Children's Hospital; Royal Manchester Children's Hospital; Royal Belfast Hospital for Sick Children; Great Ormond Street Hospital; Royal Hospital for Sick Children (Yorkhill); Bristol Children's Hospital; and Sheffield Children's Hospital.

More information is available for some of these centres than for others. It is in particular plain that the treatment regimes at Alder Hey, Yorkhill and Birmingham Children's Hospital, where commercial concentrates were the mainstay of treatment, were utterly unacceptable. It is plain also that most clinicians responsible for children with haemophilia did not pay sufficient regard to the dangers to their patients. They had all the information they needed to do better. They did not use it and as a result children suffered.

The comparison between Alder Hey and Sheffield on either side of the Pennines is telling. At Sheffield, Dr Lilleyman expressly sought to use cryoprecipitate because he foresaw that using products made from the plasma of much larger numbers of donors who were from foreign countries would create more risk of infection. There appears to have been a huge difference in outcome.

The treatment of children with bleeding disorders at general (non paediatric) haemophilia centres reveals an equally disturbing picture. The chapter looks at a number of individual cases in order to try to understand how so many children came to be infected with fatal viruses. The examples discussed reveal that, in general haemophilia centres, just as in the paediatric haemophilia centres:

- Children were treated with factor concentrates without their parents having been provided with any (or sufficient) information about the risks of treatment. They were thus treated without informed consent having been given. It was unconscionable to treat children with concentrates capable of transmitting serious viruses without explaining those risks clearly to their parents.
- Children were treated with factor concentrates when cryoprecipitate would have been a significantly safer option. Consideration was not given by those treating them to reverting to cryoprecipitate in response to the risk of AIDS.
- Children were treated with imported commercial concentrates, which were rightly understood to carry a greater risk of infection.
- Children were treated on a prophylactic basis, thus increasing their exposure to viral infections.

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- Children were treated with concentrates even where their haemophilia was mild, or where they did not have a bleeding disorder at all.
- In the general haemophilia centres there was no clear or consistent understanding of who was to be regarded as a child for treatment purposes. That will no doubt be surprising to those reading this Report. It might be thought that it is obvious that "child" encompasses those who are under 18. However, for the purposes of centres' treatment policies, the position is much less clear-cut. Children were, in effect, treated like adults, often after the age of four or five (or in some cases whilst still babies).

The Inquiry has received many more statements detailing the treatment of children in haemophilia centres, which raise similar issues and themes to the cases discussed in the chapter. This evidence, taken together with the evidence relating to the way in which children were treated at paediatric haemophilia centres, point to a single, inescapable conclusion: that children were not treated in a way that prioritised their safety above other considerations.

Ethical failings: consent and testing

The final section of this chapter examines the evidence relating to informed consent, testing and how people were informed that they had been infected.

The evidence before the Inquiry overwhelmingly establishes that people with bleeding disorders were not properly advised of the risks of hepatitis or AIDS. They had the right to know that factor concentrates might infect them with a serious or fatal disease for which there was no treatment. Parents had the right to know that such treatments might infect their children. In practice, either they were given no information at all about such risks, or they were falsely reassured that the treatments were safe.

The evidence further shows that, in many (although not all) haemophilia centres, testing for HIV in the mid 1980s and later for Hepatitis C was undertaken without the knowledge – and, it follows, without the consent – of patients (or in the case of children, their parents).

One of the consequences of people not being told that tests were being undertaken, quite apart from the affront to their personal autonomy, was that the results of such testing then came out of the blue.

The evidence before the Inquiry shows that there was no uniform approach to people being told that they, or their child, had been infected with HIV or with Hepatitis B or C. It is right to acknowledge that some were told in person, as they should have been, and that attempts were made to explain the position to them and to help them understand on the basis of the (sometimes limited) information that was then available. In some instances testing was undertaken soon after it became available and there were no significant delays before the results were communicated. But for many more that was simply not the case. Some were told in groups. Some were told by letter. Some were told casually, in passing. Some were not told at a special appointment, but at their next routine visit: one problem with that approach

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was that people, unaware that they had been tested, would not attend for the appointment, and thus remained ignorant of a positive test result. Some were not told at all for years.

Some of the evidence which the Inquiry heard from clinicians sought to explain that the 1970s and 1980s, and even the 1990s, were an era of clinical paternalism, where things were done differently – one implication being that they should not be judged by the standards of today. However, a different perspective was offered by the expert panel of medical ethicists who provided a written report to the Inquiry and gave oral evidence over two days in January 2021. There are, as the experts told us and as the Report also finds, certain fundamental ethical norms and principles which lie at the heart of medical decision-making and doctor/patient interactions. Of central importance to this Inquiry are the principles of respect for autonomy, beneficence (the imperative to do good – "you should promote people's well-being") and non-maleficence ("you shouldn't harm people").

It was unethical and wrong that people were not told the risks of factor concentrates. The failure to do so resulted in people being treated without their informed consent.

It was unethical and wrong that people were not told that they were being tested for HIV or for hepatitis. The failure to tell them was a denial of their personal autonomy.

It was unethical and wrong that people were not told, or not told promptly, of the result of such tests. As explained by the ethics experts, "*once a diagnosis is known by the doctor, then the doctor needs to inform the patient because … without that information the patient cannot actually exercise their autonomous choice about what to do next and what kind of treatment to explore and they will need accurate and transparent information about this particular diagnosis, even if it means doing nothing.*"

A culture of paternalism, a "doctor-knows-best" attitude, may explain some of these ethical failures, but it does not excuse or justify them.

4.3 Pharmaceutical Companies

This chapter describes:

- the supply of plasma and the donor pool used in the commercial manufacture of blood products imported into the UK, including the inspection and control of plasmapheresis centres and the use of plasma from prisoners and groups selected on the basis of having a high titre of antibody to Hepatitis B;
- the pool sizes used in the production of commercial blood products;
- labelling and product information, in particular warnings given (or not given) about the risks of infection with hepatitis and AIDS;
- the response to the emerging threat of AIDS in the period between the first reports of AIDS in 1981 and the isolation of HTLV-3/HIV in April 1984;

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- the approach taken to measures which might reduce the risks of transmission of AIDS, such as enhanced measures of donor screening and exclusion, surrogate testing, and the recall of products manufactured from plasma obtained from a donor known or suspected to have developed AIDS.

The focus of the chapter is on how these issues affected blood products that were made available to NHS patients in the UK.

In the period relevant to the Inquiry, the main commercial Factor 8 products sold in the UK were: Hemofil (manufactured by Hyland/Travenol, licensed in the UK from 19 February 1973); Kryobulin (manufactured by Immuno, licensed in the UK from 22 March 1973); Profilate (manufactured by Abbott/Alpha, licensed in the UK from 22 May 1975); Factorate (manufactured by Armour, licensed in the UK from 25 March 1976); and Koate (manufactured by Miles/Cutter, licensed from 27 August 1976). It is pointed out in the preface to the chapter that the use of these names is for easy readability: it needs to be borne in mind that UK companies importing, licensing and distributing products were not themselves the manufacturers: distinct companies in the US and Austria were; and although some of the same names may be in use today a number of the companies sharing those names have ceased to exist during the period covered by the Inquiry.

Estimated figures for annual UK sales from the commercial manufacturers obtained by the DHSS in 1983 showed that total usage of commercial Factor 8 products had risen over the previous seven years from 10.6 million international units to between 42 and 48.5 million.

Plasma and donors

In the early 1970s increases in demand for blood products and limitations on domestic supply and regulation resulted in American companies seeking blood and plasma from what were then low-income countries. Plasmapheresis centres supplied US companies from Nicaragua, Mexico, Belize, the Dominican Republic, Costa Rica, El Salvador, Colombia and Haiti. The US Government then decided to transfer responsibility for regulation of the blood industry to the FDA, which led to the possibility of greater intervention and inspection (although a 1995 report of the US Institute of Medicine was critical of the FDA's regulation of blood products in the early 1980s, in particular that it had failed to take a proactive approach, had relied too heavily on the pharmaceutical industry, and did not adequately use its regulatory authority). The inspection regime was introduced in around 1977. Various sources of evidence suggest that in the 1970s sources of plasma outside the US or Europe were used in the production of some factor concentrates. As manufactured product might have a shelf life of two years, concentrates derived from plasma imported into the US and manufactured in 1978 might still have been in use as late as 1980. By 1983 the position had changed: when the DHSS collated the responses of pharmaceutical companies to questions about their plasma supply, Armour, Alpha, Travenol/Hyland, Miles/Cutter and Immuno all confirmed that their plasma came from plants in the US or Europe that were licensed by the FDA, and that the origins of their plasma were identifiable.

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The evidence shows that both Hyland and Cutter obtained plasma from plasmapheresis centres in US prisons in the US, and used that plasma to make factor concentrates. Contemporaneous documents record that prison plasma accounted for 2% of the total plasma collected in the US as of the middle of 1982 and was obtained from six to eight centres. Three prison centres were included in a list of plasma sources in a document dated 8 February 1983 included in the UK product licence application for Koate. That inclusion strongly suggests that plasma from the prisons was used in blood products that were licensed for use in the UK. The investigative film-maker, Kelly Duda, explored much of the evidence relating to prisons in Arkansas and has given evidence to the Inquiry that many inmates told him of the extent of subterfuge that was practised in order to enable them to earn a few dollars by selling their plasma.

Prisoners were undoubtedly a high-risk group. It is highly likely that prison blood conveyed blood-borne disease; that it is likely to have contributed to the spread of hepatitis, both Hepatitis B and non-A non-B Hepatitis, amongst users of commercial concentrates, and that previously unidentified infections such as HIV were transmitted through this route.

Plasma companies sought out gay men as donors because their plasma was rich in Hepatitis B antibodies: it was termed "hyperimmunised". In August 1982, in response to the risk of AIDS, Hyland and other companies were urged to refrain from using plasma to make factor concentrates where that plasma had most likely been obtained from gay men. In December 1982 Dr Michael Rodell, vice president, wrote that Hyland had stopped using such plasma for factor concentrates: "*Within the past several months, we have made a commitment to withhold from AHF* [antihemophilic factor] *manufacture any plasma obtained as a result of specific recruiting activities aimed at the gay community … we no longer allow this plasma to enter those pools leading to AHF manufacture.*" An internal Cutter memorandum of 30 August 1982 recorded that: "*Until recently, Cutter's anti-HBs plasma (all collected from centers dealing predominantly with homosexuals) has been used in the manufacture of coagulation products.*" Evidence shows that three of the four major US pharmaceutical producers of concentrates were using plasma from donors at very high risk of Hepatitis B until August or September 1982. Any product made before then would remain available for distribution and used for another two years.

The licensing authority in the UK would be aware of the sources of the products which had been declared as part of the licensing applications seeking permission for distribution in this country. Though there is evidence therefore that they knew that some plasma was sourced from US prisons (in the case of some manufacturers), there is nonetheless no evidence that the authorities were alert to the particular heightened risks that this posed. Nor is there evidence that the licensing authority or the DHSS more widely had been told of the use of hyperimmunised plasma, or at least that it too might end up being used in the manufacture of factor concentrates, as well as vaccines for Hepatitis B.

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Pool sizes in pharmaceutical companies' products

In February 1984, the size of donor pools was discussed at a meeting between civil servants, American and British fractionators, clinicians and scientists:

> "*it was pointed out that the pool sizes used by the commercial fractionators ranged from 1,000 to 10,000 litres of plasma, though sometimes pools were combined at the cryoprecipitate stage, giving a possible maximum of 20,000 litres of plasma equivalent. The average volume collected from plasmapheresis donors was 680 ml, with a minimum pool size of around 1,500 donors and maximum of around 30,000 donors. The maximum pool size used by NHS producers is 1,000 kg of* [cryoprecipitate – corrected by hand to plasma]*, incorporating material from about 5,000 donors.*"

This is consistent with other evidence considered by the Inquiry. The minimum pool size (1,000 litres and around 1,500 donors) may refer to the approach taken by Armour and possibly Immuno; a maximum of around 30,000 donors is broadly consistent with the figure given in *The Lancet* for heat-treated Profilate produced by Alpha; combined plasma pools containing 20,000 donations is consistent with the evidence concerning Cutter.

When evidence of large pool sizes is combined with the purchase of plasma from the cheapest sources, and the policy of using residual material from hyperimmune plasma to make concentrates, it is fair to say that commercial concentrates fully deserved the reputation they had had since the start of the 1970s as being riskier than domestic concentrates, and far riskier than single-donor cryoprecipitate. It is unsurprising that they were a principal source of HIV infection in the UK.

Product labelling and information

There were three elements to the product information provided for factor concentrates. Most visible was the text used on the packets and labels for the products. The amount of information conveyed in this way was naturally limited by the space available and so a longer exposition was contained in the product leaflet that would be included as an insert in the package. The third element was the data sheet, which could be provided independently of the product, for example to clinicians who wished to know more about it. Data sheets were similar in length and detail to the product leaflet but were not necessarily identical. The evidence of those pharmaceutical representatives involved in the licensing process in the 1970s and 1980s is that the product information was intended to be read by the clinicians responsible for prescribing the products, and was not intended for patients.

All the pharmaceutical companies told the UK licensing authority, at the time of licensing, that their products carried a risk of transmitting and thus causing hepatitis. It was not hidden. There was a contrast when it came to the risk of AIDS, when warnings were much less emphatic. However, Alpha did issue a press release on 7 January 1983 warning of a risk that its products might transmit a virus which caused AIDS.

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Two of these leading pharmaceutical companies issued warnings in starker form than the others: thus the warning on the Hemofil bottle was unqualified ("*The risk of transmitting hepatitis is present*") although the package leaflet was less clearcut, and to the effect that the risk of hepatitis was "*unknown*". Cutter advised in respect of Koate that the presence of hepatitis virus "*should be assumed*": this was the clearest and starkest warning. Immuno, Abbott/Alpha, and Armour used formulations which could be read as suggesting that their product was really not very likely to transmit hepatitis. Thus Immuno said the risk "*cannot be entirely excluded*", and by these words which suggested it could largely be excluded (coupled with references to "*healthy*" donors and to having tested all donations for hepatitis associated antigens) conveyed a picture of minimal risk. Abbott/Alpha described that tests had been negative for the presence of hepatitis, but not "*all units*" of "*potentially*" infectious plasma could be detected so the risk (the inference is, only a little) was "*still present*" (their later data sheets did however advise the use of single-donor products where possible); and Armour, in common with Immuno and Alpha, began by emphasising the precautions taken to render the product safe before saying that despite those the product "*may contain causative agents of viral hepatitis*"; and rather than say, as Cutter did – "assume there is a risk" – it said, in a roundabout formulation that "*freedom from the causal agents of hepatitis cannot be assumed.*"

Haemophilia clinicians, and the licensing authority, either knew of the risks of non-A non-B Hepatitis or should have done. The warnings were addressed to them. If they had been read by a patient receiving home treatment, it is highly unlikely they would have understood that if they used the product there were risks to their health. It was for their clinician to tell them of these risks. However, though factor concentrates were distributed through hospitals and clinics, some clinicians who did not regularly care for people with bleeding disorders might use them and they would not necessarily know of the risk if they were not alerted by a product warning. In the absence of wording to the effect that it should be assumed that a virus was present which would cause hepatitis, with potentially serious consequences, which could not be excluded by any available test, the warnings about hepatitis were therefore inadequate for the UK market. They did not sufficiently identify a risk of non-A non-B Hepatitis by referring generally to hepatitis, especially in the case of warnings which spoke about the product having been tested and found non-reactive, for testing could not at the time have extended to non-A non-B Hepatitis.

Although the pharmaceutical companies involved in the production of concentrates did not, with the exception of Alpha, acknowledge in public until well after the start of 1983 that there was a real risk that AIDS might be transmitted or caused by using factor concentrates, they nonetheless were (or ought to have been) well aware of this risk. Evidence suggests that by March 1984 Alpha's product sheets spoke of the possibility of "AIDS causative agents" being present in and transmitted through the product. For Cutter, the earliest product warning which the Inquiry has been able to identify is also from March 1984. The Inquiry has an extensive selection of data sheets and product leaflets relating to Kryobulin produced by Immuno in the early and mid 1980s, though, and none mention AIDS, HTLV-3, LAV or HIV. Nor were there warnings in the product literature identified by the Inquiry for Factorate and

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High Potency Factorate, Armour's products, in this period. Warnings could have been given earlier. They could have been given on product data sheets. If the very firms whose products were said by many third parties to be most implicated as being potentially causative had confirmed that, as they themselves also saw it, there was a realistic case that they might indeed be linked to AIDS this would have been a powerful reaffirmation of the risk.

The response to AIDS

Two measures in particular were considered of importance by the CDC in late 1982 and early 1983: the exclusion of high-risk donors and surrogate testing. Pharmaceutical companies were amenable on the former but, with the exception of Cutter and to a lesser extent Hyland, resistant on the latter.

In December 1982 the pharmaceutical companies were asked to commit to avoiding collection centres in "high risk" areas and to improve the education and screening of donors from "*high risk populations*" – gay men, Haitians and intravenous drug users.

Alpha was the first of the companies to take significant measures in this respect, in December 1982. The measures taken on donor education and exclusion had a rapid and significant effect. Within the first three weeks, 308 gay donors had been excluded. By the summer of 1983, 800 potential donors had "*voluntarily disqualified themselves from the pool.*" These steps were prospective, affecting plasma that was yet to be collected and processed, not that which had already entered the system. There is no evidence identified by the Inquiry to show that previous plasma donated by the donors who were excluded as a result of the enhanced screening was discarded, or that product was recalled. This means that although Alpha is to be applauded for taking the steps it did at some apparent cost to its business, the claim to have taken "*all possible steps*" cannot be taken literally. The other companies subsequently adopted their own enhanced screening measures, including those in respect of questioning those who came to sell their plasma and medical examinations. Hyland did so in late January or early February 1983, and Cutter and Armour in February 1983.

In 1982 and 1983 various surrogate markers were suggested, discussed and studied. Anti-HBc testing came to be regarded, and argued over, as the most likely surrogate test, not least because the epidemiological pattern of AIDS was considered to be similar to that of Hepatitis B. With the notable exceptions of Cutter and Hyland, pharmaceutical companies joined with most blood banking organisations in opposing such tests. Surrogate testing was raised at the Blood Products Advisory Committee meeting on 3 and 4 December 1982, where the minutes recorded "*a sense of urgency because of the continuing spread of AIDS and because of its long incubation time.*" However, the committee did not recommend any immediate changes in regulations or regulatory activities, instead noting that several investigations were being "*intensely pursued*" by the relevant agencies, organisations and companies. Surrogate testing was raised again at the public meeting in Atlanta on 4 January 1983. Shortly afterwards, on 14 January 1983, the National Hemophilia Foundation called a meeting bringing together pharmaceutical companies, blood bankers, regulators, the CDC, clinicians and the National Hemophilia Foundation. Before the meeting, representatives of

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the major fractionation firms and the American Blood Resources Association met together to determine their strategy. This was to seek to delay the implementation of surrogate testing, by arguing that although they accepted the concept it should wait until a more specific test was available. The attendees at this meeting agreed that "*whenever possible we would try to deflect activity to the NIH* [National Institutes of Health]*/FDA*" rather than the CDC which it was agreed "*was getting increasingly involved in areas beyond their area of expertise*". The companies' concerns about the impending introduction of surrogate testing were not realised at the meeting. The recommendations from the National Hemophilia Foundation's Medical and Scientific Advisory Committee were for, "*Evaluation and implementation (if verified) of surrogate laboratory tests that would identify individuals at high risk of AIDS transmission.*" The immediate request was, therefore, for more research. This approach – accepting the potential value of surrogate testing but emphasising the need for further research – was maintained by the majority of the US pharmaceutical companies and blood banking organisations until HTLV-3 was isolated and a specific test for it had been developed.

Product recall

In response to the question of what was to be done over the recall of batches of concentrates that contained a donation from someone known or suspected to have developed AIDS, the pharmaceutical companies were united in adopting and encouraging consideration on a case-by-case basis, rather than the introduction of firm rules or guidance from the FDA that would result in a policy of automatic recall in given circumstances.

The decision to leave recall to be decided on a case-by-case basis was effectively to permit the distribution of product where there was not only a known risk that it might cause AIDS, but an enhanced risk of this happening. It was almost a year before the first commercial products heat treated to inactivate HIV were made available on a named patient basis, not yet licensed, in the UK. In the meantime, UK patients remained exposed to risks that products made from the plasma of donors showing some of the symptoms of AIDS or its precursor would be distributed in this jurisdiction.

4.4 Haemophilia Society

The Haemophilia Society was formed in 1950 by a small group of volunteers, with experience of the largest haemophilia treatment centres. The Society gained significant media and political traction but had limited resources. Its views on treatment and risks were effectively dictated by a small number of senior and influential haemophilia clinicians, in particular, Professor Arthur Bloom.

The Society is open to criticism for not urging the risks of non-A non-B Hepatitis more strongly; and for retreating to the comfort of the status quo so far as treatment policy went when first faced with considering the risks of AIDS that factor concentrates clearly presented. Though it did not have sufficient expertise to challenge the views of Professor Bloom, which were so influential in 1983 and early 1984, it gave a platform for those views to be voiced,

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without asking questions about them so it could better understand their basis. It could and should have asked those questions. It is clear, however, that the Society was not given the full facts which Professor Bloom knew, including that on 26 April 1983 he had reported a patient to the CDSC as a probable case of AIDS. His behaviour in misleading the Society and its members is "*unfathomable*".

The Society opposed any ban on importing commercial concentrates from the US. The Executive Committee appears to have accepted without serious question that any form of haemophilia was more dangerous than AIDS. In August 1983 they wrote to the DHSS asking that there should "*be no attempt to suspend the importation of US Commercial Products* [without] *definite evidence that this would be necessary.*" For some time after the start of September 1983 the Society did not convey generally to its members what the evidence shows to have been some growing concerns about the position it had adopted. It had adopted it in good faith, in reliance on what Professor Bloom was saying, but doubts were developing. It failed to pick up what should have been increasingly clear from other sources. Members were being told that – although they should take the advice of their haemophilia consultants – they should continue with their current treatment regimes; there was no urging of government, nor of the regulator, to revisit whether permission for importation should continue. The Society did not warn members that their haemophilia centre might be using pre-March 1983 stocks of blood product, and they should seek to have only products from plasma sourced after that date. Nor did it advise treatment policies which would lessen the risks of infection. It continued the approach that "*factor VIII concentrates must continue to be imported from the USA*".

By 1986 the Society was campaigning for compensation for people infected with HIV, and sought advice about its members' prospects in litigation. The Society shared the advice that those prospects were weak with haemophilia clinicians, and government officials. This may have been part of a strategy to secure some money from government sooner for a greater number of people. It was not unreasonable to adopt this strategy, though it might have been preferable simply to point to the difficulties in the way of success (leaving open at least some possibility of it) rather than express a considered legal view that in the light of those problems there was no chance. It happened that the strategy almost certainly resulted in sufferers receiving some money much earlier than they otherwise would have done, and did avoid the risk that individuals might fail altogether in their claims. It was bold, but it worked – to an extent. Nonetheless, sending a negative opinion of Counsel to leading haemophilia clinicians remains an indefensible action, potentially harmful to some members of the Society whilst giving no benefit to the others.

The Society was slow in reacting to the risks of Hepatitis C and probably unduly hesitant in beginning to mount a campaign for it. However, the fact that it did so, and that it was well served by Karin Pappenheim (the CEO of the Society) in this respect, ultimately bore fruit especially when it focused on Scotland as a part of the UK that might be more responsive to its arguments.

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These criticisms must be seen in the context of a small charity, whose volunteer Executive Committee consisted of members most of whom had haemophilia and were using blood products.

Volume 5 What happened and why?

After examining clinical practice in Blood Transfusion over the relevant periods (chapter 5.1) the volume examines one of the ways in which the risks of infection could be reduced – screening.

Before HIV and Hepatitis C became identifiable by a laboratory test, the only ways in which the chances of these infections entering the blood supply could be reduced were by selecting donors as carefully as possible, relying on them to say if they thought they had any illness (often in both cases with the help of a donor questionnaire or more general leaflet) or by some other laboratory screen which might identify either that the would-be donor had signs of having or having had an infection closely linked to groups thought to be at high risk of either or both HIV or non-A non-B Hepatitis (surrogate screening). In both cases, when direct tests became available time was taken before they were universally applied to all donations given in the UK. Thus a direct test of HIV was available (to a limited extent) in July/August 1984, but universal screening was not introduced until 14 October 1985. In the case of Hepatitis C, a test (a "first generation" test) became available first in April 1989, but universal screening in the UK did not begin until 1 September 1991 (by which time a second generation test had become available and was used). Undoubtedly, therefore, appreciable time passed in each case between a test being available, and being applied. The chapters consider whether this was appropriate, or whether it represented a delay which should not have occurred.

5.1 Blood Transfusion: Clinical Practice

This chapter examines clinical practices relating to blood transfusions and the adequacy of the steps that were taken to reduce the risks of viral transmission through transfusion. It should be read in conjunction with, in particular, the chapters on the *Blood Services*.

Despite the knowledge of the risks of viral infection arising from blood transfusion, in the UK in the 1970s and 1980s blood was often administered by clinicians without a detailed consideration of the risk to patients of transfusion-transmitted infections. Further, the evidence of patients, clinicians and academics, demonstrates that from the 1970s to 1990s blood was given to some patients unnecessarily. Either a transfusion was not strictly required, or patients were given more blood than they needed.

Prior to the emergence of HIV, the minority of clinicians who pressed for a reduction in the use of blood transfusion, did not reflect mainstream medical practice and the administration of blood was wrongly seen by many to be low or no risk. It took until 1998, with the creation of the Better Blood Transfusion initiative, for a UK-wide framework addressing the best practice for blood transfusion to be established and a concerted effort to be made to reduce

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unnecessary blood transfusions. It appears that there was a level of complacency about the safety of blood resulting in measures not being taken earlier throughout the UK to improve the overall safety of blood transfusions. It is clear had such measures been taken earlier, it is likely that lives would have been saved.

In 1951 Professor Patrick Mollison published the textbook that became known as the "*'bible' of blood transfusion*". It stated that, in treating anaemia, it must "*never be forgotten that transfusion carries risks which are large compared with those of conservative treatment.*" Dr George Discombe's 1960 textbook highlighted the danger of hepatitis as one that "*must never be forgotten when assessing the need for transfusion.*" He described the "*very common*" use of blood transfusion for treating pre-operative anaemia as "*inexcusable*". In 1967, Professor Mollison's updated book emphasised that pre-operative transfusions "*could be avoided if it were a routine practice to determine the patient's haemoglobin concentration at the time when operation is first considered, as there would then more often be time to treat the anaemia with iron, etc.*" Despite this recommendation, the evidence received by the Inquiry suggests that pre-operative iron was not commonplace. In the 1983 edition, Professor Mollison noted that a higher percentage of women than men were transfused after an operation involving blood loss "*because there is a tendency to use the same level of haematocrit (or Hb) in women as in men in deciding whether transfusion is required. There would be a substantial saving in blood if the normal difference in haematocrit between men and women were taken into account in deciding the need for transfusion*".

On the ground, it appears that, despite the training received and the content of medical textbooks, in the 1970s and 1980s many UK clinicians viewed blood as safe and effective. On the whole – and with notable exceptions – there was generally a liberal approach in practice to the use of blood. This was especially the case in certain medical disciplines.

With the advent of AIDS there began to be a change in attitude on the safety of blood. Dr Roger Moore, the deputy national director of the NBTS from 1989 to 1992, explained that: "*Originally the benefits of a blood transfusion had been seen as overwhelming compared with the risk. A patient either had a certainty of dying at once of blood loss or a vague possibility of an infection years into the future. The advent of AIDS changed perceptions, patients and their doctors were very concerned about getting AIDS from a transfusion, the risk/benefit equation changed*."

In the circumstances of high-volume, acute blood loss, it is clear that blood transfusions were and are necessary. However, from the 1970s a so-called "*top up*" of one or two units of blood after labour was commonly given to women even with minor blood loss to help get a woman "*up and about*" and caring for the baby. Professor Mollison's 1983 edition described "topping up" as "*widespread*" but with "*very variable opinions as to what constitutes an acceptable level*" of haemoglobin. This practice extended to using two units where one would suffice and appears to have been both widespread and persistent. A 2017 study of two large maternity units in Texas and London found that from 1988 to 2000 obstetricians prescribed two units six times more than one unit "*even when the* [estimated blood loss] *and*

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pre-transfusion haemoglobin suggest that one unit would be sufficient". It was noted that this practice "*continues to deviate from recommended guidelines*".

Topping up blood with two units was also customary for some general and orthopaedic surgeons. In the 1985 *Principles and Practice of Surgery*, the transmission of viral hepatitis was described as "*the most serious and frequent complication of the administration of blood and blood products … The best preventative measure is to avoid unnecessary transfusion*." It noted that the use of haemoglobin and haematocrit measures was "*notoriously misleading*" and the best approach to assessing haemorrhage was frequent clinical observations.

Dr Lorna Williamson told the Inquiry that the Hepatitis C lookback revealed that "*some patients who had planned surgery did not know whether or not they had been transfused while under anaesthetic*." The Inquiry has received many statements where individuals state that they were not informed of the risks of blood transfusions, and others where they were not even told that they had received blood and for many it was not recorded in the medical records that were retained after their hospital stay.

Many of the alternatives to blood transfusions used today only became widespread in the 2000s. However, iron supplements were available well before the 1970s, and could have replaced transfusion, where that was not essential. It is unclear why they were not used more widely much earlier. Tranexamic acid assists in clotting and is effective in major trauma. It "*cuts surgical bleeding by about one third to one quarter and has an excellent safety profile*." It was sometimes used in the 1970s in dental extractions and other procedures for people with bleeding disorders. Evidence that tranexamic acid prevents surgical bleeding, reducing the need for blood transfusion, has only been available "*for over a decade*" but although tranexamic acid is now much more widely available and there are NICE ("National Institute for Health and Care Excellence") guidelines for its use, usage still appears to be lower than it should be.

Significant steps to address the use of unnecessary blood transfusions were not taken until the 1990s and beyond. It is not clear why. The CMOs should earlier have added their weight in a "Dear Doctor" letter advising doctors to be sparse in their use of transfusions of red blood, and where possible to take advantage of alternatives.

The measures eventually taken include the creation of specialist working groups and committees (leading to greater awareness amongst practitioners, and ultimately to haemo-vigilance); auditing (with comparisons of blood usage); maximum blood ordering schedules (standardised for specific procedures); hospital transfusion practitioners; hospital transfusion committees; the establishment of the Serious Hazards of Transfusion ("SHOT") which reports on infections and other adverse effects, and the Better Blood Transfusion initiative.

In June 1998 Sir Kenneth Calman, the English CMO, noted that the emergence of vCJD had "*caused concern for patients and the public*" about the safety of blood. The UK CMOs together hosted a conference in London in July 1998 addressing how better blood transfusion might be encouraged and supported. This was the origin of the Better Blood Transfusion initiative. The most recent conference held in March 2019 acknowledged that "*Over the last*

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10 years there has been considerable improvement in transfusion practice supported by evidence from clinical trials, implementation of guidelines and process improvements that have resulted in an overall reduction in blood use and significant cost savings for the NHS". It also noted that: "*However, there is evidence of ongoing variability in transfusion practice within and between hospitals that may impact on patient outcomes needing further action*", and made a number of recommendations.

The fact that the National Blood Transfusion Committee has demonstrated by audit that around 20 to 30% of transfusions in major specialisms are currently outside the national recommendations shows that there is still work to be done, despite a considerable reduction in the use of red blood cells over the last 25 years.

For too long and despite repeated advice, blood and blood components were given too readily, were frequently given in too great a quantity, with insufficient consideration of whether they were needed, and little or no consideration of alternatives which had less risk (not being biological products) such as tranexamic acid, pre-operative iron, or intra-operative cell salvage. Most importantly perhaps, little or no advantage was taken of the opportunity to discuss the desirability of transfusions, their risks and benefits, and any alternatives (including no transfusion) with patients. Though plainly in emergency circumstances this may not be practicable, this should have happened in almost all other cases.

Too much blood was given unnecessarily to patients. This was particularly problematic in the treatment of pregnant and postpartum women and in non-emergency surgery. The risks of transfusion were rarely discussed with patients. The widespread failure to warn patients of the risks of infection meant that they were not alert to the signs of what in too many cases turned out to be Hepatitis C. Responsibility for this rests generally with the profession. Alternatives to transfusion were not used enough – with responsibility resting with the profession, the health departments and the blood services.

In summary:

- Over many years blood was used unnecessarily, being wrongly seen by many clinicians to be little or no risk. There was an unacceptable level of complacency about the safety of blood.
- The unnecessary use, and overuse, of blood was particularly problematic in the treatment of pregnant and postpartum women and in the undertaking of non-emergency surgery.
- It took until 1998, and the creation of the Better Blood Transfusion initiative, for a UK-wide framework addressing best practice in transfusion to be established and a concerted effort to be made to reduce unnecessary blood transfusions. This, or something as effective, should have happened earlier and there is no good reason why it took so long for coordinated action to be taken.
- Earlier action could and should have included the issue by CMOs of "Dear Doctor" letters or health circulars regarding both overuse of blood and the use of alternatives.

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- There were measures that could and should have been introduced earlier than they were: audits of blood usage; the creation of maximum blood ordering schedules; and the engagement of specialist transfusion practitioners.
- Hospital transfusion committees should have been established earlier than they were.
- There was (and remains, particularly in regard to tranexamic acid) insufficient use of alternatives to transfusion: in particular iron supplements, tranexamic acid and red cell salvage.
- SHOT, or a similar haemovigilance scheme, should have been established earlier, in the 1980s.

The measures outlined above would, if addressed earlier, have reduced the level of infection and (in all likelihood) have saved lives.

There was a widespread (and wrong) failure to warn patients of the risks of transfusion, and of alternatives, where they could reasonably have been warned, both so that they could give informed consent and so that they could be alert to, and take steps with regard to, the possible health consequences of the treatment. Many transfusions (whether on an emergency basis or because of a serious long-term condition) were undoubtedly necessary, but even in such cases patients should have been given information about the risks of viral transmission so that they too could be alert to the possible consequences and take appropriate steps to mitigate those consequences. In all cases transfusion could and should have been properly recorded in patients' medical notes.

Screening

The next four chapters examine the decision making regarding surrogate screening for Hepatitis C, surrogate screening for HIV, the introduction of HIV screening and the introduction of Hepatitis C screening.

5.2 Hepatitis C Surrogate Screening

The virus responsible for NANBH, later identified as Hepatitis C, was not discovered until 1988, and a specific test to screen blood donations was only introduced in September 1991.

In the absence of a specific test, there were alternative methods to lessen the risk of transmitting NANBH through blood transfusions through the usage of "surrogate" markers. The primary markers considered were elevated ALT, which indicate liver abnormalities, and Hepatitis B core antibody ("anti-HBc"), which signifies a past infection (a known factor in exposure to NANBH), either applied separately or in tandem. Blood was already being screened for Hepatitis B surface antigen to identify active infections of Hepatitis B.

The principal issues for consideration were: whether screening out blood donations with raised ALT levels and/or positive anti-HBc results would reduce the likelihood that transfusion

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recipients would be infected with NANBH; and whether the drawbacks of introducing such screening (reducing the number of donors) justified the anticipated benefits.

The chapter concludes that the UK's approach to the question of whether to introduce surrogate screening of blood donations for NANBH was flawed. Responsibility for this lies with both the blood services and with the government (both the DHSS and the SHHD).

A major study in the US, which had prospectively followed 1,513 transfusion recipients between 1974 and 1979 was published in April 1981 in the *New England Journal of Medicine.* It found that the incidence of hepatitis was directly related to elevated ALT levels in blood donors. The authors advocated ALT screening due to its "*high correlation*" with transfusion infectivity. A further study the same year from the US National Institutes of Health published a report in the *Journal of the American Medical Association* which showed similar results. Though it was thought that some 40% of NANBH infections could be excluded by testing for these higher ALT levels, the downside was that fewer units of blood would be available for transfusion generally, because a number of donors who did not in fact carry NANBH would be excluded. The authors of this study described the situation as a "*tenuous balance between risk and benefit*" and one that would require thought and planning.

By early 1982 US and Australian research suggested that screening for elevated ALT or anti-HBc could potentially prevent over a third or more of NANBH infections.

In the UK, in September 1982, a newly formed working party on Transfusion-Associated Hepatitis (which knew of these American and Australian studies) agreed that Dr Brian McClelland would produce a study proposal on surrogate screening methods.

There was evidence that nothing then came of the proposed study, due to attention being taken up with HIV/AIDS, and the working party did not meet again until November 1986.

The chapter deals with repeated discussions after that, in some detail, which are best summarised in this chronology (beginning before the US research from the long prospective studies was published, and taking matters up to 1988):

- On 14 February 1980 research was called for to identify the size of the problem of NANBH in relation to blood transfusions.
- On 25 June 1981 a proposal for a prospective study was present; nothing happened.
- On 27 September 1982 it was agreed that an outline study protocol would be produced; nothing happened.
- On 10 January 1983 an outline proposal was produced (again) – and it was agreed some form of study was needed; nothing happened.
- On 25 April 1986 the regional transfusion directors' meeting discussed whether the NBTS should carry out a study; nothing happened.

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- In May 1986 Dr Contreras (the director of the North West Thames RTC) wrote to the DHSS saying that a study of anti-HBc in British blood donors should be undertaken.
- On 4 September 1986 a study was discussed again between Dr Fraser (Bristol) and Dr Cash (Scotland) and on 18 September 1986 Dr Contreras wrote again to the DHSS.
- On 8 October 1986 the regional transfusion directors for England and Wales proposed a prospective study; Dr Gunson wrote a paper to suggest this; no study took place.
- On 24 November 1986 a working party proposed to "*consider a protocol*".
- By January 1987 what was being considered was now an approach for funding to undertake a study. There was no funding, nor had any study yet begun.
- Some four months later, at the very end of April, a funding proposal was submitted. A year passed waiting for a decision.
- In June 1987 Dr McClelland, Professor Cash and Scottish transfusion directors accepted in a letter that the benefit from surrogate testing could not accurately be established without a large prospective UK study. However, they noted that it was now too late to begin such a study, since an answer would only be given from the study in 3-4 years time.

Much of the failure of the Scottish transfusion directors to persuade the SHHD that surrogate testing should be introduced related to the view taken by Dr John Forrester of the SHHD. He said, in the second half of the 1980s, that NANBH was "*relatively benign*". There was no proper basis to say this, other than unjustified assumption.

The letter from Dr McClelland, Dr Cash and the Scottish transfusion directors gave three reasons why the introduction of NANBH surrogate screening was "*virtually inescapable*": European legislation on strict product liability; enhanced safety of pooled plasma products (pending the introduction of heat-treated products); and consumers wanting NANBH-tested products. The authors emphasised that the question was not if but rather when the UK transfusion services would align with US and European practices in donor screening.

By the time the multi-centre study started, the Chiron Corporation had made significant advances by identifying and cloning the NANBH virus (now known as Hepatitis C), and developing a prototype immunoassay: it was reported they had done this on 10 May 1988. While surrogate screening for NANBH remained a possibility, in practical terms the focus shifted towards implementing a direct test for Hepatitis C.

There remained some purpose in surrogate screening, notwithstanding the impending availability of direct tests. In September 1989 Dr Gunson prepared a paper (this time for the Advisory Committee on Transfusion Transmitted Diseases ("ACTTD")) recommending that routine screening of anti-HCV should be introduced when practical.

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The ACVSB (a separate body from the ACTTD) supported the general introduction of the Chiron test if approved by the FDA, but saw no justification for using surrogate tests for NANBH, effectively ending the UK's consideration of such measures.

Throughout this period there is little evidence of active involvement by the DHSS, the CMO, or ministers. The lack of a clear structure for decision-making probably contributed to this. Further, the disbanding of the MRC Working Party and the apparent failure of the Blood Transfusion Service Working Party to meet more regularly over the period between September 1983 and late 1986 resulted in there being no appropriate forum where the important issue of surrogate testing could be discussed and resolved.

The unique epidemiology of NANBH in the UK compared to that of the US highlighted the need for localised data, yet urgency for research into this was lacking, leading to indecisive discussions about the necessity of surrogate screening. Unfortunately, the discussion became circular: surrogate screening could not be justified without further study, but the necessary further study could not itself be justified. The result was a paralysis in decision-making. The failure to take timely decisions, to carry out further research into the effectiveness of surrogate testing or to introduce such testing notwithstanding limitations in the data, in order to prioritise patient safety, was coupled with a desire to search for more knowledge as a prerequisite for taking precautionary action. This failed to address the needs of public health with speed, and in searching for more knowledge was the enemy of achieving progress in safety.

Whether to introduce surrogate screening for NANBH in the UK was a complex decision, and the arrival of AIDS undoubtedly diverted attention between 1983 and 1986. However, the complexity of the decision provides little or no justification for a failure to ensure that timely decisions were taken – and implemented – around the need for further study and data collection. While the AIDS crisis diverted attention and resources away from NANBH, arguably, it should have brought into sharper focus the need to avoid delay in taking decisions in the interest of patient safety, even where those decisions had to be made on the basis of incomplete or limited information.

Would introducing surrogate testing sooner have made a difference? The answer is, probably, yes. Dr Alter noted in November 1989 and again in 1998 that surrogate assays for anti-HBc and ALT could have identified about half of the anti-HCV-positive donors linked to hepatitis transmission in the US. It was this which led to the US introduction of such screening. Similarly, a Canadian study found that 70% of Hepatitis C infections would have been avoided by the use of the two surrogate markers, ALT and anti-HBc. The US introduced surrogate screening for HCV in 1986. The chapter concludes that surrogate testing could have been introduced in the UK in the first half of the 1980s, and that following the publication of the research by Drs Alter and Dienstag in early 1986 there was no proper justification for the failure thereafter to introduce surrogate testing in the UK no later than January 1987, and probably by mid 1986.

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The chapter concludes that the case that surrogate screening should have been introduced is stronger still when the evidence on HIV surrogate screening is considered. If anti-HBc testing of donations had been introduced as a surrogate test for HIV, it would have also functioned as a partial surrogate screen for NANBH.

5.3 HIV Surrogate Screening

Until the AIDS virus had been identified, it was not possible to test blood donations directly. The only preventative measures included avoiding transfusions unless absolutely necessary, minimising the use of blood or blood products, excluding high-risk donors, and employing surrogate testing methods that indicate a high risk of infection.

During a meeting on 22 September 1983, RTDs recognised that no tests for AIDS were available, but early data suggested that high-risk populations, such as promiscuous homosexual men, could often be identified by positive result for Hepatitis B core antibody, Hepatitis B surface antigen and antibody, and TPHA syphilis, with the Hepatitis B core antibody potentially serving at the most valuable marker.

In February 1984 Dr John Petricianni of the FDA highlighted the US experience, claiming that the anti-Hepatitis B core antibody was positive in more than 90% of AIDS cases. Later that month Bristol RTC outlined a protocol for a study, proposing that 50,000 donors from Bristol and Edgware would be screened for Hepatitis B core antibody to identify past infection and correlate these with high-risk AIDS groups. Both the DHSS and the MRC were asked to support the proposal.

By April 1984, Dr Gunson pushed for funding approval from the MRC and DHSS, emphasising the importance of the study due to the potential pressures from US developments to implement anti-HBc screening. The proposal was for a two year study to begin in November 1984. However, by summer 1984, developments in screening tests for HTLV-3/HIV indicated that the study might already be outdated.

This lack of urgency in responding to the potential for blood transmission of AIDS was problematic, especially given the emerging epidemic. Despite the potential for transmission by blood and blood becoming apparent during 1982, research funding was only requested in April 1984 for a study which would not conclude until November 1986. In the teeth of an impending epidemic, this was far too slow.

The introduction of direct HIV screening in October 1985 was a significant advancement, yet earlier actions to exclude high-risk donors were impeded by a lack of consensus on costs and benefits. Donor leaflets were never likely to dissuade all high-risk donors. The responsibility for these missed opportunities to screen out some high-risk donors rests with the DHSS and the SHHD (primarily the former) and the blood services.

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5.4 HIV Screening

Only once the cause of AIDS was known to be a virus transmitted by blood and it was possible to identify the virus itself, would it have been possible with any confidence to eliminate the risks altogether, though they could be reduced.

On 23 April 1984 Professor Robert Gallo announced his identification of the HTLV-3 virus. At a press conference that day the US Secretary of State for the Department of Health and Human Services predicted that a test to screen blood for the virus would be available in six months. By June 1984 five pharmaceutical companies in the US had been chosen to manufacture blood tests. In the UK Dr (later Professor) Richard Tedder (Middlesex Hospital) and Professor Robin Weiss (Chester Beatty Institute) also began developing a test.

The importance of a test soon was reflected in an internal DHSS memo on 10 July which said that it was of "*paramount*" importance to maintain public confidence in the NBTS "*by introducing a screening test as quickly as possible*" and to "*ensure that 'our' blood is OK by the most up to date means.*" The minute proposed that the DHSS should press those concerned to proceed with research and development as quickly as possible (including going to ministers for money), considered the operational implications of screening and ended: "*In short we must give this top priority.*"

The background to this was a wide and increasing public concern about the epidemic spread of AIDS, and the fear that it might be a real threat within the UK as well as elsewhere.

By the end of August, *The Guardian* announced that a test had been developed. *The Lancet* reported that people with haemophilia receiving pooled concentrates in North London had been tested and 34% showed positive.

At that time the test used was that developed by Dr Tedder and Professor Weiss. The DHSS internal note shows it seemed "*possibly more reliable*" than other tests in the US and elsewhere.

Yet it took more than a year until blood donations throughout the UK were regularly screened to prevent HIV from entering the blood supply. It is not possible to determine how many infections resulted, and how many deaths might have been avoided, within this period if screening had been introduced earlier. The probability is that some would have been.

Screening is costly. In November 1984, the Minister of State for Health, Kenneth Clarke, did not think that screening would be cost effective since there were so few AIDS cases. He concluded that the use of the central reserve fund would be inappropriate, and that the cost of any screening should be met by the existing budgets of regional health authorities.

An Advisory Group on AIDS met in November 1984. Though there was a unanimously "*strong view*" that antibody tests for HTLV-3 "*must be used for all NBTS donors as soon as possible*" there was (in the words of one participant) "*no clear picture of when or how a serviceable assay will be provided.*"

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A screening test to be applied to the many thousands of donations given in the UK each year needed to be available in sufficient quantity – any prototype had to be capable of being "scaled up" for production both with speed and without sacrificing its sensitivity or specificity.

On New Year's Eve 1984, Alison Smithies of the DHSS set out the position to the CMO: "*It is not possible to predict when this test will be available for universal use in the RTCs because a number of scientific problems have to be overcome, but with luck it may be available although less well validated at about the time that the test from the USA will be on the market, that is in the first quarter of 1985.*"

Since regional transfusion centres in the UK already used a radioimmunoassay ("RIA") test to screen for Hepatitis B, and had the expertise and equipment readily available to do this, the DHSS favoured the UK test which was of an RIA type. The US test kits were all of the enzyme immunosorbent assay ("ELISA") type. The ELISA test was seen as the test of the future – cheaper, more reliable, easier to scale up for mass production, and easier to us and the evidence of Professor Tedder as to the position in January 1985 was that "*we were already thinking that we needed to get away from RIA to EIA*". Wellcome (the commercial partners Weiss and Tedder had chosen to scale up the test) let it be known to them that it would produce an ELISA, but not an RIA test.

Clinicians and transfusion directors pressed for early screening. Matters culminated in early January 1985. There was a submission to ministers seeking approval in principle for a screening test for AIDS antibodies in the NBTS, referring to the Tedder/Weiss test which was by then being used at both the Middlesex Hospital and the Central Public Health Laboratory at Colindale. Though the approval was granted in principle, it was at that stage that the DHSS began to consider a need to evaluate the various tests available before introducing any one of them.

There was then a period when little appears to have happened. The DHSS had decided to evaluate available tests. Four weeks after this, the evaluation process had not yet started. Matters were at the preliminary stage of "arranging" that tests should be evaluated. Three weeks later the DHSS still spoke of "plans" to evaluate, on which "*work will be started as soon as possible*". By late in March there was no progress.

It was clear that the Wellcome test was not imminent; there had been a lack of understanding about whether the test would be of RIA or ELISA type; and the results of the FDA evaluation confirmed the desirability of some evaluation in the UK. But there was, overall, a need for speed in the interests of patients' safety and public health. The CMO began to confront these questions. He went one Friday evening late in March to meet Dr Tedder, Professor Weiss and Professor Michael Adler. They confirmed that though their test worked reasonably well as a laboratory tool, adequate scaling up was still to be achieved if it was to be used. It was agreed that it would probably be necessary for the BTS to go ahead and use the first successful test that became available, which was unlikely to be the Tedder/Weiss test at first.

Though by April it had been decided that the evaluation (which had still not begun) should take place in two stages – an initial laboratory stage, followed by a field test of those still

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considered suitable – a month later it had still not started. The CMO was told that in US and Australia screening was already taking place; Finland had started it as routine; Switzerland was beginning; France expected to start by July; and West Germany had started testing as routine for the Red Cross and University Transfusions Services, and it was to be mandatory there no later than 1 October.

By the end of May progress was still being expressed in terms that anticipated a start, rather than reporting that there had been one. John Patten, the Parliamentary Under-Secretary of State for Health, heard of this and entered the fray. He questioned the CMO "*on the overall position and it is quite clear that Ministers need to know of the timescale for the evaluation of the test and, if satisfactory, for the introduction of the test at every transfusion centre*". His intervention had some but limited success in galvanising matters. Evaluation began (at the first stage); by mid July raw data had been obtained, and the results were reported at the end of July. The second stage was dispensed with, and in August DHSS announced that screening would begin on 14 October 1985.

NHS Blood and Transplant ("NHSBT") submitted at the close of the Inquiry that it was "*unclear why it took around 4 months for the work of PHLS reviewing the tests to be completed*"; that "*Considering the general agreement that testing be introduced as soon as possible, it is unfortunate that the first stage of the review was not completed at an earlier stage*"; and "*Thus, on the evidence currently available there is a case for saying that the first stage of the review of the tests was slower than was necessary*." The chapter concludes it was right in these submissions. There has been no clear reason why an evaluation process could not have been conducted in a much shorter timescale, as was appropriate to meet the urgency of the situation. It took considerable time, not so much in the process of evaluation itself once begun, but for it to begin.

It took a year from a test being developed to being used to test individual patients. This does not seem consistent with urgency. In May 1985, the CMO had been advised about the progress other countries were making and at that stage screening was already taking place in the US and Australia, with Finland, Switzerland, France and West Germany. What took most of the time was not the evaluation itself, rather the processes surrounding that evaluation. The drafting of a protocol, consideration by potential applicants, organising and then beginning the evaluation process took over five months. The overall timescale, including the laboratory evaluations which then proceeded, could and should have been quicker.

The problems that proceeding with a test would create – whether to tell donors, the availability of confirmatory testing, any hypothetical knock-on effect on the blood donation system – were secondary. Blood safety should have been the priority. It was not.

5.5 Hepatitis C Screening

This chapter considers the progress of the UK towards introducing a universal screening test, after the availability of such a test was announced on 21 April 1989. When the UK introduced one on 1 September 1991 (two and a half years later) it was one of the last

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developed nations to begin the testing of all blood donations directly for the presence of Hepatitis C infection. Many countries implemented testing on dates between 18 months and 12 months before the UK.

Chiron/Ortho test

The Chiron Corporation in California announced, on 10 May 1988 that it had cloned a protein of the blood-borne NANBH virus. This made it possible to develop a test to screen blood for the virus (now named Hepatitis C).

Once it was announced, it was clear that an effective screening test was likely to be available soon. Preparatory work for the introduction of universal screening could have started immediately. It is clear that the purpose of any such test was to identify infected donations. It follows that what donors of those units should be told needed to be considered. Questions of how best to confirm that the donation was or was not infected so that the implicated donor could be given the most reliable information of their infective status would need to be resolved. It could also be foreseen that when an acceptable test emerged, finance to implement it would need to be in place. All of this work could have begun from May 1988 onwards. No such preparatory work was undertaken.

Hepatitis C testing in the UK

The identification of Hepatitis C and the fact that a test for it was under development gave rise to concerns over the implications for the blood donation system in the UK. They began to be discussed before a test became available, but in anticipation that it would. The UK appeared to have fewer cases of post-transfusion NANBH than the US "*without any form of donor screening.*" Issues also arose over whether central funding would be provided

An anti-HCV ELISA test was announced by Chiron/Ortho on 21 April 1989 in *Science*. It was reported that the new test had a high level of sensitivity and specificity, with positive results usually appearing three to six months after the transfusion believed to have caused the infection. The article concluded that the "*sensitive test for HCV antibody described here should improve the safety of the world's blood supply as well as provide an important clinical diagnostic tool.*"

While evaluation of the Chiron/Ortho test for Hepatitis C was taking place a new body was set up to give advice on the necessary steps for ensuring the virological safety of blood in the UK. The new body was established and named the Advisory Committee on the Virological Safety of Blood ("ACVSB"). At the same time the National Directorate of the NBTS established a UK Advisory Committee on Transfusion Transmitted Diseases ("ACTTD").

In May 1989, the ACVSB met and agreed that testing blood donations for Hepatitis C should not be introduced until a UK trial had been completed. There was disagreement between the members who regarded "*the matter to be a priority*" and the Department of Health which sought to "*keep the issue of testing under review*."

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A further meeting took place on 3 July 1989. Dr Gunson tabled a paper on non-A non-B Hepatitis screening in ten other countries and showed other countries were trialling or planning to trial the Chiron/Ortho anti-HCV test.

On 26 August 1989, *The Lancet* carried two letters on the topic of "*Screening for Hepatitis C Virus Antibody*". The first, from Dr Contreras and Dr Barbara, acknowledged the Chiron/ Ortho test to be a welcome advance, but argued that "*in the context of donor screening, precipitate action should be avoided.*"

At "The First International Meeting on the Hepatitis C Virus" held in Rome on 14 and 15 September 1989, representatives from Europe and the US presented their preliminary investigations into the Chiron/Ortho anti-HCV test. It was reported that it had rapidly been introduced in a large number of blood transfusion laboratories throughout the world. Dr Gunson attended and reported (to ACTTD) that although the studies presented were small scale, they had consistently shown that the test was indeed detecting a viral marker associated with Hepatitis C. He drew a number of conclusions from the information presented at the symposium, including that "*Evidence presented suggested that routine anti-HCV tests on blood donations would reduce the incidence of transfusion transmitted NANBH*". He also added that every effort must be made to ensure that a confirmatory test was available in the UK at the time routine donor screening was introduced.

In November 1989 the ACVSB said it would support the general introduction of the Ortho test "*if the FDA approves it, and the* [planned] *pilot shows it to be feasible and non-problematic.*"

A submission was sent to Baroness Gloria Hooper, Parliamentary Under-Secretary of State for Health, in February 1990, noting that the ACVSB felt there was not sufficient scientific information about the Ortho test to advise its routine introduction. The submission did not mention that at that point, Australia was introducing routine screening, France was about to introduce it, and Japan had been screening since November.

By February 1990, Dr Frank Boulton of SNBTS expressed concern that "*there appears to be little doubt that people have contracted HCV as a result of transfusions which they would not have received had those transfusions been screened for HCV antibody.*"

On 24 April 1990, the ACVSB decided not to approve the introduction of general screening, but to commence a further pilot study: a confirmatory test was needed that could be used in RTCs and not just specialised laboratories; it would be reassuring if the FDA approved the test; and there was a need to learn more about the donor panels and the significance of a positive reaction to the test.

The FDA approved the use of the Ortho test on 4 May 1990. The next ACVSB meeting was held in July 1990, and the committee agreed, following the FDA decision, to introduce screening in the UK as a public health measure (with the pilot study on the Ortho and Abbott tests determining which test to use). The expected reduction in infections was not included in the minutes, but Dr Metters, the Deputy CMO who chaired the ACVSB, stated later that Professor Zuckerman "*spoke in terms of at least 30% of such cases could be avoided,*

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possibly more." There was no need to wait for FDA licensing; the UK had not done so with the test used for HIV, and could have evaluated the test for itself.

It had earlier been agreed that roll out of screening should take place on one and the same date across the country. Following the decision, as recommended by the ACVSB in July 1990, Dr Gunson wrote to RTC directors in February 1991 informing them that the agreed date to implement testing donations for anti-HCV was 1 July 1991.

On 3 April Dr Gunson wrote again to the RTC directors and Professor Cash, advising that a "*second-round*" evaluation of anti-HCV test kits had been agreed (which, he said, was "*undoubtedly in our interest*") and that screening would now start on 1 September 1991. Professor Cash replied that this later start date "*has the SNBTS Directors' fullest support.*" David McIntosh of SNBTS said in evidence to this Inquiry that a "*misplaced desire for Anglo-Scottish solidarity was the clear cause of the unnecessary delays in the universal implementation of HCV testing in Scotland.*" He remains convinced "*that it was utterly inappropriate and resulted in a sub-optimal outcome in terms of blood and plasma product safety, to the detriment of patients in Scotland*."

There is little evidence that the public health benefits of testing were kept in the forefront of decision-making during this period. Implementation of the less specific first-generation tests in the first instance, with evaluation and introduction of the second-generation tests undertaken at the same time as a national screening programme, would have avoided additional infections with Hepatitis C.

In April 1991, Dr Huw Lloyd decided that Newcastle RTC should begin testing unilaterally. He had a phone call with Dr Gunson on 29 April, explaining that he had started routine screening in the previous week using the second-generation Abbott test. Dr Gunson reported Dr Lloyd's decision to the Liaison Committee of the UK blood services and informed the Department of Health. It was noted that "*This action has caused problems in that the other major competitor company feels disadvantaged, and has also caused problems in Scotland.*"

On 2 May 1991 Dr Lloyd wrote to all RTC directors informing that in his view, "*not to test now that we have the ability to test would be indefensible under the current Product Liability Legislation.*" He noted that other directors might take a different stance but did not consider that Newcastle's decision would "*materially alter that judgement.*" In response to Dr Lloyd's decision, the evaluation of second-generation tests was modified to accommodate the screening programme in Newcastle.

As for government, on 30 July 1991, John Canavan recommended to Baroness Hooper that a "*low key announcement*" be released to mark the introduction of anti-HCV testing. He noted that "*there may be questions about why testing was not introduced earlier as it was in some other countries.*" As country after country introduced screening, the UK's position became increasingly indefensible.

The focus of the ACVSB had become obtaining more, and better, data, rather than the public health implications of not introducing routine screening. Dr Robert Perry, in giving

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evidence to the Penrose Inquiry and this Inquiry, thought that the ACVSB was unduly biased to virology and neglected the public health perspective. His observation was that "*the best became an enemy of the good*" and that the search was for "*perfect outcomes rather than good outcomes that could meet a public health need.*"

It was reasonable for the SHHD to take the position initially that the decision to commence routine testing would be made simultaneously throughout the UK. But they did not shift from this stance and give proper consideration to going ahead with screening in Scotland.

Responsibility for the failure to ensure the timely introduction of Hepatitis C screening lies primarily with the Department of Health, which was regarded as very much in the lead on this issue. However, it is a responsibility shared with the SHHD, and with the blood services more generally for failing to push for earlier introduction of testing.

There was no credible evidence to show that safety would or might be compromised by introduction of the Chiron test in early 1990. Although there was room for scientific debate about the accuracy of the test in identifying all cases of infection, that does not detract from the fact that it still identified many. It would have saved many individuals from suffering with infections, cirrhosis and some early deaths.

Mr Justice Burton concluded that universal screening should have been adopted by March 1990. This Inquiry agrees. Blood safety should have been prioritised. It was not.

5.6 HIV Lookback

The term "lookback" means identifying patients who were given blood from donors who were later shown to be infected with a blood-borne virus. There were two different types of HIV lookback:

- a reverse lookback – where a patient presented with AIDS and an investigation was undertaken to identify whether the patient had received blood or blood products, and if so from whom.
- a targeted lookback – where an infected blood donation was identified and recipients traced to see whether or not they had been infected.

Blood was screened for HIV from 14 October 1985, at which time, the HIV lookback started. The scope of the UK-wide HIV lookback was to consider five years prior to the date the infected blood was given.

The lookback was organised centrally and began at the same time across all four nations. The regions however experienced the lookback differently, with some regions requiring significant amounts of work, whilst others required significantly less. There was no national database that held the identity of blood donors and recipients, which meant that tracing blood donations was time consuming and often required busy practitioners to search a donor and/or patient's medical records (that were often incomplete). Differing levels of enthusiasm and engagement amongst clinicians resulted in different degrees of success in tracing patients.

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There was limited encouragement and support from the DHSS or the CMO for a formal HIV lookback. No formal lookback scheme or policy was published. There was little to no guidance produced to encourage clinicians to speak with patients about whether or not they had donated blood, save for a brief note in a CMO's "Dear Doctor" letter. In light of the decentralised nature of blood services in the UK during the 1980s top-down guidance or advice could have played a particularly significant role. As a result of this there were disparities in the approaches adopted by RTCs in relation to HIV lookbacks.

Prior to the introduction of screening blood for the HIV virus, the only type of lookback that could be undertaken was a reverse lookback. Until the introduction of a universal screening test for HTLV-3 in October 1985 such lookbacks were reactive rather than proactive.

The HIV lookback emerged when Dr Galbraith contacted Dr Gunson in March 1984 about problems that might arise when an AIDS patient had previously been a blood donor. A plan was created that contained the steps that should be taken when a patient was diagnosed with AIDS and had donated or received blood or blood products. The plan was subsequently circulated by Dr Gunson at the RTD meeting on 11 April 1984. Around the same time Dr Craske visited the CDC in Atlanta. Upon his return he provided an update to haemophilia centre directors that the CDC believed that the incubation period for AIDS could be as long as five years.

In late September/early October 1984 a blood donor was diagnosed with AIDS at Bournemouth Hospital, which resulted in a series of lookback investigations to try and find the recipients of his blood. Transfusions had been given to three recipients who had tested HTLV-3 positive. The donor's plasma was part of the source material for one batch of Factor 8 concentrate of which 38 people with haemophilia in Wessex and South Wales had received.

Dr Patricia Hewitt noted that this was in accordance with the protocol agreed on 4 April 1984. She describes this as an example of a "*necessarily reactive rather than pro-active*" lookback due to the fact that screening was yet to be introduced.

The first meeting of the Advisory Committee on the National Blood Transfusion Service Working Group on AIDS was held in November 1984 and it was agreed that donors should be told that their donations would be tested for HTLV-3. Donors whose donations tested positive should be informed, but there was no unanimity on how this should be done. The follow up of, and communication to donors and patients, and contact tracing arrangements were being considered by the communicable diseases division of the DHSS.[27]

On 30 November 1984, Dr Craske outlined a new approach to be adopted for investigating the cause of AIDS for people with haemophilia. Further investigations were to be focussed on individuals with clinical features suggestive of AIDS and possibly contaminated batches of Factor 8.

27 Referred to elsewhere as IMCD division.

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When EAGA met in May 1985, they discussed a paper indicating that people who received counselling "*modified their sexual behaviour and that counselling also alleviated distress and confusion*." It recommended both brief counselling training and a more detailed course "*lasting for a month for those intending to run their own AIDS counselling courses and those responsible for a large number of patients with AIDS related problems*."

At the EAGA meeting in July 1985, Dr Gunson advised that screening could start in October 1985. Dr Gunson outlined the process the Centres would adopt if a blood donor tested positive. The Centre would send a letter and an appointment arranged for the donor to be interviewed "*by a doctor trained in counselling*." Prior to the introduction of screening, 160 people were to be trained prior in counselling and it was hoped that by the time screening was introduced there would be a number of individuals from different regions who would be trained in counselling.

EAGA met on 26 November 1985 and was updated on the screening of donations. Discussions were ongoing about increasing the number of training courses for counselling. At the next meeting, held on 15 January 1986, no progress had been made in relation to proposals to extend the counselling.

In April 1986 the CMO sent a "*Dear Doctor*" letter to all doctors in England in which he asked clinicians to enquire whether any HTLV-3 patients had previously been blood donors. The CMO stated that "*it would be helpful to discuss this in an appropriate confidential manner with your Regional Transfusion Director*."

On 8 October 1986 at a meeting of RTDs, in the context of a discussion about participation in an epidemiological study of patients who had received infected blood, proposed by Dr Timothy Wallington of Bristol, the issue of "*what action should be taken about informing recipients of HIV infected blood*" arose again.

By February 1992 it was noted at a meeting of DHSS officials, CDSC and Dr Gunson that about 90% of all HIV positive donors who could be traced had been informed of their HIV status and told not to donate again.

Dr Craske shared interim results from a retrospective study of HIV infections associated with NHS Factor 8 and 9 at a UK Haemophilia Centre Directors' Organisation meeting on 9 October 1986. He thought there was "*under-reporting from the Directors and about 30% under-reporting of AIDS/ARC cases nationally generally to CDSC*".

By February 1992 it was noted at a meeting of DHSS officials, the CDSC and Dr Gunson that about 90% of all HIV positive donors who could be traced had been informed of their HIV status and told not to donate again.

Dr Kenneth Calman (CMO) wrote in April 1992 (after the Eileen Trust had been established to provide financial support to people infected with HIV through transfusions) to a wide range of clinicians and public health professionals. He asked for help in identifying patients who might be entitled to payment. RTDs were asked to "*check their records and remind consultants of any donations from donors subsequently found to be HIV positive*." Dr Calman

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stated that the CDSC would write "*on a confidential basis*" to consultants who had already reported cases to them.

There were limitations to the lookback: deficiencies in record keeping, no centralised database of HIV positive donors and patients, reliance on previous donors returning (as a way of identifying those who were HIV positive), lack of formal government guidance and varying enthusiasm among clinicians.

Nonetheless, these shortcomings should not detract from the fact that the lookback operated effectively to prevent a number of infections and, probably, deaths.

5.7 Hepatitis C Lookback

This chapter considers why a lookback did not take place on the date universal screening began, as it had for HIV; and some of the difficulties and questions which arose during the process.

From 1988 when Hepatitis C was first cloned and a test was likely to follow, the topic of a national lookback was regularly raised, and deferred, in national committees. Many of the individuals involved had experienced the earlier UK-wide HIV lookback but there was little appetite for a national Hepatitis C lookback because of the cost and resource implications.

From 1 September 1991 blood donations in the UK were screened for Hepatitis C. By the end of 1991 there was no agreement on full lookback, though identifying donors when a patient presented with hepatitis was carried out on an ad hoc basis. Dr Jack Gillon, at the South East Scotland Blood Transfusion Service, told the Inquiry that he found this situation "*entirely unacceptable*", highlighting the ethical need to inform affected individuals about their potentially serious condition for better management and future treatment eligibility.

Dr Gillon was supported in undertaking a Hepatitis C lookback if he described it as a "*pilot study*" and published the results. The results from the first six months of his study showed that 15 of the 20 donors found to be Hepatitis C positive were regular donors. There was little evidence of false positives and all the recipients identified were Hepatitis C positive. This pilot effectively demonstrated the feasibility and necessity of a lookback, since it showed that infections could be discovered, people informed and treatment made possible, as well as enabling individuals to adjust their lives in the knowledge of their infection and its implications.

In December 1994 a submission to Tom Sackville, the Parliamentary Under-Secretary of State for Health, set out the advice that a lookback programme should begin. It further noted the need for "*persuading the Scottish Office to stay with a UK-wide approach*" due to legal advice that they had received.

Later that month the Scottish Office wrote to SNBTS asking them to take forward "*as expeditiously as possible*" a Hepatitis C lookback for all of Scotland. The responsible Scottish Office Minister, Lord Peter Fraser, informed Tom Sackville that the advice he had received

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"*is such that I consider that it is no longer a matter of policy but of legal liability, and that the look-back should take place as soon as possible in Scotland.*"

On 22 December 1994 a more detailed submission to Tom Sackville noted that around 3,000 people were believed to have been infected with Hepatitis C by transfusion, and a further 3,000 people with haemophilia through blood products. It shared the advice of departmental lawyers that: "*Secretary of State may have a duty of care to do whatever can reasonably be done to identify, inform, counsel and treat any who may have become infected as a result of NHS treatment […] and if no such action is taken the SofS* [Secretary of State] *might have a case to answer.*"

Tom Sackville agreed to the recommended Hepatitis C lookback and agreement between the three health departments was reached by 10 January 1995. The press release stated that "*procedures have been established which make it possible to trace those at risk*" and acknowledged that people who had received a blood transfusion before 1991 "*may be worried*".

A lookback working party met in January 1995 and agreed that the initial focus should be on donors who had given blood before universal screening began in September 1991 and were later found to be positive upon subsequent donations. It was decided not to pursue donors who had not returned as the efforts required were deemed disproportionate to the benefits.

A helpline which had been set up told callers that the lookback "*is a process of identifying patients who were previously given blood from donors who have since been shown to be Hepatitis C positive.*" People may have reasonably understood that if they were not contacted then they had not been infected. That impression was wrong: donors who did not return to give blood were not identified and their donations may have transmitted Hepatitis C. The CMO issued a "Dear Doctor" letter on 3 April 1995 with guidance and procedures for the UK-wide lookback. There was no indication in the guidance that the procedures were limited to donors who returned to donate again after 1991.

During the late 1990s the lookback slowly wound down as fewer cases were identified.

The lookback was less successful than it should have been largely because of delay. It began in April 1995, four years after the blood of any identified donors had been given to a recipient, making it harder to trace them. The lookback relied on testing the blood of repeat donors who had returned after April 1995. The Inquiry heard that tracing other donors would have involved contacting at least 200,000 people each year prior to 1991. The Scottish Government thought it would be "*logistically extremely difficult*" and "*any benefit would be disproportionate to the benefit required*". While there were good reasons not to trace donations given before 1991, the decision not to run an awareness campaign to offer testing for all recipients of blood before 1991 was an error. This is especially so as the information about the lookback exercise (for the public and GPs) appeared to suggest that anyone who was infected would be identified. The Inquiry has heard evidence that individuals, and GPs, assumed that if patients had contracted Hepatitis C they would have been informed through the lookback. This was not correct, as individuals discovered when diagnosed at a later date.

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The Inquiry has heard evidence from women who, when they were identified through the lookback, were mothers of young children and worried about how they might have infected their children in the intervening years.

The Department of Health was essentially responsible for preventing Scotland from introducing lookback earlier because that might expose other regions to litigation. Deliberate delay is not prioritising the protection of patients, but rather working to the lowest common dominator – the pace of the slowest. The lack of patient focus is fundamental to these issues. A person who had received infected blood had a right to know this so they could take decisions about their life, which were for them to make and not health professionals. They had a right to know whether or not treatment was available for them. They needed to know so that they could avoid harming others, and tell any others they wished about their condition. The patient perspective – in particular their safety and autonomy – featured very little in the various discussions.

There was no good reason for distinguishing Hepatitis C and HIV infections when it came to lookback. The latter began almost immediately when there was universal screening. There is no good reason why the same approach was not adopted for Hepatitis C.

The responsibility for this delay lies mainly with government. The Department of Health, the blood services in England and the National Blood Authority were principally responsible for this. The administration in the devolved nations could be forgiven for following their lead – though a concern for public health in their own nations should have led them to press for more action to resolve the paralysis of decision-making.

5.8 Public Health

This chapter traces the history of organised public health in the UK, from the middle of the nineteenth century. It also considers the functions of the PHLS and CDSC.

The chapter notes that a substantial reorganisation of the NHS took place in 1974 with health functions transferring to regional and area health authorities and health boards. The newly established regional and area health authorities in England and Wales, and health boards in Scotland, were to be responsible for a range of services contributing to the prevention, control and treatment of communicable disease. The statutory powers for communicable disease control, however, remained with the local authorities, although these were "*with weakened capacity and complex working arrangements with new health authorities.*" It has been suggested that "*the loss of the Medical Officer of Health was a grave strategic error, because he was a person of importance, influence, with substantial independence in the local authority and he was powerful … The public health voice was weakened by this reorganisation.*" The Expert Report to the Inquiry on Public Health and Administration agreed with this.

High-profile communicable disease control failures in the 1980s – the 1984 salmonella outbreak at Stanley Royd Hospital and the 1985 Legionnaires' disease outbreak in Stafford

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– spurred the formation of the Committee of Inquiry into the Future Development of the Public Health Function, chaired by CMO Sir Donald Acheson. The report of this committee noted that both the events leading up to its establishment and the AIDS epidemic "*remind us of the crucial continuing need for an effective system for the prevention, surveillance and control of communicable disease and infection.*" It identified key problems that emerged after 1974: unclear statutory responsibilities, ineffective cooperation between health and local authorities, divided accountability and other issues within the office of the medical officer of health ("MOH"), and a general confusion about roles and responsibilities. The report found a "*set of measures which have evolved over time and which taken together, have created a system which is complicated and at times unclear, even to those who have to operate it. To others it can be positively baffling.*"

Less than 15 years after a former CMO (of England) had reported on the future of the public health function, another CMO, Sir Liam Donaldson, went to press on the same topic, though with an even greater focus on communicable disease prevention. The opening words of the executive summary of his report *Getting Ahead of the Curve: A strategy for combating infectious diseases* express the view that the basis on which the 1974 reforms had been made had been mistaken, at least so far as communicable disease control was concerned: "*Infectious diseases have been a threat to people's survival, health and well-being since human life began. Post-war optimism that their conquest was near has proved dramatically unfounded.*" He went on to say: "*One important issue is the scale of emergence of new or previously unrecognised infectious diseases. Since the early 1970s at least 30 previously unknown infectious diseases have become prominent, for which there is no fully effective treatment. Infectious diseases recognise no international boundaries, so that a newly emergent disease in another part of the world must be assessed as a potential threat to this country.*"

This report emphasised that "*It is essential to expect the unexpected*" and that "*Good surveillance, early assessment of potential problems and strong contingency plans are clearly essential if we are to recognise them early and respond efficiently to minimise their impact.*" Its proposals led to the establishment of the Health Protection Agency in 2003.

There is wide agreement in the evidence to the Inquiry that public health protections reduced significantly after 1974, as a consequence of the mindset that led to the changes made in the health service reorganisation of that year – that the threat posed by infectious disease had largely been overcome; that the emphasis now should be on protection by promoting lifestyle changes (health promotion), rather than the less individual dangers of communicable disease (health protection); that the need for expert medical epidemiology at a local level had lessened and would diminish further.

A consequence was as the Expert Group on Public Health and Administration have identified in their report to the Inquiry:

> "*Public health services in the UK have been the target of several major reorganisations in the last 50 years, which have been associated with budgetary*

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> *cuts, closures, and loss of staff and expertise. The sheer number and scale of reorganisations has inevitably been extremely disruptive, firstly weakening, and then removing, communicable disease control at local level and, from 1990, increasing marketisation and outsourcing. The overall effect has been to make public health services more fragmented and less cohesive, reducing the number of specialists, particularly those with medical training, and also reducing the overall expertise of the workforce.*"

A system which had been largely effective, and admired internationally, in which the MOH of a local authority had a central role to play in protection against the spread of infectious disease was partly dismantled when the post of MOH was abolished in 1974. A number of respected commentators reflect similar views about the weakened nature of the public health response to infectious disease after 1974, and have given broadly similar views about what might be required to put this right. Thus, in 1981 Dr Galbraith (of the CDSC) identified a need for there to be a clinical epidemiologist in each district, alongside the district medical officer, and thought that the resulting local epidemiology units should be linked through regionally located specialist epidemiologists to a national specialist unit, thus providing a degree of coordination between local identification and control of disease and the national centre that had been lacking. In 1982, the chairman of the PHLS Board observed that:

> "*As there are now so few Medical Officers (Environmental Health) with substantial experience of communicable disease control in post, active intervention by PHLS laboratories is playing an increasing part in the investigation and control of infectious disease incidents and such intervention in several places simultaneously requires co-ordination … As the incidence of infectious diseases decline, not only does knowledge and competence to diagnose and control them, but the need for vigilance increases as herd immunity diminishes.*"

By 1986, the Acheson Report identified the adverse effects of the 1974 changes on public health protection, complaining of its effect on the morale of community physicians, the reduction in the number of posts, and uncertainty about the number and nature of future jobs. The evidence put to his committee suggested that this continued uncertainty was likely to mean that fewer able doctors would in future enter the specialty. As a result, health authorities, local authorities and the public could lose access to appropriate public health advice. The Acheson Report called for an increase in the number of consultants in public health medicine. Despite these ambitions the numbers in post had dropped to 405 (less than half the number per million of the population which the Acheson Report had recommended) by 2021. The same theme of unease at the readiness of the system nationally to face serious threats of infectious disease was repeated in Sir Liam Donaldson's 2002 report.

In short, it is impossible to avoid the conclusion that the control of communicable disease by public health measures was given less value in the years 1970 to 2000 than it had been given earlier; suggesting improvements to the system did not reach ears as willing to listen as they would have been in the 1940s and 1950s when the systems in operation to control communicable disease worked well.

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5.9 vCJD

This chapter does not seek to replicate the work of the BSE inquiry – rather it traces the steps taken by government in response to the risk that vCJD might be transmissible by blood or blood products.

Bovine spongiform encephalopathy ("BSE") was first confirmed in cattle in September 1985 at a farm in Sussex. Further cases followed, rapidly rising in number. By April 1990 a Spongiform Encephalopathy Advisory Committee ("SEAC") was set up to advise government: and the National Creutzfeldt-Jakob Disease Research and Surveillance Unit ("NCJDRSU") to monitor cases of CJD.

On 8 March 1996 Dr Robert Will and Dr James Ironside formally identified that BSE had crossed from cows to people, becoming known as vCJD.

By 16 September 1997, the SEAC had considered the results of two studies due to be published in *Nature* and accepted this evidence of the link between BSE and vCJD. Although the primary candidate for transmitting the disease was eating infected beef, it was theoretically possible that it might be transmitted between humans through blood. The CMO issued a statement on 6 October 1997 that three people (and possibly a fourth) who had suffered from vCJD had been blood donors. The statement noted that "*there is no epidemiological evidence to suggest that classic CJD has been transmitted between humans through blood transfusions or the use of blood products. However we do not know whether the same will apply to nvCJD* [new variant Creutzfeldt-Jakob disease]." BPL identified that between them these donors had provided seven donations of plasma, six of which had been included in fractionation pools for the production of blood products. Recipients of the products made from pools containing this plasma had not been notified and a debate began as to whether they should be told of the risks they now faced.

A meeting of the Advisory Committee on the Microbiological Safety of Blood and Tissue recommended that when the blood services were informed of confirmed cases of vCJD the recipients of any donation from those people would have to be traced – as well as continuing with the vCJD lookback. This meeting also debated whether to inform recipients. The decisive reason for not doing so, in the chair's view, was "*whether we could do anything about a situation*". Disagreement about this continued for the next seven years.

There was no such debate about recall. On 30 October 1997 the National Blood Authority stated that it had recalled albumin and Factor 8 from 26 sites in England on the basis that a blood donor who had developed vCJD had contributed to that batch.

By 1998, precautions were being taken to reduce the risk of transmission of vCJD through blood: screening donors to exclude riskier donations (from 1 August 1996 blood transfusion services throughout the UK had been required to ask all blood donors whether they had a family history of CJD, and if so not to give blood); recalling and destroying blood products linked to donations from someone later found to have had CJD; a look-back to check if people with CJD had themselves received blood or blood products and if donations from

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people later shown to have CJD had caused symptoms in recipients. In July a £70 million programme of removing most of the white blood cells from blood destined for transfusion was started (following the advice of SEAC): this process, leucodepletion, became universal in the UK by October 1999. In November a £30 million programme began to phase out UK-sourced plasma for the manufacture of blood products; using recombinant factor concentrates as the first choice of treatment for some people with haemophilia or, if not available, concentrates made from plasma collected outside the UK; contacting the small number of people who had received donations of blood from donors known subsequently to have developed vCJD to advise them appropriately.

Some of these precautions involved considerable expense and effort. Yet the risk of transmission through blood or blood products was still purely theoretical. By contrast with both clinical and governmental reaction to the risk of AIDS in the early 1980s, the lack of conclusive proof was not used to justify inaction. Rather, the approach was to act first, just in case.

In December 2002 the Department of Health purchased the largest remaining independent plasma collector, the US company Life Resources Incorporated, to ensure continuity of supply without needing to rely on UK sourced plasma. This step was taken before the first case of a person known to have contracted vCJD from transfusion was reported.

On 17 December 2003 the Secretary of State for Health, Dr John Reid, informed Parliament that earlier in the autumn a patient who had received blood in March 1996 from an infected donor had died. That donor had died some three years later of vCJD. Dr Reid explained that: "*In the light of the facts which I have outlined, it is therefore possible that the disease was transmitted from donor to recipient by blood transfusion, in circumstances where the blood of the donor was infectious, three years before the donor developed vCJD, and where the recipient developed vCJD after a six and a half year incubation period. This is a possibility not a proven causal connection.*" This possible case led to further precautionary measures: 15 people who had received transfusions of blood from donors who subsequently developed vCJD were informed. People who had received blood products made from human plasma, and were concerned, were invited to call NHS Direct.

Less than a week later research findings were published which suggested a prevalence of infection of about 1 in 4,000 people, albeit from a study of limited size. This stimulated reconsideration of whether people who received blood from a donor later found to have vCJD should be notified, and whether to notify members of high-risk groups so that they did not donate blood, or have surgery without telling the surgeon of the increased risks.

The advice from the NHS Executive to NHS medical directors in February 1998 was that ethics experts and advisory bodies believed there was no need to inform patients of their exposure because it was thought unlikely that vCJD would be transmitted this way; there was no diagnostic test for vCJD; and there was no preventative treatment for vCJD: "*In these circumstances the general view is that patients will not benefit from this knowledge, and that uncertainty created by informing patients could have the contrary effect causing*

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unjustified worry and creating a permanent blight on their lives in relation, for example, to obtaining life or health care insurance." The advice then added that it was for individual clinicians to decide whether to follow the ethical advice.

The Advisory Committee on the Microbiological Safety of Blood and Tissue had agreed that "*in the spirit of openness*" and "*contracts with donors*" the blood services would need to consider telling, or offering to tell, the donor why their blood could not be accepted. However, discussions with such donors were to be managed on a case-by-case basis, and the appropriate health department contacted in the first instance. A protocol to deal with this was to be developed.

This Inquiry has heard evidence about Mark Buckland who was infected with vCJD in September 1997 in his early 20s as a result of receiving a blood transfusion during surgery, informed of the risk that the transfusion had transmitted vCJD in January 2004 in circumstances where this had been known since August 2000. That information should have been provided sooner.

People with a bleeding disorder were informed by their haemophilia centre in September 2004 that they were at risk of having received blood products, given an opportunity to discuss the implications and to find out if they had received an implicated batch.

By January 2005 the Health Protection Agency reported that approximately 4,000 people with bleeding disorders had been told they were at risk from vCJD. It had identified 12 other patients who by reason of their conditions and exposure to plasma products were at sufficient risk to be notified. By this time nine plasma donors who were known to have developed vCJD had been identified. Their 23 blood donations had been made into 187 batches of various plasma products.

By July 2005 it was known that three patients had developed vCJD almost certainly as a result of receiving blood transfusions. Between them, they had received the blood of 110 donors. Those donors were then traced, and advised that they should not give any further donations, nor should their tissues or organs be donated. In January 2007 a fourth case of vCJD transmission was associated with blood transfusion and reported to the press.

At this point none of the identified cases related to a person with a bleeding disorder. However, on 7 September 2009 it was confirmed that a post mortem carried out on a man with haemophilia found the vCJD prion in his spleen. He did not die of vCJD; nor was it present in the brain. However, the probability was that he had been infected and that the likeliest cause was his treatment with a plasma product. An early report of this case in *The Sunday Telegraph* on 15 February 2009 prompted an update to people with bleeding disorders that "*The information from this case does not change the public health 'at risk' status of any patients with bleeding disorders*".

By the middle of 2014, it appeared that the worst fears of a rapid rise in the number of cases of vCJD had not been realised. As of the date of this report, there have been 178 cases of vCJD in the UK and no new case of vCJD has been identified since 2016. No one now living

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in the UK has been diagnosed with vCJD. There have been five known cases where vCJD was spread through the transfusion of blood or blood products.

On the day the BSE Inquiry report was published in October 2000, the Government announced a fund to ensure improvement in the quality of care for victims of vCJD. It also announced a compensation scheme to operate through a special trust fund. This scheme was set up in April 2001 and interim payments of £25,000 were made on an ex gratia basis to families of people diagnosed with vCJD. The scheme was to be administered by an independent body, the vCJD Trust, and provide payments of up to a maximum of £55 million for the first 250 cases with a discretionary fund capped at £5 million. In addition, the Government would pay an additional £50,000 to each victim or their family, to take account of legal and other difficulties the first families had had to encounter and the additional pressures they had faced. It was chaired by a serving High Court Judge.

There are two important differences between vCJD on the one hand, and HIV and hepatitis on the other. People infected with vCJD did not have experience stigma of the nature endured by people infected with HIV in particular, but also by many with Hepatitis C; and they did not have to wait so long for substantial financial support, or a public inquiry.

Other differences highlight the inadequacies of the response to HIV infection in particular. In the case of vCJD significant, and expensive, precautionary and protective steps were taken to prevent transmission through blood and blood products.

In the face of unknown diseases which were potentially transmissible by blood the government was able in the 1990s and early 2000s to demonstrate that taking a proactive, precautionary approach could avert much disease – it will have left many people infected and affected by Hepatitis C or HIV both disappointed and angry that such an approach could not have been taken in response to earlier blood-borne infections.

Volume 6 Response of Government and Public Bodies

Volumes 3, 4 and 5 have set out to answer the questions "What happened and why?". The remaining chapters of the Report focus on the response of government and public bodies to the infection of so many people with hepatitis viruses and HIV.

6.1 The Initial Government Response 1985-1988

This chapter focuses on the first three years after the introduction of both HIV screening and the viral inactivation of blood products, at least so far as HIV was concerned. It describes how the Macfarlane Trust originated.

The Government decided against any form of "compensation" to people infected with HIV at an early stage. On 25 February 1985, Kenneth Clarke, Minister of State for Health, stated, "*There has never been a general State scheme to compensate those who suffer the unavoidable adverse effects which can unhappily arise from many medical procedures.*" The characterisation of AIDS, with high mortality and lack of treatment, as one such "*unavoidable*

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adverse effect" was ill-considered and demonstrated some lack of curiosity about what had actually happened. It set the tone for the Government's response for many years.

By 1986 the suffering of people infected with HIV through blood products was plain to see with children, parents, partners, siblings experiencing horrific physical and mental suffering, and dying, while their families desperately tried their best to care for them.

In January 1987 *The Northern Echo* began a campaign (described as "*the public cry for justice*") seeking compensation. It anticipated that a number of people were preparing to take legal claims against the Government, a health authority, or a treating doctor.

In May 1987 the Haemophilia Society's *Haemofact* publication sought to make clear its "*unanimous and strong view*" that people with haemophilia who were HIV positive deserved special financial support from the Government. Irrespective of legal responsibility, it argued that the Government had a "*clear moral duty*" to provide recompense. Meanwhile, Dr Smithies, attending the UKHCDO's AIDS Group meeting on 11 May, responded to a question about compensation by saying that there was "*no government scheme at present nor were there any plans for setting up such a scheme. Patients who felt they had a case would have to apply for compensation through the courts.*"

The House of Commons' Social Services Committee had announced an enquiry into AIDS in November 1986 and as it neared the end of that process it heard on 13 May 1987 from the Secretary of State (Norman Fowler), the Minister of State (Tony Newton) and the CMO. In relation to compensation Tony Newton suggested that it was very difficult to discern a basis to distinguish between "*medical treatment with blood products given in good faith and without negligence and medical treatment of any other kind that results in an injury or prolonged disabling condition … there has never been a general state scheme in this country to compensate those who suffer the unavoidable adverse effects which may arise from some medical procedures.*" The Committee's report, when published, noted the Government's position but suggested that "*Calls for compensation for haemophiliacs and others who have become HIV positive as a consequence of infected blood transfusions and for special life insurance arrangements for haemophiliacs deserve careful consideration.*"

At a press conference in June 1987, Tony Newton, asked why there was a refusal to provide compensation, answered that "*we see it very difficult to draw distinctions between people who experience, say, a tragic problem of this kind in this way when the treatment is on the best available knowledge and in good faith, and medical accidents that can occur in other ways.*" However he began to have doubts about the continued position against compensation in the summer of 1987.

On 7 July 1987 a submission from Dr Roger Moore referred to the Haemophilia Society's campaign, which was expected to launch in September, and advised that in anticipation of increased pressure officials were examining ways of "*compensating haemophiliacs as a special case.*"

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On 26 August Tony Newton wrote to the Secretary of State, John Moore, that it was "*quite clear that we will be under considerable parliamentary and public pressure after the recess to do something for infected haemophiliacs … It will be emotive and highly charged. I would expect it to attract considerable support on all sides of the House.*" John Moore was unconvinced, responding that he felt that the present line against compensation should be maintained.

It was against this background that in September 1987 the Haemophilia Society sought a meeting with the Secretary of State about compensation for people with haemophilia who had been infected with HIV, and launched a campaign. Pleading with the Government to stop "*prevaricating*" and to act swiftly, the Society wrote: "*The tragedy of twelve hundred people dying as a result of National Health Service treatment is a disaster in its own right. The Social and financial implications surrounding their infection and possible death place that disaster upon epic proportions. The Government is the only institution capable of minimising the distress of all those concerned.*"

At this stage John Moore remained firm in his view that there should be no compensation, writing to the Prime Minister on 24 September: "*I have looked at the case for compensation again carefully in the light of the impending campaign but have concluded that the line taken with the Social Services Committee was right. Any special arrangements for compensation could cost a minimum of £3 million and could only be funded at the expense of other priorities. Moreover, it is logistically difficult to distinguish the claim by haemophiliacs from the claim of many others damaged in the course of their medical treatment. And there is no doubt that compensating haemophiliacs would lead to pressure from many other groups for similar treatment. While all of us must have every sympathy for haemophiliacs who have been infected with the HIV virus, I do not feel it would be wise to set a general precedent by accepting that the Government should provide a special compensation scheme.*"

In October 1987, in advance of the meeting, the Haemophilia Society provided a submission to the Government. It recorded that of the 1,200 people understood to have been exposed to HIV from within the haemophilia community, to date 60 had been notified as having AIDS and 45 had died. It described the intolerable financial, social and family burden, and asked for "*immediate, positive and compassionate government action.*" And in anticipation of the meeting, *The Northern Echo* stepped up its campaign, sending a special campaigning supplement entitled *A Fight For Justice* to every MP.

At some point before the meeting with the Haemophilia Society, John Moore's stance began to shift. On or around 30 October Tony Newton sent a minute to the Prime Minister referring to John Moore's minute of 24 September, but adding that "*Whilst John and I still consider those arguments to be intellectually valid, there is a powerful practical case for recognising the particular circumstances of the infected haemophiliacs.*" Referring to the "*very strong support*" for the Society's campaign, "*particularly from our own supporters inside and outside the House*", John Moore and Tony Newton had concluded that the line which had been taken was "*unlikely to prove politically sustainable*." Their proposal was to tell the Society that the Government sympathised, was considering how best to respond, and would talk to

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them again when a decision had been reached, and to discuss the options with colleagues in advance of a further meeting with the Society with the aim "*to identify an acceptable response which runs the least risk of setting a precedent and keeps direct Government involvement to a minimum.*"

By the time of the meeting between John Moore, Tony Newton and the Society, the media pressure was intense. The meeting was on 3 November 1987. What then happened is described in the words of a civil servant, Dr Roger Moore, who was there: "*it was a very incredible meeting. I have been to thousands of meetings but that one is very clear in my mind.*" The Haemophilia Society chair and its general secretary brought with them three young men who had contracted HIV from blood products. What occurred is best described in the words of Dr Moore:

> "*what struck us, actually, was that these were people who had a right to be angry and they weren't; they were only concerned about the families that they would leave behind. And we listened and we were really moved. I mean, I don't think I've ever seen a minister weep before but John Moore – – and we were totally, totally dumbfounded, really. And, anyway, the Haemophilia Society delegation left, and we sat round and it wasn't a question of whether we do anything, it was, you know, what can we do? What actually can we do? And I've never really seen any meeting that's kind of changed direction so quickly or to such great effect as that.*"

On 4 November 1987, John Moore proposed to a Cabinet Sub-Committee that special financial assistance for people with haemophilia suffering from AIDS should be given. A lobby of MPs was due on the following day; the Haemophilia Society campaign enjoyed the backing of many Government supporters, and his memorandum said it was "*unlikely that we shall be able to sustain the present line.*" The memorandum noted that the Haemophilia Society had successfully got across their view that people with haemophilia's problems with AIDS were due to the Government's failure to ensure self-sufficiency in blood products. This was "*difficult to refute convincingly in presentational terms*." The memorandum therefore proposed that special financial help should be given to people with haemophilia and that this should take the form of a grant of up to £10 million. The memorandum was considered by the Sub-Committee on AIDS on 10 November 1987. A briefing paper advised that DHSS ministers had consistently resisted compensation; that a campaign had attracted a good deal of political and public support, such that the position was not sustainable unless concessions were made; and that "*The case for reversing the present line and singling out haemophiliacs for special compensation is essentially a political one.*" The proposed grant to the Society was "*not compensation – which could run to hundreds of thousands of pounds per person – but a gesture of limited financial assistance to meet particular needs.*" £10 million would be sufficient to provide an average payment of around £8,300 to each of those affected: "*This does not seem a great deal*".

At the conclusion of the discussion there was agreement to the announcement of a sum of £10 million to be made available for administration by the Haemophilia Society. A statement to

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the House of Commons from Tony Newton followed on 16 November 1987, which made clear that this was "*not a compensation scheme*". Following further discussions the Macfarlane Trust was set up as a body separate from the Haemophilia Society to administer the sum.

The Government plainly formed the view, at an early stage, that nothing had been done wrong, and that no financial assistance would be provided to people with bleeding disorders who had been infected with HIV. It did so without any proper investigation either into what had caused the infections or into the appalling plight of those infected. Had it done so this would have revealed systemic failures that contributed to what had occurred. Government fear of setting a precedent outweighed considerations of moral responsibility or compassion. It was largely public and political pressure which led to the change of position in November 1987.

6.2 HIV Haemophilia Litigation

During 1989, nearly 1,000 individuals in England and Wales brought claims against defendants including the Department of Health, the Welsh Office, the Licensing Authority, and the Committee on the Safety of Medicines, as well as against multiple health authorities. The fact that nearly 1,000 people with haemophilia chose the insecurities and stresses of litigation, in an effort to achieve recognition that they should not have been infected, shows the strength of their collective view and it is in itself a sad commentary on what had happened already that litigation seemed the only viable route to establish the facts. Similar claims were made, a little later, in Scotland.

This chapter looks at three principal areas concerning the litigation: the reaction of those in the Department of Health and Government to the litigation when it began, with a "line to take" being adopted that people received the best treatment in light of knowledge at the time; the process of settlement – how it began, and from whom the initiative came; and how it came about that the "waiver" was required (although not in the Scottish settlement) when the claim was not for hepatitis but for HIV infection.

The Department of Health identified some classes of documents for which they claimed public interest immunity. That issue of public interest immunity was considered by the Court of Appeal in September 1990 which observed that the Department of Health had a duty to take the immunity point. It should not therefore be criticised for doing so. However, the practical effect of the immunity point being taken was twofold: first, it prolonged the litigation, because the claim of public interest immunity had first to be evaluated by a judge, and then there was an appeal to the Court of Appeal; second, it emphasised the power imbalance between the parties in terms of knowledge. There remained some categories of documents that would not be disclosed, and those documents that were to be produced were for inspection by the judge, for him then to determine if they should be disclosed to the plaintiffs.

In June 1989 a submission was sent to the Minister of State for Health, David Mellor, on 26 June. Its focus was on immediate procedural steps; it also sought Ministers' views on the question of "*ultimate liability*". In the background information it was said: "*We believe that the government has a fair chance of successfully defending its role, given that at every*

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stage it has acted as swiftly as possible to minimise the risk of infecting haemophiliacs with AIDS in the light of the best expert opinion available at the time." Although the litigation itself raised difficult questions of law, this statement of belief contained an assertion of fact, about the speed of action.

The statement was made without any qualification, or even a suggestion that there might be another, legitimate view, and was done without investigation to check the facts. No one who saw the submission or was involved in its drafting queried the basis for the assertion.

The similar view was repeated both at this time and subsequently that patients had had the best available treatment in the light of medical knowledge at the time. Both statements make bold claims. Any such claim, as to fact, should be based upon a solid foundation of evidence. Yet those who adopted the phrase had no knowledge of any particular fact finding that had led to it. The position owed more to a sense that the Department of Health was defending the position of those who had worked in the health service and in government, and that this statement was what they would prefer to believe rather than having any clear factual basis for doing so. On the face of it, it is not only a bold but an astonishing claim that over 1,000 people had been treated with blood products and had contracted HIV as a result, and that a number of people had been given transfusions and had contracted HIV as a result, and yet that they had had the best available treatment at the time, and that government had done everything it could, as quickly as possible, to avoid what happened. It could have been so, but the idea is so counter-intuitive that asserting that it was indeed so required careful and critical examination of the available factual material.

In October 1989 a submission to ministers reviewed the position on the litigation and on the Macfarlane Trust, and in a separate part considered options for making more money available to "*the haemophiliacs*". The five options were: an out-of-court settlement; increasing the Macfarlane Trust funds; making an ex gratia payment; establishing a commission of enquiry; and publicising the Government's position, by responding to the "*allegations and misinformation contained in the Sunday Times campaign*" for example with "*a parallel history of the facts*" forming the basis of a press release.

Kenneth Clarke, Secretary of State for Health, wrote to the Prime Minister that there was no negligence on the part of the clinicians or the Government. He was against the suggested out-of-court settlement because of the liability implications for NHS treatment generally, and the "*enormous*" cost consequences. However, in light of public sympathy he secured her approval to a further allocation of £20 million as an additional payment to the Macfarlane Fund (ultimately £24 million, or £20,000 each to 1,200 people).

In June 1990 the trial judge took the unusual step of writing to the parties to set out his view that compromise was desirable because it was "*cardinally important*" that people should not die before knowing the outcome of the litigation: "*A government which takes upon itself the role of public provider of medical advice and clinical services is in a very different position to any commercial organisation. It is clearly arguable that their duty to innocent citizens who suffer injury under the aegis of such treatment has a moral dimension to it which*

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should distinguish their assessment of their position from that criteria to be adopted by other defendants of a corporate character. Government owes a duty under this to its shareholders or insurers. It should also mean that the public may be entitled to expect from government an appraisal of their position which is not confined solely to legal principles to be found in the law of negligence, or problems of proof."

He added "*I believe that the legal profession has a duty to do its best to see that the legal system does not become a scapegoat in the eyes of the public for what I fear may be perceived as the unjust and inhumane denial of any significant measure of compensation to the plaintiffs. 'The law must take its course' is not an attractive principle in the context of this case.*"

Whilst the CMO supported the judge's recommendation, senior civil servants took a different view and recommended that the route mapped out by the judge should not be followed. That too was the view of Kenneth Clarke and of the Chief Secretary to the Treasury.

On 9 November the lawyers representing the plaintiffs proposed settlement for an amount of approximately £42 million to cover all the people with haemophilia registered with the Macfarlane Trust. William Waldegrave was now Secretary of State for Health. In evidence to the Inquiry he explained that two arguments were key to winning the negotiation with the Treasury: "*The victims' lawyers have come forward with an offer that they say will be seen as fair by their clients. This will not recur, we've got to do this and do it quickly. And look at the numbers; you can afford them, we can afford them. We both knew the issues surrounding the people. This was why it had to be done now and quickly. And it was affordable.*" On 7 December he wrote to the Prime Minister (then John Major), concluding that the cost of the proposed settlement would be higher than the most favourable outcome from winning the case, but much lower than the cost of losing the case badly. John Major agreed to the proposals and announced the settlement in Parliament on 11 December 1990, indicating that the settlement still had to be formally approved by individual plaintiffs. The timing of an announcement of that settlement in principle created a pressure on plaintiffs to accept its terms, but it was not intended to be unfair to them.

The Haemophilia Society, whilst praising both William Waldegrave and John Major, expressed "*grave disappointment*" that the settlement was "*so low*". The following month David Watters wrote to William Waldegrave: "*While the vast majority of our members have indicated their intention to accept, this is being done with resignation and disquiet, recognising that there is really no option since it is financially impossible to fight on.*" It is plain too from the evidence which the Inquiry has received that many of those involved as plaintiffs in the litigation felt that they had no real choice but to accept the settlement. There was a mismatch in terms of finance, resources, and in access to knowledge between a Government and a collection of individual plaintiffs represented together as a cohort. Many of the plaintiffs were legally aided and the risk that this funding might cease if a reasonable settlement were to be refused (especially if only by a handful of plaintiffs) might well have been in the minds of some of the plaintiffs or their lawyers. Some were not entitled to legal aid and were having to make financial contributions towards the costs of the litigation. There may also have been a desperation for individuals to avoid any delay in getting further funds

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necessary to avoid the worst of their financial poverty. There is, however, little evidence that the Government intentionally used its power and position to browbeat the plaintiffs into settlement. Nor is there any evidence that the defendants used the likely short lifespan of many of the plaintiffs as a means to persuade the plaintiffs to take an otherwise inadequate settlement. The plaintiffs would nonetheless be very much aware of it. The real vice is that people were forced to litigate at all, rather than being offered – without the need for litigation – that proper compensation which they are yet to receive.

Settlement negotiations in Northern Ireland and in Scotland proceeded separately from those in England and Wales, although the expectation within the Department of Health was that settlement would be on the same basis. Those who pursued claims in Scotland should have been consulted.

Under the settlement that was negotiated regarding plaintiffs in England and Wales, anyone who wished to take advantage of the settlement sums, and anyone who had not been a plaintiff but had been infected with HIV by treatment with blood or blood products prior to 13 December 1990, would have to sign a document (a "waiver") with an undertaking not to bring proceedings. As such waivers were usual in litigation, lawyers acting for both parties would not have been surprised to see this precluding any further action arising from the same set of facts. Some form of waiver was contemplated from the time that settlement was reached in principle and was reflected in every draft.

It was only in the later drafts that the word "hepatitis" appeared. Whilst the first reference to hepatitis in this context of which there is any documentary record appears in a memo from Dr Andrzej Rejman (a senior medical officer in the Department of Health) in February 1991, the express reference to hepatitis viruses in the draft settlement terms was put forward as an amendment by the plaintiffs' lawyers in April 1991.

The evidence to this Inquiry is that many plaintiffs felt that they had no choice but to sign the waiver. The evidence also indicates that few, if any, of those infected had been told enough for them to be in a position to understand the importance of what they might be signing away – they did not know they had been infected with hepatitis. They could not exercise an informed choice whether they should sign or refuse to sign the waiver. It follows that to insist, by relying upon the waiver, that a person who had suffered hepatitis as a result of being infected (and had probably been infected before 13 December 1990) could not sue for being infected with hepatitis would be unfair. Fairness would demand that the infection and its consequences be known in broad terms if further proceedings in respect of them were to be excluded.

By contrast, following negotiation, the settlement in Scotland was made on the basis that it did not preclude any future action in respect of hepatitis. The undertakings to be given by Scottish litigants were different from those applying in England and Wales. In the latter, an undertaking not to make or continue any claim in respect of hepatitis as well as HIV was required, whereas in Scotland it was not. There is no record which clearly sets out the reasons why English and Welsh plaintiffs were excluded from making future claims in respect

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specifically of hepatitis as well as HIV. The lack of reasons reinforces the overall conclusion that its inclusion was indeed unfair, at least without a condition providing that the courts should have a discretion to permit cases to proceed where it would be unjust not to do so.

Overall, the reality is that the settlement did not – and did not purport to – compensate people for the damage which had been done to them. It did not remove the financial burden from them. It was "*a blunt instrument in the attempted righting*" of the wrong done to people through infecting them with HIV.

6.3 Macfarlane Trust

The Macfarlane Trust was set up as an autonomous body, and the trust deed finalised on 10 March 1988. The £10 million paid by the government was subject to the terms of the trust whose objects were: "*to relieve those persons suffering from haemophilia who as a result of receiving infected blood products in the United Kingdom are suffering from Acquired Immune Deficiency Syndrome or are infected with human immunodeficiency virus and who are in need of assistance or the needy spouses parents children and other dependants of such persons and the needy spouses, parents, children or other dependants of such persons who have died.*" Two features of this provision are highlighted: first, the class of beneficiaries was not restricted to those who had been directly infected – it specifically included spouses, parents and children (including the spouses, parents and children of those who had died) and even went so far as to include a class of people ("*other dependants*") who did not necessarily have any immediate familial relationship; and second, "*need*" was not defined as financial need, nor was "*assistance*" specifically limited to the provision of money.

The way the Trust was established led to five central problems:

(a) The basis for the ex gratia payments was the additional difficulties caused by HIV for people already living with haemophilia but no detailed assessment was made of the particular financial impacts, without which whether any particular sum of money was appropriate was pure guesswork, and the amount provided was always likely to fall far short of need.

(b) The Trust was set up as a charity which led to many people feeling forced to hold out a begging bowl.

(c) It was unclear what assumptions were being made about future needs and there was no assurance built into the scheme that further funds would be provided to meet future needs. This led inexorably to trustees being cautious about how much money they could allocate to grants in any particular year.

(d) The lack of funds became ever more apparent over time. In 1987 few expected many of those infected to survive for long. People's needs changed as they now faced the problems of survival, with continuing illness and treatment. Even with inspired leadership, adapting to these changed circumstances would have been a challenge.

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(e) The charity was small by comparison with many other grant-making bodies, meaning it was especially vulnerable to the absence of any staff member.

Relations with beneficiaries

After a positive start to its work, relations with beneficiaries began to deteriorate in the second decade. Susan Daniels, a caseworker, reported to trustees on a 2005 visit in Birmingham, commenting: "*I feel deeply saddened, after all my years with the Trust and the excellent work it has done in the past, that it has now come to the point when registrants inform me that 'The MFT is a major stress point in my life' and are frightened by the prospect of my visit.*" Jude Cohen, the head of support services from 2004 to 2005, was clear in her evidence that there was a "*horrible undercurrent*" of distrust in both directions. Many beneficiaries felt misinformed by, and fearful of, the then chief executive, Martin Harvey; some trustees distrusted the beneficiaries. There is no material to show that the Macfarlane Trust actively addressed these reports of a growing loss of confidence.

In February 2005 a report by Kingston Smith (chartered accountants) identified that consultation with beneficiaries in respect of changes in funding was necessary; and that the Trust's application forms and literature "*should be clear and user friendly and should include … what the trust will and will not support*" and include "*any upper or lower limits on grant size*".

Katie Rendle (a Macfarlane trustee) carried out a survey of communications between the Trust and beneficiaries, reporting to the Board in January 2013. Overall, around two thirds of beneficiaries reported that they did not receive enough information about grants, causing confusion, frustration and delay. One of the strongest themes was that there appeared to be a practice of withholding information from beneficiaries. More than half of those who responded complained that they did not understand and had not been consulted about the way in which the Trust distributed its funds.

No substantive action was taken in response to these reviews.

What upset many – indeed, it seems, most – beneficiaries was the lack of anything more than the rudimentary information they were being given. They knew they could apply for a grant, but did not have clarity about how to do it, what it could be for, how much would be allowed, when they should apply, how long it would take, and what criteria would be applied in determining it. This was then coupled for those who did apply with a process which was time-taking and bureaucratic, required (usually) more than one quote, had to have support in most cases from their treating clinician, might involve giving details of income and expenditure (despite the fact that many of the details had already been provided), might involve being visited at home or photographs being taken of the quality of their environment in order to show it was sufficiently poor, and required it to be shown that other sources of support and funding were not available. Both the lack of information from the Trust and the characteristics of the process described above were unfair to, and caused unnecessary

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distress and anxiety to, applicants; this was obviously not the right way to treat people who had already been profoundly harmed by the state.

Insecurity of funding and failure sufficiently to meet need

Some 18 months after operating under the Trust deed, it was becoming clear to the trustees that the expenditure was exceeding the income received from investments. Trustees raised the question of future funding from the Department of Health. The response fell short of a commitment to make further payments, and did not say how much might be provided. This left the Trust with uncertainty as to the appropriate level at which it should disburse its capital, and concerned to keep a reserve if it could to meet the considerable financial uncertainties of the future.

This pattern was repeated over the following years. It remains unclear why the Department of Health was reluctant to be open and transparent with the Macfarlane Trust from the outset as to their specific intentions to top up the Trust on a periodic basis. It may have been because ultimately spending decisions depended on the Treasury, which had to balance a range of commitments. If, however, its reticence was intended to discourage the Macfarlane Trust from being too generous in its disbursements of the funds then it was effective. By March 1993, assets had dropped to just over £4 million and in that year there had been a decrease by 3.6% from the previous year on the sums paid out to beneficiaries.

The Inquiry heard evidence from Peter Stevens that during this period, the Macfarlane Trust was underfunded. Charles Lister gave evidence that during his tenure the Department of Health always found the money that the Macfarlane Trust asked for, and sometimes even a little more. However, this may reflect the fact that the Trust was very careful about what it asked for from the Department of Health in terms of funding, not wanting to appear "*greedy*". The Trust only asked for what they thought they would receive.

Peter Stevens requested a top-up payment of £4 million for 2001-02 from the Government to meet needs which had been identified in a strategic review of 1999 which revealed that poverty and despair about money were common; that many were bogged down by debt; that few had any leeway to meet unexpected bills. The review recommended that the Trust should approach the Department of Health to secure an assurance of continued funding, and that this should be at a level sufficient to meet registrants' needs. However, Peter Stevens told the Inquiry that this suggestion was "*kicked into the long grass*" by the Department of Health. Despite an apparent acceptance of the case being put forward by the Trust for increased funding the Department commissioned a further review of the Trust.

The financial history of the first 14 years of operation of the Macfarlane Trust is one of a fear, on the part of the Trust, that funds might in future prove inadequate to meet the very real needs with which they had to deal day by day. General reassurances were given that money might be found if really necessary, but no particular level of income was assured on a continuing basis. Nor had sums been given annually. Funding was ad hoc. This was not a satisfactory way of funding any organisation. The impact of these funding uncertainties

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before 2003 caused problems for the trustees of the Macfarlane Trust in that it affected their ability to respond to requests made to the Trust and hampered any proper long term planning as to how to best meet the needs of beneficiaries.

A bid for the Trust's funding was included by Charles Lister within the bids for the Spending Review (covering the 2003-2005 period). As a result of this, the Trust was allocated a budget for three years within the Spending Review, with the first payment of £3 million being paid in May 2003). Thus it was not until 14 years into its existence that the Macfarlane Trust had some level of financial security from the Department of Health. Nonetheless, the needs of the beneficiaries were still far from satisfied by these sums.

In 2003 there was a further review – "the Long-Term Review" conducted by Hilary Barnard. This was seen as a means to establish new priorities for the Trust and to look at different ways to use limited funds: its commissioning reflected that the trustees wanted to establish "*a firm basis on which the Department* [of Health] *would be unable to resist* [their] *pleas for more money.*" This long-term review was entitled *A Full Life – Not Just Existence*. It concluded that: "*The Trust is not and should not be solely a grant giving Trust but has equal and integral roles in providing non financial help to the registrants, infected intimates, widows and dependents* [sic]" and that it should aim "*to support lives, not just existence.*" It said: "*It is rare that the Trust has much to do with parents these days but some remain as significant carers who the Trust should keep close contact with. Longer term survival of sick registrants carries with it far greater demands and impact on the lives of their supporters … Addressing the needs of widows and dependents* [sic] *is a significant and extended claim on the resources of the Trust and its funder, the Government.*"

Although the report had suggested approaching the Government in the immediate future, this did not happen. The reason it was not pursued straight away was because the focus of Peter Stevens' work, and that of Martin Harvey, had now (August 2003) shifted to setting up the Skipton Fund. The delayed business case was eventually put to the Government in late November 2005. Peter Stevens commented that the Trust had started out with £10 million and had been expected to last five to seven years. It was "*topped up, topped up, topped up, at some stage you actually had to say no, we started in the wrong place, we've got to start again at a much higher level.*" He asked for an increase in funding to £7 million per year, supported by the business case. The business case did not reach the relevant junior minister's office until the middle of June 2006. By the time the information came to her, she was told that nothing more than £400,000 was available, and was advised that blood policy colleagues did not consider any increase in overall funding was justified. It is unclear how officials could have come to this view after reading the business case, supported as it was by the Barnard review. On 28 July Caroline Flint wrote to Peter Stevens with the decision to increase funding by £400,000.

By September 2007 there was something of an impasse between the Trust and the Department of Health regarding funding. The Trust, now under the chairmanship of Christopher FitzGerald, met the Department of Health on 4 September 2007. The minutes record that the board of trustees "*are unable to satisfactorily fulfil their objectives set out*

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in the Trust Deed to 'relieve the need of its beneficiaries' and the Department are not in a position to increase the annual level of funding it grants to the Trust". The incoming Minister of State, Dawn Primarolo, was informed in a letter from Christopher FitzGerald that the trustees considered the level of funding to be inadequate and he gave evidence to that effect at the Archer Inquiry. He added: "*I would simply wish to reiterate that it is simply unacceptable on any basis, whether you call it moral, legal or whatever – – it is simply unacceptable that the funding the consequences of the greatest catastrophe in the history of the NHS should be constrained by the current financial difficulties or incompetencies in the NHS.*" Christopher FitzGerald wrote to the Government to complain that unless more money were given the Trust could not meet its objectives adequately and said the same to officials, though the Archer Inquiry was his main hope. He did eventually achieve an assurance in 2008 that there would be annual funding indefinitely. This allowed for a gradual reduction in the amount of the reserves since (given that assurance) they no longer had to be maintained as insurance against the uncertainty of funding in the future. Further, following the report of the Archer Inquiry the Government announced that in future there would be annual payments of £12,800 to each infected individual "*thus eliminating the need for them to make repeated detailed applications*" and, in effect, doubling their current average annual payments (these payments were made through a limited company called MFET Ltd, so that they were not dependent upon an assessment in each case of the precise charitable needs the payment was to meet). It also agreed to increase the funding to Macfarlane Trust for dependants, whose applications for funding would continue to be dealt with by the trustees on a case by case basis.

In 2012 the Trust came under repeated pressure to meet some of its expenses from its reserves. The Department of Health asked that a business case be submitted to support its funding request. It asked that the case should detail why the reserve had not been used for charitable purposes and what had changed to merit its distribution now. It asked specifically for an analysis of the data that had been obtained from a survey the Macfarlane Trust had commissioned, including an anonymised assessment of each beneficiary's current ability to pay for items, for a statement as to the standard of charitable need the Trust intended to apply to applications for grants from reserves, and to be told how the Trust planned to assess need. Although Roger Evans accepted this was none of the Department of Health's business – which it was not: they were plainly over-reaching themselves – he did not say so to the Department of Health in writing. Nor did he say that he was unwilling to provide information on the three points just mentioned. He told the Inquiry he had nonetheless made these points orally – it was not his "*style to put immoderate words into a letter and email.*" The leadership of the Macfarlane Trust was less independent of its paymaster, and less observant of its obligation to serve the interests of its beneficiaries, than it should have been: and it suggests that there was in consequence a lack of vigour in pursuing better funding. There is also disturbing evidence of serious tensions between board members which went well beyond those normally to be expected in healthy debate, and were sometimes expressed in unnecessarily personal terms.

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The extent to which those reserves were exhausted began to affect, even more, the Trust's ability to meet the needs of its beneficiaries. By November 2014 the annual shortfall experienced by the Trust between the Department of Health's allocation and their grant giving programme was £800,000. In a letter from Roger Evans to the Department of Health, the Trust made the point that its "*inability to meet this need remains as a result of continued underfunding.*" By October 2015 the Trust's position had become serious. It was made clear to the Department of Health in a meeting that, leaving £750,000 in reserve in accordance with reserves policy, there was only enough money to supplement the annual allocation for disbursements until March 2017. However, by the end of 2016 it was plain that the writing was on the wall for the Trust. It would continue to operate for a while during the financial year 2017/2018, and for that period the Department of Health intended to provide quarterly allocations. However, it was made clear to the Trust that during that period it would be expected to use up much of its reserve.

Decisions on allocation of funds

Throughout there was a lack of openness and transparency. This was despite a number of "wake-up calls", and despite the fact that each witness who had been involved in running the Trust who was asked in evidence about the criteria and processes accepted that they needed to be open, transparent, and fair. The absence of sufficient information for beneficiaries stemmed from a misplaced distrust of them by the trustees. This distrust led to policies which demanded that need be established in some detail, and that two or three quotations were to be obtained. For ease of administration, office staff were permitted to authorise grant applications in accordance with broad "office guidelines". However, these guidelines were not published to the beneficiaries. Peter Stevens said that no guidelines were published because "*they became shopping lists*". His view was also that if a guideline had provided, say, for the purchase of a mattress up to a particular maximum sum, there would instantly be a lot of requests for that sort of mattress, costing that sort of money. Regular payments ("Regpay") required the completion of a census form setting out, in broad terms, household income, and single grants required other sources of potential funding to have been exhausted; three quotes to have been obtained; sometimes the submission of details of household income and expenditure; and usually the support of a medical practitioner (normally the applicant's haemophilia clinician). With requirements of this nature, it is not difficult to understand why applying to the Trust for support was not only seen as bureaucratic but also as demeaning, intrusive, demotivating and embittering. By 2009 the National Support Services Committee ("NSSC") had adopted "*exceptional circumstances*" as the principal criterion for assessing grant applications, but there was no definition of this test until mid 2012 and even then it lacked precision. The NSSC having become quite bureaucratic in its approach, it was replaced by a Grants Committee but it took over 16 months for the Trust to introduce new guidelines for grants.

One of the issues which epitomises the way in which difficulties for beneficiaries were made worse than they needed to have been, with distressing consequences, was the issue of assistance with conception: the failure of the Trust, over a number of years, to adopt a

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clear, humane and compassionate approach to funding applications for assistance with conception is detailed in this chapter.

Perceptions of uncaring attitude

The lack of openness and transparency was accentuated by the poor quality of personal relations. There were mechanisms for engagement such as a consultative panel and the Partnership Group but this ultimately fell into disuse.

Peter Stevens referred to the Partnership Group as a "*lot of moaners*", and did not object to phrases such as "*the great unwashed*" being used to describe beneficiaries. He forwarded a courteous email from Haydn Lewis to his colleague Martin Harvey describing Haydn Lewis as "*thick*" and coming up with "*such meddlesome suggestions*". He agreed in evidence this was totally inappropriate, and indeed at the time went to Cardiff to meet with Haydn and his brother to apologise for his use of language.

In March 2006, a letter to Clair Walton from Peter Stevens led to a formal complaint and ultimately an apology from the subsequent chair, Christopher Fitzgerald. Incidents such as these became known and created a perception, especially among beneficiaries involved in support or campaign groups, that trustees did not respect them as individuals. The processes required to apply for funds were seen, with justification, as indicating a failure to recognise the ill-health of beneficiaries, and the manifestation of a callous indifference towards them.

A dispute between the Haemophilia Society and the Trust soured their relations and further reinforced the negative views many beneficiaries had of the Trust. Following the All-Party Parliamentary Group ("APPG") report on the Trusts and Schemes Liz Carroll, CEO of the Society, wrote on 10 February 2015 to the Minister to respond to this publication, suggesting that Jan Barlow and Roger Evans "*expressed the opinion that the Department of Health should wait before responding to Penrose so more people will have died and they will have less to pay out.*" This incident has assumed a significance beyond that deserved, and was a sorry episode. It caused further upset and irritation to many beneficiaries, seeming to justify their suspicion that neither Roger Evans nor Jan Barlow had their interests at heart. There was no evidence that Roger Evans expressed any such opinion; whilst Liz Carroll's evidence to the Inquiry was that Jan Barlow did, it remains uncertain whether or not the words were spoken as reported, though the likeliest scenario is that what happened owed much to the way in which the protagonists thought of each other at the time and that Liz Carroll may have heard what she expected to hear rather than what was actually being said. Liz Carroll did not act professionally by not calling out what was said at the time, if it was as she a little while later recalled hearing it; and by including the allegation that she heard it in a widely copied letter to the Minister without first telling Jan Barlow and Roger Evans. In other hands the matter would have been resolved differently.

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Closure of the Trust

Once it was decided that the Alliance House Organisations would be replaced by four separate schemes, one for each of the four nations, the Macfarlane Trust had to decide how to dispose of any remaining assets. At a meeting in July 2017, the Board decided to distribute the reserves through a targeted, time-limited grants programme but by November 2018, there were still substantial reserves. At its meeting in November 2018, the trustees decided to remove the restriction on the Honeycombe Memorial Fund (support to widows and bereaved partners without children) and add it to the unrestricted reserves, and to transfer the remaining funds and assets to the Terrence Higgins Trust. Beneficiaries were not consulted about this transfer. There was ample time to do this and beneficiaries would have had the chance to raise the concerns which have subsequently been expressed. The consequence for many has been a perpetuated sense of grievance.

In conclusion, the worst aspect of the approach of the Macfarlane Trust is the impact on a group of people who deserved to be supported properly and were not. People whose hardship was supposed to be alleviated by the payment scheme instead had that exacerbated: they felt kicked, and kicked again, when they were already down. They were repeatedly rebuffed in their attempts to argue that they deserved more and better from authority. The Government's response to serious failures of regulation, administration and treatment on its part, by setting up this Trust – operated in the way it was – added further layers of psychological, economic, and social damage to an already devastating infection with its resulting poor health, stigma and isolation.

As a summary of the chapter's findings:

- The Trust should not have been set up as it was: as a charity, redolent of the begging bowl; without any assessment of actual financial needs; with no guarantees of, or plan for future funding, leading to insecurities about funding; with inadequate resources, both of money and of staffing; and too small to function as well as it might.
- The Trust should not have been run as it was:
  - The Trust felt itself subordinate to the Government when it should not have been, and as a result did not campaign when campaigning might have been productive.
  - A climate of anxiety, fear and distrust was created, recognised by at least some chief executives and chairs, and left unaddressed.
  - The decision to have "office guidelines" which were not to be published to beneficiaries was simply wrong.
  - A consequence was unfairness, added distress and anxiety.
  - Decisions were delayed, though needs were urgent.
  - The way in which the Trust dealt with some applications made in respect of needs is epitomised by its handling up to 2005 of the issue of assistance for those of

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its beneficiaries who sought to have a baby as safely as was possible. The Trust could and should have dealt with this issue better: promptly, decisively, keeping in mind the human suffering at its heart.

- The Trust was found weak in monitoring and evaluation, without which it would be unable to answer whether it was helping those in greatest need, yet appears to have done nothing to rectify this;
- The application process for grants was time-taking and bureaucratic; had to have support in most cases from the treating clinician; might involve giving details of household income and expenditure (despite the fact that many of the details had already been provided); might involve being visited at home or photographs being taken of the quality of the home in order to show it was sufficiently poor; required it to be shown that other sources of support and funding were not available;
- the Trust started to require applicants for grants to show "exceptional circumstances" without applicants having any clear idea of what they could be, and how they were defined;
- the criteria and process for appealing the refusal of a grant were unclear and poorly understood; it may not even have been recognised by an applicant that there was that possibility;
- the Trust did not sufficiently ensure any effective way in which the views of beneficiaries could be fed back to trustees.
- the leadership of the Trust between 2012 and 2016 lacked the vigour it should have had in pursuing better funding, and was less observant of its duty to serve the interests of its beneficiaries;
- beneficiaries were treated by some trustees, and by Martin Harvey as CEO, in an apparently uncaring, dismissive, disparaging and disdainful manner;
- Peter Stevens spoke (with Martin Harvey) and wrote internally in unacceptable and disdainful terms about some beneficiaries;
- Roger Evans when chair recognised that aspects of the system were "*humiliating and intrusive*", causing unhappiness amongst beneficiaries, and "*the whole thing was not the right way to go about it*": allowing that to be the case was wrong, but what was worse was that when it was realised that this was the case little or nothing was done to rectify it;
- when a survey of beneficiaries was reported to the trustees in 2013, identifying sources of dissatisfaction, Jan Barlow was asked to take steps to action its recommendations but did not;
- the Trust received a report from the APPG in 2015 identifying failings and did little or nothing in response;

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- relations between the trustees became very difficult such that the Board did not function as it should have done: this was largely the fault of Roger Evans;
- when the Trust was superseded by the England Infected Blood Support Scheme, Welsh Infected Blood Support Scheme, Scotland Infected Blood Support Scheme and Northern Ireland Infected Blood Payment Scheme, the process of disbursing its reserves (including the Honeycombe monies) should have been determined in consultation with the beneficiaries, in a way which best ensured the funds were distributed fairly and contemporaneously amongst beneficiaries.

6.4 Government Response to HIV Infections through Blood or Tissue Transfer

This chapter considers the Government's response to the question whether to make payments to individuals infected with HIV by blood transfusion or tissue transfer. Such individuals were deliberately not included in the November 1987 announcement of the £10 million ex gratia payment to provide financial help to people with haemophilia infected with HIV and their families.

In February 1988 it was noted that a number of MPs had written seeking special financial payments for those infected with HIV by blood transfusions in line with the ex gratia payments for people with haemophilia. The suggested line to take was that "*After careful consideration*" the DHSS concluded that the combination of circumstances applicable to those with haemophilia "*does not apply to those who unfortunately have become infected with HIV through blood transfusion.*" In July 1988 officials advised against introducing a scheme of payment, "*although that may seem a harsh view to take*", for three main reasons: it could not be ring-fenced as the haemophilia scheme had been; reaching fair decisions would be "*extremely difficult*" (especially if extended to those who may have been infected overseas); and "*the wider we extend help for those with HIV infection, the more we raise the general issue of compensation for NHS linked infection.*"

On 25 July 1988, John Moore was succeeded as Secretary of State for Health by Kenneth Clarke, and by 28 July 1988 the decision had been taken not to make any ex gratia payments to transfusion recipients infected with HIV.

The focus within Government then shifted to the HIV haemophilia litigation and any active consideration of financial support for transfusion patients infected with HIV appears to have receded for the next 18 months or so.

MPs pressed for support to be provided: John Marshall MP said that "*To argue that we are compensating haemophiliacs because their illness is hereditary but will not compensate others is bad morality, poor logic and bad politics.*" Robin Cook MP, writing to the Secretary of State on 31 January 1991, expressed the view that the purported distinction was "*wholly untenable*".

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As the negotiations in the HIV Haemophilia litigation neared conclusion, a submission in April 1991 argued strongly against expanding financial support to transfusion recipients.

In May 1991, a campaign was launched by *The Observer* to "*win compensation for the forgotten NHS victims of AIDS*". The issue was taken up in Parliament by MPs "*across the political spectrum. Nearly 100 have now signed an Early Day Motion calling on Health Secretary William Waldegrave to reverse his department's 'callous and illogical' refusal to compensate the non-haemophiliac NHS victims.*" *The Observer* commented that the delay in agreeing to provide payments to people with haemophilia had meant that many had died before they or their families could receive anything.

The Government's position remained that no payments should be made but by November 1991 the Secretary of State's (William Waldegrave) view had changed. In December 1991, he wrote to the Chief Secretary to the Treasury that, if the Government continued "*to refuse any help there is a real prospect that the campaign will gather pace and become a damaging and running sore over the next few months.*" He proposed that the Government should move to resolve the matter by "*recognising the needs of these people and their families in the same way as we have recognised those of haemophiliacs.*" The Chief Secretary disagreed and commented that, by "*compensating those acquiring HIV from blood transfusion, we will be taking a further long stride towards no-fault compensation in general.*"

In early February 1992, the Prime Minister was provided with a Department of Health briefing which maintained its support for the existing ring-fence around people with haemophilia. However, the cover note from William Chapman, the PM's Private Secretary, commented that the Government would have to give way and better to do that sooner. He questioned the logic of a ring-fence for people with haemophilia, and said that the "*Government's position seems increasingly untenable.*" After further discussion it was announced on 17 February 1992 that financial support would be extended to people infected with HIV as a result of blood transfusion or tissue transfer and that the scheme would include spouses, partners and children who had also been infected.

Two features of this decision-making process stand out. First, the decision-making process took too long. Second, despite some politicians being responsive to the claims for financial support, civil servants remained determined in their opposition to this. In oral evidence, Sir John Major described the government as being "*sometimes like a great tanker*" which "*takes time to turn around*". He explained that he would not "*argue with the argument that it could have been done sooner. I can only say in retrospect you could often see things a little more clearly than you can when you have a dozen other things in front of you at the same time and perhaps that was true of everyone involved.*"

I accept that policies which require significant expenditure may need to be developed incrementally. There is also little doubt that fears about a precedent being set were real, though once a decision had been taken to establish the Macfarlane Trust the obvious ring-fence was around the nature of the disease transmitted by NHS treatment rather than the condition which caused people to seek treatment in the first place. However this does not

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justify the lengthy period it took the government to change its position. The context was crucial: patients had been infected several years earlier with a life-altering – and possibly fatal – virus. Patients and their families did not have time on their side. The Government should have recognised that its position was logically unsustainable and have changed course significantly earlier than it did. If any group was to be kept waiting, it should not have been this one.

There is, further, a strong sense that departmental officials were keen throughout to advise their ministers of the risks, rather than the justice, of what ministers had asked them to explore.

6.5 Eileen Trust

The Eileen Trust was established in April 1992, with initial capital funding of £500,000, to make payments for people infected with HIV through NHS blood or tissue transfer. It began work at the end of March 1993 and paid fixed sums to people directly and indirectly infected in different categories, depending on whether they were adult, were married, and had dependent children.

The staff were shared with the Macfarlane Trust for ease of administration. The total number of beneficiaries remained in the region of 20 to 30 at any one time, though it varied from year to year. The number was rather lower than government had anticipated. The Eileen Trust made regular payments from August 1993, with increases in January 1994 and a health-related supplement from March 1994. Widows and widowers with children received regular payments from 1998. The Trust preferred beneficiaries to have regular income to give them greater personal autonomy. Single grants were also available on a case-by-case basis, on the basis of either financial or health need. People knew what they could apply for thanks to regular contact with staff and a newsletter.

The Eileen Trust did not suffer to the same extent from the difficulties which beset registrants of the Macfarlane Trust. There was a similar lack of written information given to beneficiaries and a similar degree of subjectivity in the assessment of individual grant applications, but the relations between the trustees and the beneficiaries did not give rise to similar problems.

A principal problem was identifying those who might benefit, although the number of beneficiaries of the Eileen Trust increased as more people became aware of its existence. The increases were small in comparative terms, but they were significant for a small organisation and the Trust's expenditure increased. However as Peter Stevens stated in his evidence to the Archer Inquiry "*the DoH have shown no understanding of, or willingness to increase ET's funding for, increases in the number of ET registrants.*"

The approach taken by successive governments to funding the Eileen Trust was of the same kind taken when first funding the Macfarlane Trust: it did not reflect in any meaningful way the individual needs of the beneficiaries but was rather an arbitrary sum.

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6.6 Government Response to Hepatitis C Infections

When, in 1992, the Government (with some reluctance) agreed to make ex gratia payments to transfusion and tissue recipients infected with HIV, it did so on the basis that the line would be drawn at this group and that further groups would not receive similar treatment. For over a decade it maintained that line, refusing to provide any form of financial assistance or ex gratia payment to those infected with Hepatitis C through blood or blood products. This chapter examines the maintenance of this position and the circumstances which led, finally, to a change of position.

During 1994 the Government's position was that there were "*no plans to extend the settlement scheme for haemophilia patients with HIV to those who may have been infected with hepatitis.*" It was noted in December 1994 by Roger Scofield (the head of the Department of Health's Corporate Affairs Operational Unit) that there had been "*increased interest*" in Hepatitis C and that "*we can expect the campaign for compensation for those infected through NHS treatment to be stepped up over the next few months.*" Hepatitis C had, he said, moved from being "*a problem on the horizon to a highly political and volatile policy issue*". The pressure was "*building up.*"

In March 1995 the Haemophilia Society launched its campaign for financial help for people with haemophilia infected with Hepatitis C. A statement from the Reverend Tanner explained that

> "*People with haemophilia were infected with the hepatitis C virus through contaminated blood products … Many were not told that there was a risk of hepatitis when they were given the treatment. They were infected in exactly the same way as over 1,200 people with haemophilia contracted the HIV virus – through treatment with contaminated blood products. Yet while those infected with HIV receive financial help from the government those with HCV receive nothing … The government have said that they do not intend to provide financial help for people infected with hepatitis C. I would ask the government how many more should die before they decide that HCV is an immediate threat to people with haemophilia … parliamentarians are taking the subject seriously. I would like the government to take it seriously as well and would make the plea for them to accept their moral responsibility and act swiftly and decisively to provide help for people with haemophilia infected with this dreadful disease.*"

That same month John Marshall MP, who had been instrumental in the efforts to obtain assistance for transfusion recipients infected with HIV, met the Minister of State for Health, Gerald Malone, to discuss this question. This intervention plainly had some impact upon the Minister, because he agreed that the Department of Health should give very careful consideration to whether those suffering from the worst complications of Hepatitis C might be granted ex gratia payments. This willingness on the part of the Minister of State simply to consider John Marshall's proposal gave rise to consternation in the Department. Officials, other ministers and the Permanent Secretary discouraged it. Whether as a result of the firm advice from the Permanent Secretary, or the opposition of ministerial colleagues, or

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otherwise, by May 1995 Gerald Malone changed his mind, and at a meeting in June 1995 it was "*agreed that it would be desirable to maintain the status quo and not extend the principle of no-fault compensation either to those infected with Hepatitis C or CJD. The precedent of payments to those infected with HIV/AIDS through blood and blood products was not helpful in this context but it was agreed that a justifiable distinction could be drawn between HIV/AIDS and other viruses.*"

In December 1995 the Haemophilia Society had published a report which it had commissioned to examine the needs of people with haemophilia and Hepatitis C. John Horam, the new Parliamentary Under Secretary of State, indicated that he would like to read the Haemophilia Society's report thoroughly and that he would be interested to hear details of the "*relatively modest and restricted proposal*" made by John Marshall MP during a parliamentary debate on the issue. Just as his predecessor Gerald Malone's willingness to consider the possibility of a shift in policy had caused consternation within government, so too did John Horam's. Concern was expressed by the Treasury and by civil servants within the Department of Health. One official wrote to the Permanent Secretary as follows:

> "*The Permanent Secretary may wish to be aware of the attached minute. I mentioned to him the other day that PS (H)* [Parliamentary Under-Secretary of State for Health] *was clearly not happy with the firm line Ministers have taken up to now on compensation for haemophiliacs infected with hepatitis C. It is quite clear that he is trying to change the line, little by little. He has had plenty of briefing (written and oral) on the subject, but his sympathy for those concerned is clearly uppermost in his mind. Cost comes second – hence his readiness to consider proposals for a scheme limited to those who have actually developed chronic illness, rather than extending to all who have been infected.*"

The decision, however, was not to make any form of payments for those infected with Hepatitis C and this was communicated to the Haemophilia Society in October 1996.

Alf Morris MP and John Marshall MP continued to press for a change of position. In a powerful speech in Parliament on 11 December 1996 John Marshall emphasised that many would die from Hepatitis C, and that for many others "*the quality of life will deteriorate dramatically, and they will suffer severe physical and economic hardship*". He was indeed right, as the evidence which this Inquiry has heard attests. John Horam, in response, maintained the government line.

On 1 May 1997 a general election was held. A new government, under Tony Blair, came in. A new Secretary of State for Health, Frank Dobson, was appointed. The Haemophilia Society renewed its efforts to persuade the Government to establish a financial assistance scheme for those infected with Hepatitis C. Frank Dobson was sympathetic and in March 1998 decided to write to the Prime Minister on the question. This alarmed officials. With echoes of the departmental response to former ministers Gerald Malone and John Horam, they sent a minute the next day to Dr Graham Winyard, the Deputy CMO, "*expressing concern that while SoS accepts that the Government could not afford a large compensation*

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package, he feels that a small hardship fund like the MacFarlane Trust would be possible. Officials are concerned that significant funds would need to be diverted from patient care to fund it and that Treasury remain fundamentally opposed." A meeting to discuss the issue subsequently took place between Frank Dobson and Baroness Jay on 13 July 1998 and it appears to be at this meeting that Frank Dobson agreed to maintain the existing policy. That decision was communicated to the Haemophilia Society on 28 July 1998. The Secretary of State explained that the Government had decided not to set up any form of payment scheme for the "*inadvertent harm*" of people with haemophilia infected with Hepatitis C. Thus Frank Dobson joined the small group of ministers (Gerald Malone, John Horam) who had seemingly wanted to make some provision for some Hepatitis C sufferers at least but who encountered resistance within the Department and ultimately continued the existing departmental line.

The Haemophilia Society did not let matters rest there and continued to press its campaign. There was no change of policy on the part of the Government, however, and the line was maintained in Parliament and in correspondence. It is clear from the evidence considered by the Inquiry that the Government was finding it increasingly difficult to justify the distinction between HIV and Hepatitis C.

In March 2000 Lord Hunt asked about the scope for doing more for people with haemophilia infected with Hepatitis C and requested an outline costing of a hardship fund. This advice was provided on 27 March and said that such a fund would be unlikely to be acceptable and that there would be a continuing demand for parity with the HIV scheme. In October 2000 Lord Hunt sought advice on what could be offered in terms of a package of care for those who had contracted Hepatitis C from blood products – with it being suggested that he was hoping to seek the permission of the Secretary of State "*to work up something more for HCV.*"

In 2001 there was a further intensification of the campaign for financial assistance, with requests from Lord Morris and Edward O'Hara MP to meet the Prime Minister, campaigners from the Manor House Group and Haemophilia Action UK staging a protest march demanding compensation; an adjournment debate in the House of Lords; repeated parliamentary questions from Lord Morris; an Early Day Motion from Dr Brian Iddon MP; and the Haemophilia Society commencing a "Carpet of Lilies" campaign in May. Moreover on 26 March 2001 the judgment of Mr Justice Burton in *A and Others v National Blood Authority* was handed down, which set out the High Court's judgment that, on the facts, surrogate screening for HCV should have been introduced, and direct screening should have begun no later than May 1990.

In July 2001 the Parliamentary Under-Secretary of State for Public Health, Yvette Cooper, requested a position paper in light of the High Court judgment, setting out options. The range of options identified included lump sum payments and/or a hardship fund for all or some people with haemophilia infected with Hepatitis C. The advice from officials was that if ministers wished to consider payments, the recommended option was a hardship fund solely for people with haemophilia whose Hepatitis C had caused severe liver disease.

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At the beginning of October 2001, the Scottish Parliament's Health Community Care Committee published a report calling on the Scottish Executive to provide financial support to all who were infected with Hepatitis C as a result of blood transfusion or blood products in Scotland. The report further recommended that the level of financial assistance awarded should be determined on the basis of need. A briefing prepared for the meeting of the Joint Ministerial Committee on Health (involving ministers from across the UK) on 22 October 2001 recognised that the existing line would be difficult to sustain in the rest of the UK if the Scottish Executive "*commits to the Scottish Parliament report.*"

On 13 November the Minister of State for Health John Hutton agreed to hold the policy line that no payments would be made in respect of Hepatitis C infection through blood and blood products except where awarded by the courts. The next day, responding to an adjournment debate, and whilst acknowledging that the issue of compensation was "*the most difficult decision of all,*" he reiterated the policy of successive governments ("*that compensation, or other financial help to patients, is paid only when the NHS or individuals working in it are at fault*") and his belief that the NHS had not been at fault. The same day he spoke to Susan Deacon MSP, explaining that he was "*holding the line on compensation.*" He told her that there was "*anxiety*" that a new administration in Scotland might opt for a "*different and conscious change of position*", which would "*create significant difficulties for us if people in Scotland can be compensated but those in England cannot.*" Susan Deacon indicated that she was not planning to do so (although she recognised that she could not predict the position "*further down track*") and that the Scottish Executive wanted to look at the issue from a UK perspective ("*this is an issue which shouldn't have a different approach north and south of the border.*")

By February 2002 the decision had been taken in Scotland to establish an expert committee under the chairmanship of Lord Donald Ross to report on the question of compensation. In May 2002 Charles Lister advised Yvette Cooper that "*Until late last year, Scottish Ministers were taking the same line as us on the hepatitis C compensation issue. Under pressure from the Scottish Parliament, this can no longer be guaranteed.*" It was also noted that Michael Connarty MP had made a request for papers relating to Frank Dobson's consideration of the compensation issue, which had been made "*under the assumption that a detailed analysis would have been undertaken by the Department.*" Charles Lister advised that the papers showed this not to have been the case, and that the debate had been focused around concerns that such a scheme would open the floodgates to further claims. Further, if the papers were released, "*they will show that Frank Dobson was minded to support a scheme limited to haemophiliacs with hepatitis C but was persuaded from this by officials and Margaret Jay.*"

On 4 November 2002 Malcolm Chisholm, the Minister for Health and Community Care in the Scottish Government, called Alan Milburn to inform him that the expert group under Lord Ross was about to publish a preliminary report calling for financial and other practical support for all people infected with Hepatitis C through blood, blood products and tissues, and that Scottish ministers felt that they "*had to offer something*". It was intended that an

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announcement would be made on 6 November. The Secretary of State suggested that this would be a "*grave mistake*", "*a slippery slope to payments running into millions across the UK*" and that Malcolm Chisholm should "*tough it out.*" On 29 January 2003 the Scottish Executive Cabinet agreed that £25,000 be paid to those currently alive with Hepatitis C and a further £25,000 to those who developed cirrhosis. A review of costings by Scottish officials led to a decision that the figures would be £20,000 and £25,000 and this was reported to the Health and Community Care Committee in a statement from Malcolm Chisholm. It was subject to resolution of the issue regarding devolved powers, in relation to which the advice of Law Officers was sought.

Handover notes prepared in May 2003 by Charles Lister for his successor recorded the current position that: "*Ministers here are sticking strongly to the no compensation line but Scottish Ministers have weakened … SofS asked us to see if a way could be found to stop this. The result was a legal challenge saying that any payment scheme to haemophiliacs would be a social security scheme and therefore outside Scotland's devolved powers. This issue is currently with the law officers for a determination and we are expecting them to give a view very soon.*"

On 13 June 2003 John Reid replaced Alan Milburn as Secretary of State for Health and on 17 June 2003 Richard Gutowski, who had taken over from Charles Lister, provided a background note and a line to take for the Secretary of State which described some recipients of blood products having been "*inadvertently infected*" prior to the viral inactivation of blood products in 1984 and the introduction of donor screening in 1991. Officials saw no justification to move away from the existing line to take. A few days later the Law Officers' opinion was received confirming that this was a devolved matter. The effect of this was that the UK Government had no power to stop Scotland proceeding with its proposed scheme.

By 23 June the new Secretary of State had formed the view that "*given both the precedent on HIV and the likely Scottish decision to now go ahead, it looks as though we will on the basis of fairness have to go down the compensation (ex-gratia) route.*" A meeting with the Chief Secretary to the Treasury and the Secretaries of State for Scotland and for Work and Pensions took place on 25 June, at which it was agreed that "*Wales and Northern Ireland will also need to be brought on board*". The Chief Secretary to the Treasury was "*very non-committal*" on the financing of an English scheme. Further discussions took place between officials and ministers over the following weeks about how a scheme could be structured and what payments should be made. As at 31 July 2003 a UK wide scheme was favoured, but Wales and Northern Ireland had not yet been informed of developments.

On 29 August 2003 John Reid announced that England would have an ex gratia payment scheme, a decision made "*on compassionate grounds*". Similar announcements were made in Scotland, Wales and Northern Ireland. This resulted in the establishment of the Skipton Fund in 2004.

Ten days after taking up his position as Secretary of State, John Reid reversed the line that had been adhered to for over ten years, and opted for a form of financial support for

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Hepatitis C sufferers infected through blood and blood products (albeit one that still fell far short of being compensatory in nature). Lord Reid told the Inquiry that he did not take this decision on the basis the Scottish Government had done so – rather the decision of the Scottish Government was, he said, the catalyst for prompting these discussions and making him think about it. Lord Reid added "*if the line is wrong, you change the line.*"

These events reveal a deep institutional reluctance within government to, and the lack of an open mind to, the provision of financial support to those infected with Hepatitis C through blood and blood products. A line was adopted, and adhered to for over a decade, for reasons that do not, on analysis, stand up to scrutiny. Those ministers who, from time to time, voiced the wish to make some (albeit limited) provision were firmly steered away from that course by civil servants in the Department of Health.

Three factors predominated in the decision-making of the Department of Health on this issue: the fear that the making of payments to people infected with Hepatitis C would be a major step on the slippery slope to a general system of no-fault compensation; the belief that those infected had received the best treatment available at the time; and the attempt to distinguish the position of those infected with HIV through blood or blood products, from the position of those infected with Hepatitis C through the same route.

The fear that the making of payments to those infected with Hepatitis C would, or might, lead to no-fault compensation more generally was misplaced and illogical. If it was necessary to establish a ring fence, that could easily have been done with a scheme where the relevant cohort was those infected through blood, blood products or tissue. As for the belief that those infected had received the best treatment available, the difficulty with the Department of Health's position is that it was simply wrong to view the treatment in that light. There was no proper basis for saying that those people who were infected by their treatments were given the best possible treatment in the light of available medical knowledge, let alone to say it repeatedly, let alone for over a decade. The attempt to hold the line by distinguishing the position in respect of HIV and Hepatitis C involved the Department of Health in searching for differences rather than dispassionately considering the similarities: those who contracted it from treatment were infected in the same way, from the same sources, with viral conditions that had similar consequences. Both could be debilitating and lead to death. It is plain in any event from the narrative above that those within the Department of Health were well aware of the difficulties of maintaining this distinction. Thus Tom Sackville observed, this was "*a tricky one: if HIV, why not Hepatitis*", officials in Scotland considered that "*the 'no-compensation' position is becoming increasingly untenable*"; in Wales the view was that "*it would be difficult to sustain rejection of claims for compensation on the grounds of a distinction between those infected with HIV and HCV*"; officials in Northern Ireland thought it difficult "*from point of view of equity to resist comparisons with HIV compensation*"; Departmental officials tacitly recognised in 1996 that the distinction was "*looking increasingly tenuous*"; in 1999 it was described as difficult to explain logically. Rather than face these difficulties, the Government clung to this distinction in the mistaken belief that the sky would fall in – in terms of no-fault compensation – if it did not.

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The Government became so fixated on maintaining that ring fence that it lost sight of the desperate circumstances of those whose lives had been and were continuing to be devastated as a result of their treatment by the NHS. The question of moral responsibility, and the compelling need for a compassionate response, did not feature in the Government's thinking until a combination of factors – the campaigning of the Haemophilia Society, of other campaign groups and of individuals, the events in Scotland (themselves the product of the actions of campaigners), the High Court judgment in *A and Others v National Blood Authority*, and a change of Minister to one who was unpersuaded by the Department – brought about a rethink and a change of direction. That mounting political pressure might eventually render the maintenance of the policy untenable and force the Government to concede was recognised within the Department of Health by the mid 1990s. It should also have been apparent that if Government waited until that point, almost certainly towards the start of the 2000s there would inevitably be individuals who had died, in desperate circumstances and without any financial support other than social security (which was not designed to provide for the needs of those with this debilitating illness), in the intervening period.

It took until 2003 for any form of payment to be announced for those with Hepatitis C and no payment was actually to be made until 2004. This deprived those individuals, and their families, of some valuable support before then. It prolonged and exacerbated the suffering of those who survived. And it further entrenched deep feelings of injustice.

6.7 Skipton Fund

The Skipton Fund was set up as a corporation, and operated specifically as an agent of the Department of Health. It had a board of directors, a secretary and administrator, supported in part by a financial team shared with other Alliance House Organisations. Appeals against the refusal of an application were made to a body independent of the Skipton Fund and of government.

There was no discretion as to the amount to be paid. "Stage 1" lump sum payments, initially of £20,000, were made to applicants who could prove on the balance of probabilities that they had "*contracted the hepatitis C virus because of receiving blood, blood products or tissue from the NHS prior to September 1991 or, in certain circumstances … from a person who has received such treatment*".

A further "Stage 2" payment of £25,000 was payable to a qualifying person who "*has an advanced stage of illness due to hepatitis C virus because of receiving blood, blood products or tissues from the NHS prior to September 1991. In this context, persons with cirrhosis or primary liver cancer and those who have received, or are on the waiting list to receive, a liver transplant are eligible to apply*".

Only people who were alive on 29 August 2003 and who had received the relevant transfusion or treatment before September 1991 could be an eligible "*qualifying person*". People who had acquired Hepatitis C but had "*spontaneously cleared the virus in the acute*

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stage" and never developed chronic (lasting more than six months) Hepatitis C infection were not eligible for payments.

The applicant had to complete an online registration form, providing basic details, after which a paper form was completed by the applicant's doctor. The purpose was to "'*confirm that the patient has been chronically infected*'" and also "'*that the infection most probably arose through treatment with NHS blood or blood products*'". There was no opportunity for applicants to provide any direct evidence themselves as to whether they had received blood or blood products prior to September 1991. The application process became more onerous after the first administrator, Keith Foster, defrauded the Fund of around £400,000, despite there being no criticism of the integrity of any applicant.

Around one fifth of applications were declined, with the main grounds being that the applicant was a "natural clearer" (around one third of applicants were initially declined on this basis); a lack of evidence of transfusion and/or lack of medical records; intravenous drug use, and that the implicated blood product or transfusion was received after 1 September 1991. There may be many reasons for this but less than one quarter of those who were probably infected as a result of treatment made a claim.

The exclusion of Hepatitis B was unfair (and persists in the national support schemes to this day). Whilst in 1972 blood donations began to be screened for Hepatitis B throughout the UK, the screening tests used then were imprecise; Hepatitis B not infrequently continued to be transmitted by blood at least until the early 1980s when screening tests became much improved. Moreover, the availability of screening was not the only precautionary measure. Avoiding unsatisfactory or risky donors was another. So too was ensuring that transfusions were given only when needed, and then only in no greater quantity than actually required. When a person developed Hepatitis B after a transfusion, there could and should have been a check back to see from whom the donation had come. Records were frequently inadequate for this purpose, or were missing. Considerations such as these are persuasive of the need for a compensation scheme to include support for those with Hepatitis B as a result of their treatment.

A clear-cut rule such as the date of 1 September 1991 used by the Skipton Fund can be helpful for administrators and consistent for applicants. However, in this case it ruled out some infections. Screening picks up viral loads only above a minimum which might not be reached in the early stages of incubating a virus. A virus in a donation made during this "window period" would then continue to incubate and to replicate. If that blood donation is then transfused, it may manifest itself eventually in infection. The rule excluding any donation made after 1 September 1991 could not accommodate such a case, however deserving. It was a mistake not to allow the Skipton directors to exercise discretion for the genuinely exceptional case.

There was disagreement as to the approach to natural clearers. There were three problems in particular. First, the uncertainties around natural clearers at the start of the Fund's operations meant that a number of applicants were not put forward by their doctors

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but would have qualified once the position had been clarified. There is no record of any deliberate attempt to invite them to re-apply. Second, the application form did not allow a person to explain why they considered that they had continued to suffer Hepatitis C infection beyond six months, nor could the Fund examine their evidence on the point. Third, there were cases in which psychological or psychiatric damage had resulted, though there was no physiological damage. The Fund did not account for these so these long-lasting effects remained unrecognised.

Applicants had to prove the cause of their infection. The fact of having had a blood transfusion would often not be recorded. Records which identified a particular blood transfusion were comparatively rare. In the absence of medical records showing that there had been a transfusion linked to emerging symptoms, a claim would be rejected by Skipton. This was despite it being wholly unrealistic to assume there would be records, and that these (or a discharge letter to a GP) would show whether there had been a transfusion. This was indefensible: a person infected in the course of NHS treatment was now faced with a failure of record keeping in the NHS, which led to the failure of their claim for help from the Skipton Fund.

In his oral evidence to the Inquiry Professor Thomas explained that the expert group had been looking for objectivity in relation to stage 2 payments and felt that the development of cirrhosis was such a "*solid break-point*". This understanding was overtaken by developments in medical knowledge and the rules were amended to allow stage 2 payments to people who, though not (or not yet) cirrhotic, were experiencing significant symptoms from chronic hepatitis.

The Skipton Appeals Panel generally worked well. It had no hesitation in reaching a conclusion different from that reached by the office team and did so in around half of the cases. The evidence suggests this was likely to have been a combination of incorrect first decisions, and more information being available on appeal. However, there was no scope for oral hearings such that the Appeals Panel could hear from the individual personally, which was unfair, and the Panel provided only short reasons for a refusal.

There were a number of flaws in how Skipton operated:

- there was no opportunity in the application process for applicants to provide any of their own evidence
- too much emphasis was placed on records to show the individual had received a blood transfusion – despite the fact that such records were too often unavailable
- the lack of records will inevitably have led to applications being declined when they should not have been
- the Fund operated a policy which regarded any possibility of intravenous drug use as excluding a claim altogether – this was unfair, as there was no scope for the individual to be invited to a short hearing where their evidence about possible drug

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use could be assessed, and as the Ramsay report, on which the Fund relied, was not provided to applicants

- the original criteria for the Stage 2 payment were too narrow, and ruled out claims from people who were very ill but did not yet have cirrhosis
- the exclusion of people infected with Hepatitis B was wrong

The responsibility for these shortcomings rests with the Department of Health and not those involved in the day-to-day administration of the Fund.

6.8 Government Response to the Archer Inquiry

The Archer Inquiry – an independent, privately funded, inquiry, under Lord Peter Archer – published its report on 23 February 2009. Amongst its conclusions were: that a full public inquiry should have been held much earlier to address the concerns of the haemophilia community; that there had been "*procrastination in achieving national self-sufficiency to avoid the use of high-risk blood products from overseas*"; and that "*Commercial priorities should never again override the interests of public health.*"

The Archer Inquiry made a number of recommendations including: the establishment of a statutory committee to advise on the management of haemophilia in the UK; the issue of cards to people infected entitling the holder to benefits not freely available under the NHS; funding for the Haemophilia Society; improving access to insurance; a lookback exercise to identify individuals who might have been unknowingly infected by infected blood products. Of particular importance was the Archer Inquiry's recommendation that there should be direct financial relief, with payments at least equivalent to the scheme in Ireland.

The day after it was published, on 24 February 2009, Dr Rowena Jecock, who was the head of blood policy within the Department of Health, sent a note to the Minister of State for Public Health, Dawn Primarolo. The note summarised Lord Archer's recommendations and set out the policy team's "*Initial Reactions*" to each of them. On the question of payments, the note stated that a review of the payments system would need to be carefully considered and costed: "*However, the financial implications are enormous if we were to operate in line with the Irish system, as Archer recommends. (An initial estimate applying the average Irish payment to our 4-5,000 cases would be £3-3.5 billion. We need more work to properly quantify these recommendations.)*". The strong recommendation was that there should be no immediate commitment to a timetable for response, and that the necessary consultation, costing of options, and decision time "*may require three months.*"

The Minister's Assistant Private Secretary, Morven Smith, commented that:

- "*The Government at the time (1980s) did not accept that there was a case to be answered and did not accept blame. In Ireland, the Government did accept blame and thus offered compensation.*

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- *Response to this report does not intend to revisit decision to not accept blame. I asked officials about reasons why the Government of the day did not accept blame – no information about this is held.*
- *Officials are seeking legal advice on how apologising and using the terms 'health disaster' might affect us.*"

In relation to the first of these comments, this reason for distinguishing the position in Ireland (that the Irish Government "*did accept blame and thus offered compensation*") became a central refrain in the Government's response to the Archer report. In relation to the second comment, it is surprising to read that "*no information* [was] *held*" about the reasoning of the Government of the day for not accepting blame. As for the third point, that officials were seeking legal advice on the effect on the Department of Health of apologising and using the term "*health disaster*" suggests that a primary focus of the Department of Health may have been the reputational or litigious consequence for the Department rather than the position of those whose lives, and the lives of those close to them, had been devastated by infection.

Dawn Primarolo was not satisfied with the note from Rowena Jecock: "*It is clearly not acceptable in such tragic & unique circumstances for DH to claim no liability and no more money to Trust*." She asked the blood policy team to provide further information and analysis in order to formulate a response to the Archer report.

A briefing provided to ministers in advance of a meeting with Lord Archer on 11 March 2009 set out the Government's position as including the following: that while "*this is a tragedy and there is every sympathy for those infected*", the treatment given to people with haemophilia "*was the best available at the time and action was taken in good faith*" and technologies to improve safety (heat treatment and testing) had been introduced as soon as available. For reasons explained elsewhere in this Report, these lines were incorrect. The briefing noted that several of Lord Archer's recommendations were based on measures that had been implemented in Ireland, and stated that: "*The situation in the UK is different to that in Ireland, where it was acknowledged that action to reduce the risk could have been taken earlier. The Irish Blood Service issues an apology acknowledging 'failures' in the past and their payment regime reflects this admission of mistakes.*"

A submission from April 2009 put forward, at the Minister's request, some more positive options, including increasing annual payments made by the Macfarlane and Eileen Trusts to either £10,000 or £12,800 per year. The Minister preferred the latter option. These figures were arrived at on the basis of what was affordable and which ministers could "*live with politically*": there was no assessment of need and in that sense the figure was arbitrary.

The Government's formal response to the Archer Inquiry's report was published on 20 May 2009. The recommendation concerning financial assistance was addressed by the increase in annual payments from the Macfarlane and Eileen Trusts. However, the recommendation that payments should be at least the equivalent of those in Ireland was not mentioned. The Haemophilia Society was fiercely critical of the Government's response.

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In discussions following the publication of the Government's response, Dawn Primarolo sought further information from officials, in particular as regards the substantive reasons for thinking that the situation in Ireland was very different. A submission was sent to her on 2 June but before she could make any decision, there was a Cabinet reshuffle. A brief for her successor, Gillian Merron, sought to explain that in Ireland an inquiry had found the blood transfusion service to have been responsible for failures which led to infection and this explanation was repeated in subsequent briefings. This line was repeated by the minister in response to questions about the position in Ireland.

In August 2009 campaigner Andrew March brought judicial review proceedings challenging the government's reasoning (based on the Irish government accepting liability, and that it had been found at fault, whereas it had begun making such payments without any such acceptance) in failing to accept Lord Archer's recommendation of payments equivalent to those in Ireland. Judgment was delivered in April 2010 with the judge concluding that the Government's approach to the recommendation regarding parity with Ireland had been "*infected by an error*". The claim for judicial review succeeded, and the Government would have to take a fresh decision.

Following the general election, officials provided a submission to the new minister, Anne Milton, with advice as to how to approach making a new decision. The recommendation was made at that point to reject the recommendation "*on the basis that it is unmeritorious, on grounds of both: (i) the factual difference between RoI & UK; and (ii) affordability.*" In respect of the first, the findings of the Finlay Tribunal in Ireland were again relied upon as a relevant distinguishing factor, notwithstanding the outcome of the judicial review claim. In respect of the second, the rough initial costing of £3-3.5 billion to achieve parity was said to be "*an underestimate.*" An international comparison of contaminated blood compensation schemes was provided in an annex to the briefing. The briefing also suggested that the Minister should reconsider the previously announced decision to bring forward the review of the Skipton Fund; as the review had not yet commenced, the Minister could decide whether it should proceed.

In October 2010 a written ministerial statement was published:

> "*Having carefully compared the circumstances pertaining here and in the Republic of Ireland during the period when most of the infections occurred, and having taken account of the fact that this tragedy similarly affected many other countries; I do not consider there is a case for accepting Lord Archer's recommendation 6(h) that levels of payment here should match those made in Ireland. Every country must make its own decisions on financial support for those affected, taking account of its own particular circumstances, and affordability. The scheme in Ireland was set up on that basis, and has not been replicated in any other country, as far as we know. However, our ex-gratia payment schemes for HIV compare well with those of other countries.*

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In addition, it is estimated that implementing a similar scheme to Ireland's here in the UK, would cost in excess of £3 billion."

Consideration of the Archer Inquiry recommendations led to some changes. Additional measures were announced on 10 January 2011: an increase in stage 2 Skipton Fund payments from £25,000 to £50,000, an annual payment of £12,800 for people infected with Hepatitis C who reached stage 2, and the establishment of what became the Caxton Trust.

The response of the Department of Health had been to avoid endorsing the Archer Inquiry. Though it provided documents this did not amount to an unfettered access to the Departmental files. It did not facilitate the appearance of witnesses. It did not waive legal professional privilege. The Archer Inquiry lacked the powers available to a statutory inquiry, or the resources necessary to conduct a full investigation. As a result its conclusions were always likely to fall short of a full picture of what had happened, and why.

Thus, repeatedly, officials repeated that there was no proper comparison with Ireland because the government there had accepted blame, and had been found at fault. They had been told this was not so, yet it took a further court case (of judicial review) to confirm it. Linked to the Irish issue was a reluctance to accept the financial recommendations the Archer Inquiry made. Although the belief that nothing wrong had been done, that there was no fault, and that the best available treatment was given was waning it was nonetheless proving hard to shake off. Its influence is clear in the Department of Health response to the Archer Inquiry and in its persistent belief in the difference between the UK and Ireland. The response to the Archer Inquiry was too concerned with the financial consequences that might follow. The events highlight how civil servants repeatedly took care to steer ministers away from anything that might involve expenditure, or be an implicit acceptance of fault. If there had been such an acceptance, expenditure would be bound to follow. They also show how long it may take for government to take a fresh look at evidence to see if the facts do indeed support some of its views, or to look again at practices hallowed by their repetition repeatedly over years.

What is most disappointing about the response to the Archer Inquiry is the sense it leaves that government was looking to see what was the least that was required of it.

6.9 Caxton Foundation

People who contracted Hepatitis C from NHS treatment were entitled to specific payments from the Skipton Fund, but not to one-off payments to meet particular needs. The Archer Inquiry highlighted the considerable difficulties this could cause. Partly in response to its 2009 report, the Government set up the Caxton Foundation in March 2011 to provide such grants.

The Caxton Foundation faced a number of challenges:

- Raising awareness among those eligible: the likelihood is that a very large number of potential beneficiaries (registered with the Skipton Fund) needed the further

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assistance they could get from Caxton but it actively served only a small proportion of those entitled to its support.

- Relations with government: Though technically independent as a charity, Caxton was required to account for its expenditure to government and not allowed to retain a reserve. It was reluctant to press its case for additional funds too strongly, or publicly.
- Staffing levels: The lack of sufficient staff to perform essential tasks, let alone consider improvements, caused many of the operational problems.
- Dealing with each beneficiary with sensitivity: Beneficiaries were likely to feel aggrieved by the fact that due to being infected they were now forced to seek what felt like charity.

The evidence was all one way by the end of 2012. The Caxton Foundation was not working effectively. Grants were initially paid by means of a voucher system, which was stigmatising. It took far too long to process applications. In the first 6 months of active operation a third of applications were left undecided because more information was needed. By the end of the next six months it was still more than one in five.

Beneficiaries felt they were being repeatedly quizzed about the same details of their income and expenditure. Although over half the applicants were recognisably in poverty, and (by definition) had a chronic infection, they were expected to provide additional financial details, and then sometimes further details, and then wait.

As late as June 2013 no guidance had been made available to beneficiaries about support for which they could apply. Not sharing the guidelines left beneficiaries invited to register with a trust which could give them money, but would not tell them how much they might get or what for. No proper explanation was given to the Inquiry as to why the Caxton Foundation needed to be so secretive. The absence of clear published criteria for assessing applications must have made it difficult to ensure consistency.

Pressure was put on funding by a rise in the number of beneficiaries. Four months into the 2014/15 financial year the Department of Health asked the Skipton Fund to contact anyone who had ever received a Skipton Stage 1 payment, but with whom there had been no subsequent communication. The result was that the number of Caxton beneficiaries rose by nearly 60 per cent. The business case requesting increased funding for 2014-15 was rejected in February 2014.

The difficulties which beset the Caxton Foundation, and contributed to poor relations between beneficiaries and the Foundation, were principally:

- an absence of a user trustee (although Charles Gore had experience of Hepatitis C and Margaret Kennedy was appointed in 2014 as someone who could represent the user voice)
- the close links with the Macfarlane Trust where dissatisfaction had been expressed by beneficiaries

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- the failure to take more proactive steps to ensure that those who would be eligible to apply to Caxton were aware of its existence
- the poorer practices during Caxton's first year of operation
- the initial shortage of staff to achieve a proper turnaround of applications
- the frequent referral back to applicants for further information
- the feeling of many that they were supplicants rather than applicants
- a lack of any clear information as to what might be applied for, and on what basis an application was determined, coupled with uninformative rejections of applications
- the absence of any developed forum for an exchange of views between the Board and the beneficiaries.

The Caxton Foundation was proactive in supporting beneficiaries dealing with debt. They hired debt counsellors to advise beneficiaries how they might access other sources of funding, and the counsellors were able to act as advocates in managing debt on favourable terms. This deserves to be recognised as an achievement.

6.10 Medical Records

The Inquiry has heard evidence from many infected and affected individuals who have identified either incomplete, inaccurate or missing medical records. This chapter examines the problems faced by individuals, the possible reasons for these issues as well as evidence from individual clinicians and NHS trusts and boards regarding record-keeping policies, retention policies and destruction policies.

The lack of availability of records is so widespread that many people who were infected through blood or blood products have wondered whether the reason is something more sinister than the result of the passing of time, and human error.

It is without doubt that the destruction and disappearance of medical records has caused both practical difficulties and significant anxieties for individuals who were infected and their family members. The effectiveness of the HIV and Hepatitis C lookback exercises were significantly hindered due to incomplete, inaccurate and missing medical records. More recently, individuals have faced issues in accessing support schemes and financial assistance, because medical records have been destroyed or could not be obtained from hospitals, GPs and health boards, meaning that people have struggled to evidence the source of their infection.

For adults who were infected as children, there is a particular desire to understand what happened to them as children. Family members of deceased individuals have a desire to understand their family members' treatment and what caused their death, particularly so for children seeking to reconstruct what happened to their parent or parents who were infected. The emotional toll of trying to obtain the records has been significant for some people.

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The legal framework that applies to medical records, has changed with guidance being issued over the years requiring records to be kept for specified retention periods. In very broad terms, until the 1980s the guidance required records to be kept for 6 years after the end of treatment or the death of a patient. From 1980 there were different rules for patients depending on whether adult, paediatric or obstetric. In all four nations obstetric records were to be retained for 25 years with these rules in other cases:

- In England and Wales, adult records were to be kept for 8 years after the end of treatment or the death of the patient; and paediatric records until the patient turned 25 (or 26 if 17 at the time of treatment) or 8 years after the patient's death
- In Scotland, adult records were to be retained for 6 years after the last entry or 3 years from death, and paediatric records until 25 (or 26 if 17 at the time of treatment) or 3 years after death
- In Northern Ireland adult records were to be retained for 8 years after the end of treatment or death, and paediatric until 25 (or 26 if 17 at the time of treatment) or 8 years after a death before the age of 18.

Nevertheless, accessing records has continued to be problematic. A fundamental difficulty lies in the fact that there was, and remains, no central system where medical records are held. These issues have been made worse through the closures of a large number of hospitals, particularly maternity hospitals, which has resulted in medical records having been destroyed without any prior notification to patients. The very widely experienced delays in diagnosis of Hepatitis C inevitably meant that for many people these dates had passed by the time they had a need to request their records.

There has been no consistency in the responses from hospital trusts and boards given to people trying to access their records. Some hospital trusts and boards have failed to respond, some have provided vague replies and for some there have been long delays and hard work involved in obtaining records. On the other hand, some have been better equipped to provide a speedy, substantive response.

The Inquiry obtained evidence from a sample of NHS trusts and health boards that confirmed that they currently follow national guidance and provide current policies on document destruction, and they believe that guidance was followed historically, though copies of older policies have generally been unavailable.

From the evidence it is apparent that there are a number of possible reasons why medical records have been destroyed or lost:

- reorganisations in the NHS
- records management across multiple locations with separate repositories, later transferred to centralised records, with opportunities for human error
- multiple changes in computer systems removing access to earlier systems

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- changes in name, address etc
- haemophilia centre patient records being kept separately from the main hospital records
- physical damage caused by water or fire.

When records have been obtained by individuals, a number of concerns have been raised about the quality and content of medical records. In particular, concerns relate to inconsistency between what is recorded in the notes and the information that was given, or not given, to a patient; and inaccurate information being recorded in the records. The Inquiry has heard substantial evidence about the differences between what individuals recall being told, or not told, orally and what is recorded in their medical records. There are examples of matters recorded in medical records which simply have been wrong. One common concern for a number of witnesses of this is the accuracy, or otherwise, of references to alcohol use, particularly for those with Hepatitis C.

There are a handful of examples that raise serious issues of intentional interference in medical records. Due to the passage of time, it is difficult to reach any firm conclusions on what happened in these individual situations. They do however raise concerns that there may have been a closing of ranks in certain situations resulting in somebody thinking it would be wise to remove items from medical records.

Professor David Armstrong gave evidence about the poor quality of records systems and said that despite attempts to bring structure and coherence to medical records, removing what was extraneous continued to be haphazard "*everywhere*".

What lessons are to be learned from this? On any view the destruction and disappearance of medical records has caused significant harm to individuals. It has also resulted in a loss of trust that is harmful both to patients and to the NHS more widely. It is critical to the future of the NHS that patients can generally trust what they are told, and trust that the NHS has their best interests at heart. Keeping accurate and complete records, and making them available on request, demonstrates the openness, transparency and rigour which patients and those close to them associate with a careful, caring system of healthcare.

There is considerable material to show that patient records were not well kept, and had not been well kept for years before the periods of central interest to the Inquiry.

Given the evidence of the general poor quality of records systems across the whole of the NHS, the likelihood is that in the majority of cases records were not available due to a mixture of incompetence, a lack of proper systems, and the problems inherent in keeping paper records. Although there are suspicions that some health authorities or individuals hid, removed or destroyed records that might be an embarrassment, there is no evidence sufficient to make a general finding of that nature.

The possibility that there may have been occasions in the past when records may have been left incomplete deliberately or have been filleted nonetheless still remains. The filleting

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of records by some health professionals in respect of blood-borne infections would be much less difficult to achieve, may involve no other health professionals, and is thus perhaps easier to contemplate as having happened.

6.11 National Support Schemes

This chapter sets out the evidence on how the current National Support Schemes were established.

Dissatisfaction with the Alliance House Organisations increased during the 2000s and by 2013 reform began to be considered by ministers. Anna Soubry expressed exasperation about the time it took "*to sort anything out*"; and heard that "*the systems set up by successive Governments are divisive and people are being dealt with in an uncompassionate and ineffective way.*" She told the Inquiry that when briefed about the schemes she "*could not understand why there were different funds or why they were so complicated and difficult for applicants to access. It struck me as illogical and profoundly wrong*" and that "*the 'cap in hand' nature of it was humiliating for the beneficiaries.*" She asked her officials to provide her with options for reforming the Hepatitis C payments system, although her recollection was that there was little political will to change the system. Jane Ellison succeeded Anna Soubry in that ministerial role in October 2013, and also sought advice on options for reform.

The issue reached Prime Minister David Cameron, and when he met a group of campaigners with Alistair Burt MP he came to believe "*the system was not fit for purpose*." A submission to ministers in January 2014 suggested that there was no additional money available for reform and that "*we will need to consider what might be done to reform the current system to address the key concerns of campaigners and MPs, within the current, or lower, budget envelope of the system.*" The submission noted that the payment levels under the existing system were "*for the most part arbitrary, and, with some exceptions, not based on any assessment of impact or need.*"

In November 2014 the Prime Minister was asked to approve a proposed consultation about the different schemes, but a view appears to have been taken that this should await the delivery of the Penrose report. In January 2015 the APPG published its "*Inquiry into the current support for those affected by the contaminated blood scandal in the UK*", accurately describing the current position as "*a haphazard financial support system, established piecemeal by successive governments*".

On 25 March 2015 (the date of publication of the Penrose report) the Prime Minister announced a consultation into reform of the payment schemes and pledged up to £25 million that financial year to support transitional arrangements to a better system. A meeting of the UK health departments took place on 17 April 2015 to discuss reforming the infected blood payments scheme reform. The minutes of the meeting record the desire of the English, Welsh and Northern Ireland Health Departments to work towards a UK-wide approach, and although it was noted that some "*affected patients*" in Scotland favoured a Scottish scheme

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in Scotland, Shona Robison was said to recognise that a UK-wide scheme would reduce service delivery costs.

On 30 June 2015 the Secretary of State for Health Jeremy Hunt wrote to David Cameron, suggesting that it was "*basically impossible*" to bridge the gap between the expectations of families who had suffered "*and what we can realistically afford.*" Three options were advanced: (a) austerity; (b) one-off payments to people infected and bereaved, shutting down the schemes, but providing accelerated access to direct acting antiviral treatments to everyone who had been infected, or (c) funding accelerated treatment for those in the early stages of the disease. The Prime Minister's response was "*I don't think these work. A scheme that is meant to help but actually takes money away from people who currently get it is hopeless. And I accept we don't have £480m* [the estimated cost of the second option that Jeremy Hunt personally favoured] *lying around. Surely there is a route where we increase the £25m to £100m or some such and fill in the worst payment gaps & merge all the charities into 1.*" Following further deliberations, a submission to Jane Ellison and Jeremy Hunt in early August 2015 identified three different options, observing that "*The reputational risk of failing to make substantive changes to the scheme is high. Successive Governments have promised to address the concerns of beneficiaries for a number of years.*" One of these options was to reform the current schemes into one, with £25m additional funding a year for the next five years. In November 2015 the Spending Review resulted in an agreement that a further £25m a year would be allocated from Department of Health central funds to the financial support schemes over the following five years.

In December 2015 the Scottish Financial Review Group (established following the publication of the Penrose Report) made a number of recommendations including that annual payments be increased to reflect Scottish full-time gross median income and that bereaved partners should receive a pension of 100% of the annual payment in the first year and 75% thereafter. The Group "*favoured a new Scottish scheme that would not be constrained by UK-wide discussions/agreement*". The recommendations were accepted by the Scottish Government in March 2016, and resulted in the establishment of the Scottish Infected Blood Support Scheme which began operations on 1 April 2017.

In January 2016, ten months after the publication of the Penrose Report, the Department of Health launched its consultation on reform of the Alliance House Organisations, setting out a number of proposals for a new scheme in England. Little notice of the consultation was given to health ministers in Scotland, Wales and Northern Ireland. In July 2016 the Department of Health published its response to the consultation, and David Cameron announced the decision that there would be a single scheme administrator for England from 2017/2018 (later confirmed to be the NHS Business Services Authority).

In October 2017, the Department of Health announced, following further consultation, a "special category" mechanism to allow a beneficiary with a stage 1 infection with a substantial, long-term negative impact on daily life to apply for a higher annual payment. Annual support payments were also increased. The England Infected Blood Support Scheme ("EIBSS") started work on 1 November 2017.

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Advance notice of the Department of Health's response to the consultation on reform of the Alliance House Organisations had not been provided to Northern Ireland. A submission to ministers in July 2016 explained that the Department of Health had informed the devolved administrations that no additional money would be available to them. In December 2016 the Minister for Health announced that the new provisions in England were being replicated in Northern Ireland. In January 2017 the Northern Ireland Executive collapsed, leaving the Department of Health without a minister and limited ability to implement reforms. The Infected Blood Payment Scheme Northern Ireland began work on 1 November 2017, although with no special category mechanism.

Wales likewise did not receive advance notice of the consultation or the DH's response. In October 2016 Vaughan Gething, noting that the UK wide nature of the schemes had "*now fragmented through new schemes announced for Scotland and England*", announced that as an interim measure payments for the remainder of the 2016-17 financial year would be at the same levels as England. Following consultation a new scheme, the Wales Infected Blood Support Scheme (administered by Velindre NHS Trust), began to operate in October 2017.

In mid-2017 the Scottish Government asked Professor David Goldberg to establish an expert group to assess the health and wellbeing of individuals, chronically infected with the Hepatitis C virus (at stage 1) who had not yet reached advanced Hepatitis C (eligible for Skipton Fund stage 2). In addition to recommending that renal disease be added to the latter criteria, the group considered the method of assessment used by the scheme. The group noted that any entirely clinically-based assessment would ignore the considerable non-clinical, especially psychosocial, impacts described in its report and recommended that people with chronic Hepatitis C, including those who had cleared their virus through treatment, or their widows, widowers or partners who were eligible for support were asked to "*self-declare hepatitis C impact*" based on whether the infection had affected their life but not seriously (lower award), had seriously affected and continued to affect their life (higher award) or had not appreciably affected their life (no award). This was an innovative approach which the Inquiry has been told works well with no claim that the system has encouraged overpayment.

Changes have been made to all four schemes since their inception, often following dogged campaigning by those infected and affected.

On 30 April 2019 the Prime Minister announced that £30 million of additional funding would be made available. This announcement coincided with the first day on which the Inquiry heard evidence; it appears likely that the publicity of the start of the Inquiry hearings focused the departmental/governmental mind. This was an announcement that applied only in England and intensified calls for parity between the four schemes.

In summer 2020 Penny Mordaunt (then Paymaster General) wrote to the Chancellor of the Exchequer, Rishi Sunak, to explain the work being undertaken to resolve the remaining disparities in support between the schemes. She pointed out that this was "*one of the main requests of the victims and their families*" and her "*strong belief*" that "*it would be*

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the right thing to do." Penny Mordaunt wrote to the Chancellor again on 21 September 2020 providing the costings for parity of financial support and seeking his views "*on how this additional funding would be integrated best into the 2020 Comprehensive Spending Review.*" She wrote "*I cannot stress enough the urgency of taking long overdue action on financial support and compensation.*" By the end of 2020 there had been no significant progress and in February 2021 Penny Mordaunt wrote to the Secretary of State for Health, Matt Hancock, setting out her view that resolving the disparities was "*a matter of justice*" and that the Government "*must find a way to fund this – either through existing budgets or by making a further approach to the Treasury.*"

On 25 March 2021 Penny Mordaunt announced that the UK Government would provide funding to enable broad parity of annual and lump sum payments between the four national schemes. These changes were backdated to April 2019. Equivalent statements were made in the other nations and changes to the schemes were made within the following months.

Although there have been some criticisms of the operation of the national support schemes (in particular EIBSS), there is little doubt that the decision to cease funding the Alliance House Organisations and establish different schemes was inevitable. Scotland and Wales took particular advantage of the opportunity to improve provision by introducing (in Scotland) ongoing support for bereaved partners and self-assessment to identify the full impact of infection with Hepatitis C in Scotland, and by introducing (in Wales) more holistic support to people infected and affected. Both seem to have worked well.

There are two significant areas where the response of governments fell short. The first is the time it took to move to the new schemes, given what was increasingly apparent about the unsatisfactory ways in which they had been functioning. Though it takes time to arrange a consultation on potential change, and consider the responses, four years was too long. Responsibility for this delay lies with the Department of Health.

The second is that the way in which the new schemes were set up meant that there were significant disparities from the outset. The support provided was a response to what was a UK problem, the seeds of which were sown long before any devolution of government. However, when the Department of Health consultation was carried out on changes to the schemes, the devolved administrations were not informed about that consultation or the resulting decisions. Given the decisions made in England and Scotland, Wales and Northern Ireland were left with no real alternative but to set up their own schemes, which was responsible for some of the disparity. It is, of course, inherent in devolution that each nation of the UK was constitutionally free to do this. Nonetheless, as part of the UK it is reasonable that where common issues cross the borders there should be an attempt at joined up planning. It did not happen at the start of the national schemes. It took too long after that to achieve a reasonable degree of parity. Responsibility for this lies with the departments of health, but principally the Department of Health in Westminster.

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6.12 Access to Treatment

Where harm has been done, it might be thought that, as a matter of justice, the state should do all that it reasonably can to alleviate the consequences of that harm. With that thought in mind, this chapter examines four aspects of medical treatment: lack of access to specialist treatment; the availability of treatments for Hepatitis C, palliative and end of life care; and the availability of recombinant factor product.

Lack of access to specialist treatment

People with bleeding disorders who became infected with HIV or hepatitis were too often treated for those infections by doctors whose expertise was the treatment of bleeding disorders. Instead, they should have been treated by expert clinicians or multidisciplinary teams (as were people infected through transfusions). It is clear from accounts provided to the Inquiry that this often did not happen. Treatment of HIV or hepatitis by haemophilia doctors also meant that people were often obliged to see the same doctor (who had given the implicated treatment), and in whom they had lost trust.

It is also clear from accounts given to the Inquiry that people infected through transfusions have faced wide variations in provision, with not all receiving treatment from an appropriate specialist multidisciplinary team.

People who have been infected with such serious viruses as HIV and hepatitis in the course of NHS treatment, deserve nothing less from the NHS than the reassurance of the right expertise, the absence of delay, and the knowledge that their continuing health problems are dealt with by specialists. Having been infected by the NHS, it was and is incumbent upon the health service to do all that could reasonably be done to alleviate the consequences.

Treatment of Hepatitis C

A common account provided to the Inquiry has been of difficulties or delays in accessing treatments for Hepatitis C, often caused by lack of resources.

In the period from licensing interferon in 1994 to 2000 there were repeated difficulties for some in accessing interferon treatment under the NHS in England. Provision was not consistent across the country. There was no central funding and whether patients received it or not was up to their local health authority. Measures that could have helped to address problems over access to treatment, such as clinical guidelines, purchasing guidelines and centralised funding, were still not in place after five years. In his written statement to the Inquiry, Professor Sir Kenneth Calman noted that the issues "*were common across the NHS when new drugs or treatments emerged.*" Dr Rejman noted in his statement that "*it appears that DH* [Department of Health] *was encouraging the use of Interferon, where it was appropriate, but accepting that the final decision rested with the purchasers.*"

In Scotland a working party of the Royal College of Physicians of Edinburgh produced a report on Hepatitis C in February 1996 and noted: "*There is currently no general agreement*

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as to who should meet the drugs costs, general practitioner or hospital … In the smaller regions the additional numbers generated by a lookback survey are relatively modest and may be largely absorbable into existing budgets. In the west of Scotland, in particular, the additional costs are likely to be substantial." Dr Aileen Keel "*advised that 'ring fenced' funding for interferon treatment would not materialise.*"

In April 1999, the National Institute for Clinical Excellence ("NICE") was established to provide clinical guidelines for England and Wales and reduce postcode prescribing. In May 1999 ribavirin was licensed for distribution in the UK and in October 2000 NICE guidelines for the use of interferon and ribavirin were introduced. While interferon had low cure rates, the addition of ribavirin increased cure rates of Hepatitis C "*quite significantly*". The NICE guidelines recommended that combination therapy be used to treat moderate to severe Hepatitis C. Pegylated interferon was licensed as a combination therapy with ribavirin, and recommended by NICE on 28 January 2004. Between 2002 and 2010, all four nations of the United Kingdom developed action plans to improve treatment services for Hepatitis C. In 2006, an article on the variation in Hepatitis C services across the UK, based on a survey conducted in 2002, found that 72% of consultants who responded identified funding as a barrier to treatment. The survey found that the majority of patients were not receiving antiviral treatment, in contrast with practice in Europe.

From 2014 new direct-acting antivirals ("DAAs") became available which were a combination of sofosbuvir and other agents (without interferon). However the costs were high and caps on the number of people who could receive treatment in each area limited access. In England, the first early access programme began in April 2014 and provided treatment with sofosbuvir to patients with decompensated cirrhosis, "*at risk of death or irreversible harm within 12 months*" with either decompensated cirrhosis, other life-threatening complications and/or awaiting liver transplantation. Access for "*critically urgent*" patients was considered on an individual basis by NHS England clinical experts. In 2015 it became clear that funding was affecting access to treatment. NICE issued guidelines for treatment with sofosbuvir in February but at NHS England's request there was an extension of the period for their implementation. Following the implementation of NICE guidelines, funding for DAAs was provided through operational delivery networks across England. Each one was provided with a proportion of the budget for Hepatitis C treatment based on the estimated treatment figures for the area covered and the local prevalence of Hepatitis C. There were some examples of patients not receiving treatment due to the resultant limit on allocations, and the experience of patients, as described to the Inquiry, is that there have been difficulties with access to treatment.

Wales had previously experienced a "*postcode lottery*" where availability and quality differed across parts of Wales but the announcement in September 2015 of funding for interferon-free treatment was seen as a turning point, and there was no central process of capping the numbers of patients who could be treated with DAAs. In Northern Ireland there were delays in accessing the treatments but this resulted from the limited capacity of the hepatology service rather than funding constraints.

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Had the failures detailed in this Report not occurred, there would have been less need for sofosbuvir-based treatments than arose. If it had been appreciated by then, as it should have been, that the infections from blood and blood products were serious failures for which authority was ultimately responsible, those infected by blood and blood products would have had priority for funding; and therefore there should not have been any such difficulty as there was in England in receiving treatment with direct-acting antiviral drugs such as sofosbuvir. Funding was tight across government: but this was a question not of extra spending, so much as one of allocating priorities. And it would have been fair as a priority to allocate enough funding to help moderate the harm done to individuals as a result of the several, interconnecting, failures that led to their having to live with otherwise relentless infection.

Ongoing monitoring

Evidence provided to the Inquiry demonstrates that a lack of ongoing monitoring is an area of concern for people who were infected with Hepatitis C and have cleared the virus. The Expert Group on Hepatitis advised the Inquiry that successful treatment for Hepatitis C can considerably reduce (by approximately 70%) but not eliminate the risk of cancer. The major factor determining the long-term impact of Hepatitis C is the degree of liver fibrosis at the time when the Hepatitis C PCR test became negative. People with significant fibrosis or cirrhosis are likely to require lifelong surveillance for the risk of hepatocellular carcinoma, with six monthly testing usually involving an ultrasound of the liver and an alpha fetoprotein ("AFP") blood test. The expert group advised that people who did not have such liver scarring may be discharged from specialist care.

Professor Michael Makris recommends that patients with an inherited bleeding disorder who have cleared Hepatitis C should be seen by a consultant hepatologist and have blood tests, an ultrasound scan and a fibroscan. Where patients have no signs of advanced fibrosis/ cirrhosis but have abnormal liver enzymes, these should be assessed and they should be given advice on lifestyle factors to minimise the risk of liver failure. He recommends that patients with advanced fibrosis or cirrhosis are entered into a hepatocellular screening program, with six-monthly ultrasound scans and regular hepatology follow-up to detect early signs of liver failure.

Leigh Day solicitors submitted that one of the most important issues for their clients infected with Hepatitis C through transfusions was access to monitoring and follow up after having "cleared" the virus. They are understandably worried about the harm of long-untreated Hepatitis C and their increased risk of developing end-stage liver disease or hepatocellular carcinoma. In February 2020 at the end of the hearings with the hepatitis experts I said: "*I would like to draw the attention publicly now of NHS England and hospital trusts and boards throughout the country to the fact that the need for specialist treatment by professionals who have a special understanding of infected blood and blood products has not gone away, now that there is greater success in treatment of the underlying conditions – that there is a need to ensure that the standards of follow-up of those who have cleared hepatitis C but*

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have been left with a compromised liver are maintained in accordance with what the experts have set out this week."

The consistent delivery of appropriate follow-up monitoring is a legitimate concern. For this reason, the Recommendations include that those bodies responsible for commissioning hepatology services in each of the home nations should publish the steps they have taken to satisfy themselves that the services they are commissioning meet the particular needs of this group of people harmed by NHS treatment.

Palliative care

There is variability throughout the UK in referral to specialist palliative care and access to palliative care services for patients with chronic liver disease. In some cases palliative care services have struggled to provide adequate care for people suffering from Hepatitis C, or hospitals have failed to recognise that palliative care was necessary.

Advanced liver disease is characterised by a multitude of distressing physical and psychological symptoms, poor quality of life, frequent hospital admissions and a high burden on caregivers. Palliative care can help alleviate distress and is of demonstrable benefit to patients and carers. Despite a growing body of evidence supporting the integration of palliative care in the management of advanced liver disease, the provision of palliative care for patients with advanced liver disease remains patchy across the UK. The patient and carer experience of healthcare for advanced liver disease too often remains very poor.

HIV was a life-threatening disease. In the days before highly active antiviral therapy began it called out for palliative care. Though palliative care should have been an integral part of the care pathway in the 1990s, the stigma of HIV tended to make it less likely to be offered or accepted.

The provision of palliative and end of life care – these are not identical, though the first may overlap with the second) – to many of those infected by NHS blood and blood products has been inadequate, and a further way in which people infected and affected have been let down through a lack of access to good care.

Recombinant factor products

As a precaution against the transmission of blood-borne viruses, synthetic forms of treatment were developed using advanced recombinant DNA technology. Modern recombinant factor products are widely understood to be free of transfusion transmitted viruses.

Recombinant Factor 8 was made available to UK health services in 1994. It was not cheap and concerns about the lack of availability of recombinant Factor 8 due to cost started to arise during the next year. A survey reported to the Secretary of State for Health in late 1995 suggested that only two centres had secured the funds to purchase recombinant for some or all of their patients outside clinical trials. The position at the end of 1996 was that the

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government did not intend to provide any extra money or advise or require health authorities to fund recombinant – it would be a matter for health authorities to decide.

Concerns about the possible transmission of vCJD by blood led to a decision in 1998 to introduce leucodepletion. It also led, in February 1998, to an announcement from Frank Dobson, the Secretary of State for Health, that recombinant products would be made available to children under 16 and previously untreated patients. There were however no plans to roll out recombinant to all patients.

In May 2001, the Haemophilia Society led a national campaign for the universal availability of recombinant Factor 8. The society encouraged individuals to write to their local MPs or government officials outlining the importance of funding recombinant Factor 8 for all Haemophilia A patients, and that "*treatment by postcode is unfair and distressing to the haemophilia community*."

Wales decided in 1997 to make recombinant Factor 8 available to everyone with Haemophilia A, and it achieved this over the next two years. It was the first country, anywhere, to offer recombinant Factor 8 to all its patients. By the end of 2000 Scotland and Northern Ireland had confirmed that all haemophilia patients would be placed on recombinant treatment. In England, it was decided in January 2001 that recombinant would be made available for all adult haemophilia patients on a phased basis over a 4-5 year period starting in 2002-03. Due to issues with funding, it was not until the financial year 2004/2005 that all patients with Haemophilia A, of whatever age, had access to recombinant Factor 8.

Recombinant was desirable for two reasons. First, many people with haemophilia who had been alive before 1992, and survived, had been infected with HIV, and more (possibly almost all) had been infected with Hepatitis C. They would have seen many of their friends die, often painfully, and had to face indignities and stigma. They knew their families and close friends had been significantly affected in almost every aspect of their lives. In each case, the cause was blood products of human origin. They – and parents also concerned about the treatment available for the next generation – had every right to be seriously worried. This group had been harmed by treatment from the NHS which was now threatening to expose them to harm again, as they reasonably saw it, and they were (generally) in no position to fund more acceptable treatment for themselves.

Second, the predominant concern should be the safety of the patient. It is right to acknowledge that using money to fund one treatment may deprive another patient with a different condition from having their treatment funded. However, recombinant was undoubtedly safer so that even before risks of vCJD being transmitted by blood there was a powerful argument for recombinant being funded for everyone who needed it. Once those risks were recognised it became unanswerable. Recombinant treatment should have been funded earlier than it was across the whole of the UK.

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6.13 Inquests, Fatal Accident Inquiries and Death Certificates

This chapter looks at death certification, and identifies differences in the approaches of different coroners that have been taken to recording death from, or causatively related to, HIV.

The right to life is of fundamental importance. When a person dies, it is important to know if this has been interfered with, either by the state or in a way which the state could put right. It is important for their family and friends to know why the death has occurred and for society more generally to know that it has happened and what the cause was – especially because there may be lessons to be learned from one death which will help prevent other deaths occurring in a similar manner.

A fatal accident inquiry (in Scotland) or investigation by a coroner (in England, Wales and Northern Ireland) is usually the first time that people bereaved by a death can have an independent professional review the circumstances of that death. This is particularly significant where the death may have been caused by failings within a state-funded organisation such as the NHS.

There were clearly weaknesses in the system of death certification and investigation: it was described as fragmented, inconsistent in its standards, and failing to satisfy the public interest in the true causes of death in the population. These weaknesses have since been addressed, including by the Shipman Inquiry and legislation following a Fundamental Review in 2003 (England and Wales) and a review by Lord Cullen in 2009 (Scotland).

Death certificates

It would be difficult to obtain much statistically useful information from death certificates produced during the 1970s and 1980s, and indeed into the 1990s, because of the lack of consistency in the language used to reveal (or avoid revealing) that hepatitis or HIV infections were the underlying cause of the death. There was little to no guidance and training available to doctors during the relevant period on how to fill out death certificates. Any apparent trends would always be surrounded by uncertainties.

The Inquiry has heard a range of views on whether or not AIDS, HIV or Hepatitis C should have been recorded on death certificates. Some families made a specific request for the information to be withheld due to concerns about people finding out about the deceased's true cause of death and the stigma involved. Others, however, felt the truth should have been recorded. For some, the information on the death certificate has caused further pain. Some have told the Inquiry that they felt not referring to AIDS, HIV or Hepatitis on death certificates was an attempt to cover up the truth and to protect doctors, not the deceased or their families.

The evidence provided to the Inquiry shows wide differences of view as to what should have been recorded and also highlights the importance of respect for the autonomy of the bereaved individual or family, and their wishes. Experiences of paternalism (even if well meant) led to distress, and misunderstanding of motives. The Inquiry's sense is that

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doctors may not have appreciated the importance of the wording of death certificates to the bereaved. It is unclear why a system that allowed AIDS to be confidentially recorded was not established.

Disparities in coronial practices

Until 2013, when the role of Chief Coroner was introduced, there was no oversight of the practices of individual coroners. Some coroners held inquests into cases involving infected blood and blood products but some did not. Whilst there is no evidence that this was specific to infected blood, it appears that some coroners sought and would have welcomed guidance on how to deal with inquests in these cases.

The disparity in investigations by coroners across England and Wales was a reflection of the way the coronial system operated. The autonomy of local coroners meant that determinations were unpredictable and often too dependent on their relationships with local clinicians.

In Scotland, the disparities were less apparent in that no Fatal Accident Inquiries were held into deaths caused by infected blood and blood products, although there was a wide discretion there too. Judicial reviews were brought before the Scottish courts in respect of this failure, which were upheld, resulting in the Penrose Inquiry being established.

This system was intended to provide answers, to establish the prevalence of certain causes of death, and to inform public health. As it was, until well into this millennium, it proved an unreliable source of information, which hid rather than revealed causes of death. An opportunity was missed.

Volume 7 Response of Government

7.1 Document Destruction

This chapter examines the circumstances in which three separate sets of documents have been lost or destroyed: files relevant to the HIV litigation; papers relating to the Advisory Committee on the Virological Safety of Blood ("ACVSB"), in particular from 1989-91; and the Private Office papers of Lord David Owen.

The exploration of what happened to these documents is not easy to summarise. What is set out below, therefore, are simply the main conclusions that have been reached. The evidence on which those conclusions are based is described in some detail in the chapter itself.

When a class action in respect of Hepatitis C was mooted, an early question was whether the number of people "*who might have been saved from infection*" could be estimated and it was thought that the ACVSB papers might provide the answer.

A number of registered files containing ACVSB papers (referred to as GEB/1) had been sent to the Departmental Records Office repository in early 1993. In mid 1995 it was discovered that one of the volumes, covering part of 1989, had been destroyed. Steps were not then

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taken, as they should have been, to ensure that the remaining files were properly looked after, or to reconstruct the missing file.

The file in question (registered file GEB/1 volume 4) had been destroyed on 29 September 1994. This was before the 19 July 1995 date set for its branch review (in other words, a review which considers whether the documents should continue to be retained). The file should never have been destroyed at all, but in any event it should not have been destroyed in advance of its review date.

The other GEB/1 files had been reviewed on dates between December 1994 and April 1997 but were not destroyed until between October 1997 and November 1998. None of these files should have been destroyed, given their nature and importance. If the files had been recalled by September 1997, these documents would have been saved.

Copies of ACVSB papers kept by Dr Metters, the Deputy CMO who had chaired the ACVSB, were destroyed shortly after his retirement in 1999. The likelihood is that these copies were destroyed to make room for his successor's files and the evidence does not establish who was responsible for that.

In November 1999, the Department of Health agreed to voluntary disclosure to claimants in the Hepatitis C litigation. This led to work to identify documents, including the ACVSB papers. Although some of the missing documents were found from other sources, it was recognised that "*the registered files are irreplaceable*" and the Department was advised by leading counsel (who described his reaction as being "*how could this possibly have been allowed to happen?*") to undertake an internal investigation to try to establish why the files were destroyed.

The Department of Health's internal audit department undertook the investigation and concluded that "*an arbitrary and unjustified decision, most likely taken by an inexperienced member of staff, was responsible for the destruction of a series of files containing the minutes and background papers of the ACVSB.*"

The chapter concludes that the audit investigation was ineffectual in finding out what had actually happened. It ought to have been relatively easy to identify the person responsible for the destruction of the documents, to ask them why the documents had been marked for destruction, and why those files were destroyed related to litigation about Hepatitis C. The audit investigation did not interview all those who should have been interviewed, nor did it seek to ask each person who worked in the relevant section of the Department of Health at the time what had happened.

There has never been a satisfactory explanation for the loss of the ACVSB documents. The files were deliberately destroyed. The issue is why they were. The chapter concludes that it is more likely than not that their destruction was authorised because the documents contained material dealing with delays in the UK to the introduction of screening of blood donations for Hepatitis C. It was a deliberate attempt to make the truth more difficult to

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reveal. It is not, however, now possible to identify the individual responsible for marking them for destruction.

It is possible but not probable that the same person was responsible for the loss of documents relevant to the HIV litigation. Some documents (in particular relating to self-sufficiency) that were relevant to the HIV litigation were lost prior to 1990 and were not available during the litigation. Some were lost after the conclusion of the litigation; they were discovered to have been lost in 1996 (although some of those were subsequently located).

In relation to Lord Owen's private office papers, which were destroyed at an unknown date and in unknown circumstances, there is no sufficient evidence of impropriety to lead to a conclusion that Lord Owen's papers were destroyed because of their contents, rather than because destruction was thought to be an appropriate procedure. There was at the time a regrettable lack of clarity, and some confusion, about what should happen to private office papers in the Department of Health

7.2 Self-Sufficiency Report

This chapter examines the origins of, and the drafting of, a report that was published by the Department of Health in 2006: a report entitled *Self-Sufficiency in Blood Products in England and Wales: a Chronology from 1973 to 1991.*

In June 2002 the Parliamentary Under-Secretary of State for Public Health, Yvette Cooper, decided that a formal internal review should be undertaken on self-sufficiency between about 1973 and 1985, because the Department "*did not have a clear account of decisions that had been taken in the 1970s and 1980s, and therefore I could not be confident in the advice I was being given to answer campaigners' serious questions, nor could I be confident that previous official advice or subsequent Ministerial decisions on this issue were right as a result.*" She expected the review to address the destruction of Departmental papers and Lord Owen's Ministerial papers.

Peter Burgin, a senior executive officer at the Department of Health, started work in September 2002, reviewing documents and carrying out a small number of interviews. He emailed his draft report to Charles Lister on 24 December 2002.

There were substantial differences between the project as envisaged initially and as eventually made public in 2006:

- Whereas Peter Burgin considered the period from 1973-1985, the report published covered from 1973 to 1991.
- It was originally intended to be an internal review, to assess gaps from missing documentation so that ministers could take informed decisions, but became a published document.
- It moved from a factual account of what documents said about self-sufficiency to one expressing opinions about what had happened.

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- There were very significant changes in the content of the document. None of those who might be thought responsible for producing the document accept that this was the result of their input. They seek to say that the Self-Sufficiency Report, as it became known, was in essence the same as the initial report, with no change to the substance of what was reported. This is not the case.

There was very considerable delay in finalising the report. It had been substantially completed by Peter Burgin when he handed over a draft on Christmas Eve 2002. But it was not published until 27 February 2006, over three years later. The delay was inexcusable.

In June 2003 Charles Lister was succeeded by Richard Gutowski as the civil servant principally responsible for blood policy. In his handover notes Charles Lister said the report needed an executive summary, references to the documents quoted and to back up statements which otherwise would remain unsubstantiated; and that a final draft should be shared with some of the people consulted for comments on the factual accuracy. Due to other work pressures, Richard Gutowski decided external consultants were required to finalise the report and a contract with Dianthus Medical Ltd was signed on 7 June 2004. Dianthus sent their final version of the report to Richard Gutowski in October 2004. A further version was produced by July 2005, with there being only one minor change after that before eventual publication.

In the draft produced by Peter Burgin, there was material supportive of an argument that although risks of infection were known by clinicians and virologists, and that many of them saw these risks as potentially serious, little was done to advise patients of this or to protect them from those risks. The documents reviewed by his draft report might fuel an argument that commercial concentrates carried with them greater risks than the concentrates that would have been available to patients in the UK if self-sufficiency had been achieved. The draft report supported the view that these risks arose because of the nature of the populations from which the plasma supplies to make the products were drawn, but also because of the pool sizes used. He noted that self-sufficiency remained the policy throughout this period and his review showed that the problems in achieving this were linked to BPL's capacity.

There is a striking contrast between these matters and the messages the Government felt able to relay from the final version of the report in 2006. By the time the review was to be published in February 2006 the communications unit of the Department of Health briefed the Parliamentary Under-Secretary of State for Public Health that:

"*The review concludes that:*

- *Clinicians acted in the best interest of their patients in the light of the evidence available at the time.*
- *The more serious consequences of hepatitis C only became apparent in 1989 and the development of reliable tests for its recognition in 1991.*
- *Attempts to devise a procedure to make the virus inactive, tests were developed and introduced as soon as practicable.*

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- *Self sufficiency in blood products would not have prevented haemophiliacs from being infected with hepatitis C. Even if the UK had been self sufficient, the prevalence of hepatitis C in the donor population would have been enough to spread the virus throughout the pool.*"

These comments would not have represented a fair reading of the material which Peter Burgin had set out over three years earlier.

In evaluating the evidence about the development of this report, the first question is whether Peter Burgin's draft was a fair reflection of the documents available to him. There is nothing to suggest it was not. The next question is why it was changed. One reason may be the decision to publish, which necessitated an executive summary, and full references. Another reason may be that the period covered was extended from 1973 to 1985 to 1973 to 1991.

Part of the reason is more troubling: there was clearly also a change of approach. Yvette Cooper's purpose in commissioning the study was to see if the conclusions of fact which had hitherto been expressed by ministers and by the Department of Health were justified or not, and to find out what had become of Lord Owen's papers. The document became, instead, one intended for publication with conclusions in support of the official government line to take.

A particularly egregious example of this is the very last words before the conclusions are stated: "*It is now known that it is an indisputable reality that very few counties [sic] are capable of completely satisfying their blood needs (i.e. becoming self-sufficient) without acquiring a proportion of blood from paid donors [158].*" The reference for this is an article which says what is effectively the opposite. "*Unpaid donation is proven to be much safer for receivers and supply problems can be attributed fundamentally to inefficiencies in the organization of transfusion services. Voluntary and non-remunerated donation may be sufficient for a country/region to cover all its blood product needs, but requires an efficient organization and the elimination of 'spurious altruism', non-monetary forms of compensation that harm the social image of voluntary donation and obstruct its further development.*" In other words, if countries organise their transfusion services efficiently there is no supply problem, and safety is provided better by a system of voluntary donations than one which involves supplies which are bought from individual people wishing to sell their blood.

The doctor from Dianthus working on the report appears to have been looking for material which might be taken to support the Departmental line as taken thus far. She must have thought this is what the Department of Health wanted. Ultimately, what started out as a project to inform ministers about self-sufficiency, so that they could consider whether the current line was properly justified, became itself a document which attempted to justify that line. The likeliest cause of the changes is that Dianthus took their line from what they experienced as the prevailing attitudes within the Department of Health – essentially, that the Department of Health was keen to defend the position they had habitually adopted.

The production of the Self-Sufficiency Report in the form it eventually took was part of the government response to what had happened. The Self-Sufficiency Report was promised, expected and then unjustifiably delayed. As this Inquiry now knows, but the public receiving

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the report will not have realised until very recently if, indeed, at all, it represented a report which had undergone substantial change from draft to draft, altering the timescale, and its essential nature. As published it was defensive of the line which had been taken but, as examined elsewhere in this Inquiry, much of what was recorded in it presented an incomplete picture of the material that was there to be seen.

The Self-Sufficiency Report was an inadequate response to the request made by Yvette Cooper and a disservice to campaigners who, despite the challenges of ill-health and grief, had determinedly pieced together a fuller understanding of self-sufficiency than the report published by the Department of Health.

7.3 Lines to Take

This chapter explores the repeated use of "lines to take" by successive governments, lines which repeatedly asserted or suggested that there was no wrongdoing or fault.

The use of three particular lines to take are examined: the line that people were given "the best treatment available"; the line that screening for Hepatitis C was introduced as soon as it could be; and the characterisation of what had happened and the harm which it had caused as "inadvertent". Some examples are set out below, but the use of these lines is considered in more detail in the chapter.

"*Best treatment available*"

In November 1989, Prime Minister Margaret Thatcher stated at a Downing Street meeting that people infected with HIV from blood products "*had been given the best treatment available on the then current medical advice, and without it many of the haemophiliacs would have died.*" The line was thus first used as part of the justification for not providing compensation to people with haemophilia who had been infected with HIV.

There are then multiple examples of this line being used over the following years: in correspondence, in briefings, and in Parliament. A briefing for Prime Minister John Major in November 1994 included that: "*We have great sympathy with those who may have been infected with hepatitis C through NHS treatment. These patients will have received the best treatment available in the light of the medical knowledge at the time.*" There were, said the briefing, no plans to extend the HIV settlement scheme to those infected with Hepatitis C.

A briefing prepared for a parliamentary question in the House of Lords in January 1995 included that: "*These patients received the best treatment available in the light of medical knowledge at the time*". It was further suggested that non-A non-B Hepatitis was considered to be an "*acceptable side effect*" of treatment with blood products, "*both by physicians and the patients themselves.*" There is no evidence of any enquiries being undertaken to justify the assertion that patients regarded Hepatitis C as an "*acceptable side effect*" of their treatment

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Another use of the line in January 1995 covered people infected with Hepatitis C following transfusion in addition to people infected through blood products. A briefing included the line that: "*We do not accept that there has been negligence. These patients will have received the best treatment available in the light of medical knowledge at the time. We therefore have no plans to compensate those who may have been infected with Hepatitis C.*"

The same line was adopted in Scotland and in Wales to justify not providing compensation. The line continued to be used under the next government. In December 1998 the Department of Health, writing to an individual with regard to the Government's decision not to set up a special payment scheme for people infected with Hepatitis C, stated that: "*Regrettably, some people were infected with hepatitis C through NHS treatment, but this was not through negligence. Patients received the best treatment available based on the knowledge which existed at the time.*" In May 2006, at a time of renewed calls for a public inquiry, Lord Norman Warner, Minister of State within the Department of Health, asserted that: "*This was blood given to people when it was a matter of life or death whether they received that blood, and we were acting on the best scientific and clinical advice at the time.*"

The "best treatment available" line was used by officials advising ministers on how to respond to the Archer report. The briefing for a meeting in March 2009 between the Secretary of State (Alan Johnson) and Lord Archer emphasised that it was "*important to remember*" that "*the treatment given to haemophiliacs was the best available at the time and action was taken in good faith*"; and in June 2009 a submission to the Minister of State for Public Health sought to distinguish the position in Ireland on the basis that "*The Government here has never accepted any liability. We believe that people were offered the best treatment available at the time*".

The reality is that this use of this blanket line to take – sometimes applied to the position of people with bleeding disorders, sometimes to all those infected with Hepatitis C from blood or blood products – was inappropriate. It was wrong and its use was unacceptable. It became a mantra and was never questioned.

Hepatitis C screening

A further line to take which began to feature prominently in the 2000s was the assertion that screening for Hepatitis C could not have been introduced earlier than September 1991. This line was used even after the judgment of Mr Justice Burton in *A and Others v National Blood Authority*, in which he concluded that surrogate testing should have been introduced at the latest by March 1987, and that Hepatitis C screening should have been routinely introduced by March 1990, and even after campaigners pointed out that it was wrong.

Thus, by way of example, in September 2003 Baroness Kay Andrews asserted on behalf of the Government that "*there was no liability when this unfortunate event occurred. There was no test until 1991 for hepatitis C*". This was based on a briefing that asserted that "*The NHS introduced measures to reduce the risk of transmitting Hep C in blood or blood products as soon as the technology existed to do so.*" A briefing for an oral parliamentary

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question in January 2004 suggested the following answer to any call for a public inquiry: "*Donor screening for hepatitis C was introduced in the UK in 1991 and the development of this test marked a major advance in microbiological technology, which could not have been implemented before this time.*"

A brief by Scottish Executive officials for the meeting of the Minister for Health and Community Care with the Scottish Haemophilia Groups Forum on 1 February 2005 stated, in relation to the introduction of Hepatitis C screening in 1991, that this development was introduced "*as early as* [it] *reasonably could be in the light of the current scientific knowledge and technical capabilities at that time.*" And an update for the Secretary of State dated 29 March 2005 emphasised that "*Donor screening for hepatitis C was introduced in the UK in 1991 and the development of this test marked a major advance in microbiological technology, which could not have been implemented before this time.*" In a letter to the Haemophilia Society on 8 February 2006, Caroline Flint repeated that "*Donor screening for hepatitis C was introduced in the UK in 1991 and the development of this test marked a major advance in microbiological technology, which could not have been implemented before this time.*" This was advanced as part of the rationale for rejecting a public inquiry.

On 2 June 2009 a submission to the Minister of State for Public Health, Dawn Primarolo, regarding the Government's response to the Archer report stated, as part of an explanation why the position in Ireland was different, that "*as soon as blood screening tests were available they were implemented.*"

The repetition of this line to take at this stage is particularly incomprehensible because the Archer report had itself set out the facts regarding testing, and Mr Justice Burton's judgment and conclusions, very clearly. No one reading the Archer report could have genuinely believed that "*as soon as blood screening tests were available they were implemented.*"

The line that the screening of blood for Hepatitis C was introduced as soon as possible was untrue. It must have been known to be untrue by the Department of Health, given the judgment in *A and Others v National Blood Authority*. There has been no explanation as to how the line came to be formulated in the first place or why it was parroted without question for years. Poor corporate memory is not an adequate answer, though it explains why use of the line persisted for so long. It is clear that the claim that the screening of blood for Hepatitis C was introduced as early as it could have been influenced the decision-making of successive governments. In particular: it influenced the decision as to whether there should be a payment scheme for those infected with Hepatitis C; it was advanced as a reason as to why no such scheme should be established. It influenced the response to the Archer report. It influenced the decision not to hold a public inquiry.

"*Inadvertent*"

Numerous documents from the Department of Health in the time periods discussed above also referred to the infection of people with HIV or Hepatitis C from blood or blood products being "inadvertent". To suggest, in this context, that something was inadvertent is to suggest

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that it was accidental and unintentional. It hints at something that could not have been known about – a mishap, a chance by-product. Yet the risks of transmission of hepatitis were well known. Such transmission was not the purpose of the treatment, but that it might result was well recognised by clinicians and within government. It had been known for years in medical and public health circles. To characterise it as inadvertent is thus to downplay the significance of what happened.

In their repeated use of these lines to take, successive governments were more concerned about reputational damage than openness and honesty; more defensive than candid; more interested in avoiding financial exposure than in admitting shortcomings.

7.4 Delay in Holding a Public Inquiry

The question why it took until 2017 for a UK wide public inquiry to be established into the worst treatment disaster in the history of the NHS is considered in this chapter. The summary below describes some of the occasions when the possibility of an inquiry was raised or considered but a more detailed narrative is set out in the chapter.

By 1986 the Government can have been under no illusion about the scale of what had happened to people with haemophilia – many had been infected with HIV, a virus with an exceptionally high mortality rate for which there was no known treatment, and sufferers experienced public hostility. The Government knew that the direct cause of this disaster was the treatment which they had received from the NHS. Public inquiries were not unknown in the 1980s. Yet there is no documentary evidence to show that it occurred to anyone within Government before 1989 either that there might be an important public interest in investigating and understanding precisely how this had occurred, or that those whose lives had been devastated in this way might deserve answers as to how and why it had happened. It ought to have been clear that there were lessons to be learned for the future if something similar were not to recur.

In June 1990 a submission on the HIV litigation was sent to the Minister of State for Health, Virginia Bottomley, following Mr Justice Ognall's suggestion of an out-of-court settlement. This referred to the alternative option of a Commission of Enquiry, but noted this might be no quicker than allowing the litigation to take its course and could set a precedent.

In June 1999 Prime Minister Tony Blair responded to Lord Morris's request for a meeting about the case for a public inquiry: "*Though I recognise that people with haemophilia and their families feel a sense of injustice, I am not convinced that a public inquiry would provide greater insight into the problem or pave the way for any further improvements in the safety controls which are now in place.*"

In December 1999, a petition called on the Scottish Parliament "*to hold an independent inquiry into hepatitis C and other infections of people with haemophilia contracted from contaminated blood products in Scotland.*"

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In July 2001 a briefing to Yvette Cooper, Parliamentary Under-Secretary of State for Public Health, noted there was "*considerable parliamentary concern on this issue. Lord Morris … and a number of backbench MPs regularly raise questions in both Houses*." It also referenced the "*high profile*" campaign by the Haemophilia Society that was "*calling again for a Public Inquiry.*"

The briefing included a list of options following the judgment of Mr Justice Burton in *A and Others v National Blood Authority*. One option was a public inquiry alongside the provision of a lump sum and hardship fund. The arguments against this stated that the relevant facts were largely established and the information was in the public domain. Further arguments against included the concern that a "*Public Inquiry would raise the profile of potential no fault compensation at a time when litigation in the NHS is an increasing problem.*"

In December 2003 Lord Warner told the House of Lords that: "*I have to make it as clear in as gentle a way as I can that the Government does not accept that any wrongful practices were employed, and do not consider that a public inquiry is justified*".

In Scotland Andy Kerr, Minister for Health and Community Care, stated in November 2004 that "*It is our view that there is nothing to be learned from a public inquiry that has not already been learned. We have, however, stated that should any new evidence come to light that this would be reconsidered.*"

In a briefing to Westminster ministers in June 2006, the "*considerable pressure*" for a public inquiry was noted and that "*patient groups continue to press for higher levels of compensation and believe an inquiry could help to achieve this by demonstrating the Department was culpable*". The advice of officials was that, on balance, "*we consider an inquiry to be disproportionate and not justified in the circumstances.*"

Lord Warner suggested that rather than a public inquiry the powers under the National Health Service Act 1977 could be used "*to commission a review of ALL the documents (new ones, old ones and if possible Scottish ones) with a view to producing an independent legal/ judicial commentary on them and putting all these into the public arena.*" He thought a retired judge or Queen's Counsel could do this with an administrative support team. Ultimately, this review was carried out internally by a Departmental official. When asked whether the internal review fulfilled its objective Sir Hugh Taylor (Permanent Secretary of the Department at that time) stated that it: "*could be said to have met its, inevitably limited, objectives. However, reflecting on this question now, there is a limit to how far an internal Departmental review of this kind was likely to assuage public concern, given its limitations. The review rehearsed rather than re-examined the Department's previous analysis of the history, which the new documentation did not appear to undermine, but which was still being challenged by campaigners. It was not resourced to put the original decision making on these issues under the microscope in the way that, given the passage of time that had already elapsed, only a statutory inquiry with the power to call witnesses and with the resources and expertise to apply an objective forensic analysis to the evidence could do.*"

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In August 2007, it was confirmed that a separate Scottish inquiry would be held, and the Penrose Inquiry was announced in April 2008. Throughout the period of that inquiry, the campaign for a public inquiry in England continued. The Department of Health's position remained that no public inquiry was required.

On 25 March 2015, the Penrose Inquiry report was published. On the same day the Prime Minister, David Cameron, made an apology in the House of Commons. In a Commons debate the following day, Andy Burnham MP stated: "*The 2010 to 2015 Parliament will be remembered for some extraordinary work to right historical wrong – on Bloody Sunday, on Hillsborough, on child abuse – but as it comes to an end this Parliament has not made enough progress on perhaps the greatest injustice of them all: the loss and ruination of many thousands of lives through the use of contaminated blood.*" He asked for "*a further process of Inquiry in the next Parliament*".

Jane Ellison, Parliamentary Under-Secretary of State for Public Health, replied that: "*The Government's initial reaction is that another inquiry would not be in the best interests of sufferers and their families as it would further delay action to address their concerns. The strong message I have had is that it is time for action*".

Jeremy Hunt told the Inquiry that it was made clear to him when he became Secretary of State for Health in 2012 that "*the Treasury would not support an inquiry because of the potential cost to the taxpayer which (taking into account any decisions on financial support which might follow, such as a recommendation for a compensation scheme similar to that in place in Ireland) could amount to billions of pounds.*" He did not therefore pursue the issue and followed the official Government line in correspondence with all campaigners.

Following further pressure from Diana Johnson MP, a submission on 7 July 2017 noted that the leaders of opposition parties had written to the Prime Minister Theresa May calling for a public inquiry and that pressure for an inquiry had increased because of recent events "*including the announced inquiry into the Grenfell Tower fire and recent media articles on infected blood*". It concluded with a recommendation that the Government announce its intention to establish an inquiry. Jeremy Hunt informed the Prime Minister on 10 July that he was minded to hold an inquiry. In identifying the turning point in the Government's stance, he said: "*I think the real thing that caused, if I can put it this way, the goal to be open, was the threat of losing a vote in Parliament which was subsequent to this when the Speaker said that he would allow a debate. And I think that was really what allowed me to go to Theresa May and say, 'Look, I think this is the right thing to do and this is the moment to do it.'*"

This Inquiry was announced on 11 July 2017. The concerns expressed in 2017 were largely the same concerns that had been voiced by campaigners and others (including parliamentarians) for the previous two and a half decades.

The reasons that were given over the years for declining to hold a public inquiry do not stand up to scrutiny. It was said that there was no evidence of wrongdoing. But that was a self-serving assessment. Given the extensive concerns raised by campaigners and others there was an imperative for an independent inquiry to examine and determine the question

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of fault rather than leave the Department of Health to mark its own homework. It was said that the relevant facts were all in the public domain. They self-evidently were not. It was suggested that this was a problem linked to the state of science and technology. That was (plainly) an exceptionally and unduly restrictive way of looking at the issues (and, as detailed in the *Lines to Take* chapter, the Department of Health repeatedly asserted that "*technology*" for Hepatitis C screening was not available before 1991, when in fact it was). It was even said that these matters had been looked at by Lord Archer and Lord Penrose, in circumstances where the Department of Health had sought to distance itself from each. It was said that these events were historic. They were not, and are not, to those who survived and live with the impact of the infections and to the families of those who had died. Perhaps most astonishing was the assertion that an inquiry would not help those infected and their families: to do so would not be in their interests. Just as clinicians had purported to know what was in patients' interests in terms of the treatment that infected them, now politicians and civil servants purported to know better than those whose lives had been devastated.

There are many who, having been repeatedly denied a public inquiry, have felt obliged to try and piece together the truth themselves, whether through undertaking careful and painstaking research, targeted Freedom of Information requests; patiently raising questions through MPs time and again; or participating in demonstrations. The people infected and their families, and the campaigning organisations they formed, have demonstrated persistence and resilience as they were answered with repeated variations of the same lines to take. They were "*fobbed off time and time again.*"

One reason to refuse an inquiry was an inherent defensiveness – a reluctance for the decisions, actions and omissions of both the NHS and government to be assessed and exposed. Jeremy Hunt said that the state, including the civil service, "*didn't have an open mind to this issue. They basically had decided that the State in the 1970s and 80s had done the best it could in the circumstances*". The second and related reason was what Jeremy Hunt described as the "*massive institutional reluctance in the NHS to listen to the stories of ordinary people when things have gone wrong … there was certainly a very strong view that harm to patients is part of the cost of doing business. It's part of what happens.*" That description is as equally applicable to government as to the NHS.

This was a collective failure by civil servants and ministers of successive governments, and is all the more serious for being so.

7.5 Accountability in the Absence of a Public Inquiry

In the absence of a public inquiry, some of the people infected tried to get answers and/or hold people and organisations to account by other means: NHS complaints, the Ombudsman, the General Medical Council and the police.

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NHS complaints procedures

The Inquiry has reviewed a number of different complaints made under the informal processes of a number of NHS trusts and health boards. No particular patterns are discernible in the type of complaint made, or the likelihood of the outcome.

The adequacy of NHS internal complaints procedures has been analysed and subjected to criticism by external bodies over the years – see, for example, the 1994 Wilson Report *Being Heard*, the 1999 Public Law Project report *Cause for Complaint?,* the Department of Health's publication in 2003 of *NHS Complaints Reform – Making things Right,* the fifth report of the Shipman inquiry in December 2004, the report of the public inquiry into Mid Staffordshire NHS Foundation Trust, and a December 2015 report into the quality of NHS complaints which found that 40% of investigations were not adequate to find out what happened and there was a wide variation between and within trusts in terms of how patient safety incidents were investigated. It also found that "*Worryingly, medical records, statements and interviews were missing from almost a fifth of investigations making it even harder for trusts to arrive at what went wrong and why.*"

In light of these earlier analyses, this Inquiry does not need to make any additional findings about the limitations of the complaints procedures. It notes, however, that whilst a complaint about a specific clinician or hospital might address specific concerns regarding the treatment of an individual, such complaints could not be a substitute for a public inquiry into how so many people had been infected.

Ombudsman

Individuals who were not satisfied with the outcome of their complaint under NHS procedures could take the matter to one of the Ombudsman services across the four nations. As with the NHS complaints processes, there is in the material available to the Inquiry considerable variety in the complaints that have been made to an ombudsman.

The Parliamentary and Health Service Ombudsman can consider complaints about government departments. The limitations of that role are apparent from the terms of a letter in response to a complaint about the Department of Health: "*I see no evidence here of maladministration in the government's decision-making process and so there is no basis on which I could reasonably question the merits of the decisions reached, or ask for them to be reviewed. […] While I do not, of course, condone the Department's premature destruction of key papers, they have investigated how and why this occurred; and they have taken appropriate action to help prevent a recurrence. They have also apologised … I can find no evidence in the papers that would lead me to question the Department's explanation, and so there is no basis to justify my intervention.*"

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General Medical Council

The General Medical Council ("GMC") is the professional regulator responsible for the regulation of doctors. It is empowered to undertake fitness to practise investigations and to erase or suspend a doctor's right to practise in the UK.

There were, unsurprisingly, a number of complaints to the GMC by individuals who had been infected with HIV or Hepatitis C in relation to the clinicians who had treated them with blood or blood products. The GMC has told this Inquiry that the question of consent was raised in the majority of the complaints it received against clinicians in relation to infections caused by blood transfusion or blood products, and that there were "*no cases where a finding was made that a doctor's fitness to practise was impaired or where a doctor was found guilty of serious professional misconduct. No action was taken on the registration of any of the doctors complained about.*"

In closing submissions on behalf of core participants, the GMC's process as it was in earlier years was characterised as being "*such an opaque complaints procedure that the complaints were never properly investigated, and patients were never given sight of the response evidence provided by doctors*" and as a "*woeful response*".

Police

Some people have also felt driven to go to the police but the Inquiry does not have any evidence of investigations being pursued beyond an initial stage. As observed in submissions to the Inquiry, "*it is incontrovertible that campaigners looked down every alley in their search for justice*". They should not have had to do so.

The Public Administration Select Committee in 2005 referred to the six functions of an inquiry identified by Sir Ian Kennedy: the recognition and identification of different, genuine perceptions of the truth; learning; healing; catharsis; prescribing; and accountability. Plainly none of the other avenues – NHS complaints, the Ombudsman, the GMC, the police – that people infected and their families felt driven to pursue could have met these objectives. In particular none could have provided a full and fair account of what had happened, or provide any real form of accountability.

7.6 Scotland

The purpose of this chapter is to consider the response of the government within Scotland to the position of people who were infected and their families.

Prior to 1999, there was administrative devolution in Scotland: other than matters such as foreign policy, defence and social security, everything – including policy in relation to health – fell within the powers of the Scottish Office. At the same time, "*we were one Government*". On matters of health, the Scottish Office, through the SHHD, largely followed the lead of the Department of Health. That position fundamentally changed in 1999 with the establishment of the Scottish Parliament and of a Scottish Executive.

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This chapter considers the following issues: the calls for compensation for people with haemophilia infected with HIV; the HIV litigation; the response to the position of people infected with HIV through transfusion; the use of "lines to take"; the calls for compensation for people infected with Hepatitis C; the Scottish Executive's investigation and report; the investigation by the Health and Care Committee of the Scottish Parliament; and the approach to holding a public inquiry.

On the question of calls for compensation for people with haemophilia infected with HIV, ministers and civil servants adopted a "no negligence, no compensation" approach, following the lead of the Department of Health. The Secretary of State for Scotland did attend the Cabinet sub-committee which decided in November 1987 to make the ex gratia payment that led to the establishment of the Macfarlane Trust, but there is no evidence of Scottish Office involvement in the announcement two years later to make a further payment to the Macfarlane Trust.

There was, as described in the chapter on the *HIV Haemophilia Litigation*, no prior consultation with the Scottish Office before the announcement by Prime Minister John Major in December 1990 that the Government had agreed in principle to proposals to settle the litigation, and there had been no parallel negotiations with Scottish litigants and their lawyers. The claims in Scotland were eventually settled on terms similar, although not identical, to those in England and Wales.

On the question of making ex gratia payments to people infected with HIV through transfusion, William Waldegrave's letter of 2 December 1991 to the Chief Secretary to the Treasury, recommending a change of policy, was copied, among others, to the Secretary of State for Scotland, Ian Lang. Scottish officials recommended he support the proposal, noting that the media was sympathetic and that the arguments defending the differences between people with haemophilia and this group of patients "*have increasingly been recognised as untenable.*" Michael Forsyth, the Minister of State for Scotland, had previously expressed the view that the scheme should be extended to those infected through transfusion, but had been told by officials that "*The Scottish Office could not adopt a policy which would undermine the stance taken by other UK Health Departments.*"

The "best treatment available" line was used by Scottish officials and ministers, with the aim of ensuring "*a consistent line between Health Departments*", as was the suggestion of "*inadvertent harm*". Professor Aileen Keel, who had been a senior medical officer in the SHHD in the 1990s, sought to defend the "best available treatment" line in her evidence to the Inquiry, but the line was a wrong one to take.

In August 1995 the CMO of Scotland, Dr Robert Kendall, advised the Minister of State at the Scottish Office (who had expressed some sympathy with the calls for compensation for Hepatitis C) that financial redress for infection with Hepatitis C would have to be decided on a UK basis. He drew attention to a recent statement by the Secretary of State for Health, Stephen Dorrell, which "*very strongly*" suggested that the Department of Health would resist

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offering compensation and advised that it would be extremely difficult for Scotland to attempt to adopt a different policy.

This was the position when the Scotland Act 1998 created the Scottish Parliament and the Scottish Executive took over responsibility for health from 1 July 1999.

In July 1999 a briefing to the Minister for Health and Community Care, Susan Deacon, informed her about the Haemophilia Society's continuing campaign for compensation for people with haemophilia infected with Hepatitis C. In August 1999, the Health and Community Care Committee called for an immediate Executive inquiry into delays in introducing heat-treated concentrates in Scotland. Susan Deacon told the Inquiry that she then decided to instruct officials to pool together "*proper facts*". The chapter considers in some detail the approach taken by the Scottish Executive in undertaking this investigation and finds that the process was flawed.

The resulting report was published in late October 2000. It did not consider more general questions about the infections, as the Haemophilia Society had asked and anticipated from their meetings with the minister and officials. The Haemophilia Society was gravely disappointed as it did not address their concerns that patients had not been given information about the risks of their treatment; that some patients had been tested and not told the results; that in many cases there was delay ("*well over a decade*") in being told; and that in some centres testing had not been done properly. The report had concluded that there was "*no evidence that clinicians had a policy to deliberately mislead their patients about the risks of using Factor VIII*." The Haemophilia Society observed that in order to reach this conclusion the authors of the report had spoken only to doctors, and had not obtained information directly from patients.

The Health and Community Care Committee of the Scottish Parliament undertook its own evidence gathering exercise and in September 2001 issued a report which considered three principal issues: whether ALT testing should have been introduced; the delay in introducing heat treatment for Scottish concentrates; and the failure to inform patients fully of the risks involved. The Committee also considered what it described as a fundamental question of fairness and consistency. It pointed to the recent *A and Others v National Blood Authority* decision, and the existence of the Macfarlane Trust, and was persuaded by the moral case for providing financial assistance to people infected with Hepatitis C through blood and blood products, concluding that: "*financial and other practical assistance, awarded on a no-fault basis, is the clearest solution to the issues raised in these petitions. We believe as a matter of fairness that individuals who have suffered serious, long-term harm as a result of NHS treatment should receive some practical assistance. We also believe that this solution is required for reasons of consistency, in recognition of the fact that HIV sufferers already receive assistance, under clearly analogous circumstances, via the MacFarlane Trust.*" The committee recommended that a mechanism for achieving this should be set up and come into operation within a period of twelve months.

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On 11 December the Executive announced it would establish an expert group to look at "*the pros and cons of a system to offer financial and other support for people who have been harmed by health service treatment and where the NHS is not at fault.*" The press release stated that extending the current regime to people infected with Hepatitis C would be unfair to those affected by "*other conditions in a similar way*" and would create a risk-averse culture within the NHS.

The expert group was established under Lord Ross. Its preliminary report in September 2002 concluded that it was inequitable that people infected with Hepatitis C had not received any financial support, and recommended that they receive specific lump sum payments. In November 2002 the Scottish Executive's response noted the complex medical, legal and financial considerations, and that the Executive needed to "*think carefully about who needs help, what is the best way to design a scheme and structure payments so that the individuals involved benefit fully, while taking account of the costs of any payment scheme in the light of other health priorities.*"

In January 2003 Malcolm Chisholm who had replaced Susan Deacon as Minister for Health and Community Care sought Cabinet agreement to an approach for making lump sum payments to people experiencing long-term symptoms or signs of liver inflammation, with increased awards to those developing more serious conditions such as cirrhosis. Three options were identified, with the Minister supporting the third option (£25,000 (later adjusted to £20,000) + £25,000).

The final Expert Group report in March 2003 confirmed the recommendation that the Scottish Executive should agree to make compensation payments as a matter of urgency to anyone who could demonstrate on the balance of probabilities that they had been infected with Hepatitis C from blood, blood products or tissue received in the NHS in Scotland. The group believed there was a moral obligation to provide compensation and that justice would not be done unless its recommendations were implemented.

In fact, none of the Ross recommendations were implemented. A combination of reluctance in the Scottish Executive to commit to the expenditure and the alarm engendered in Westminster, led eventually to the introduction of the more limited scheme that became the Skipton Fund.

Continued campaigning activities, a call from the Health and Care Committee in 2006 for an independent public inquiry, the judicial review claims which succeeded before the Court of Session in early 2008, and the new Scottish Government's commitment to a public inquiry, led to the announcement in April 2008 of the Penrose Inquiry.

The chapter concludes that in the period prior to July 1999 the Scottish Office essentially followed the path mapped out by the Department of Health. Accordingly, the same damaging approach – an unwillingness to provide financial support, a misplaced fear of setting precedents, the repetition of inaccurate and harmful lines to take, the absence of any meaningful or robust or independent investigation – was mirrored in Scotland.

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The chapter further concludes that the move to devolved government in 1999 did not bring about the sea change campaigners had hoped for.

7.7 Northern Ireland and Wales

This chapter looks at the (very limited) evidence available as to the response of government within Wales and Northern Ireland.

In Northern Ireland the response of the DHSSNI in the 1990s and 2000s (both before and after the enactment of the Northern Ireland Act 1998) largely echoed the response of government in Westminster. On matters relating to the infection of people with hepatitis and HIV through blood and blood products, the relationship largely remained one of "*mirrored subservience*". Thus, there is no evidence to suggest any substantive involvement in the decision-making that led to the decision to make a payment of £10 million to what became the Macfarlane Trust. There is little evidence of any meaningful involvement of ministers within the Northern Ireland Office in the decision-making that led to the announcement of an additional payment to the Macfarlane Trust in November 1989. There is little evidence relating to the involvement of the Northern Ireland Office in the settlement discussions relating to the HIV haemophilia litigation. The Secretary of State for Northern Ireland, Peter Brooke, supported the proposal from William Waldegrave to make ex gratia payments available to those infected with HIV through blood transfusion, expressing the view that "*there is little public understanding or sympathy for the Government's position on this matter and that the campaign for a settlement is likely to gather momentum in the months ahead.*" In 1995 John Breen, a civil servant who worked in the Health Promotion branch, prepared a submission dated 31 May 1995 which noted that many similar representations could be expected over the coming months. The submission suggested that preliminary estimates would put the number infected with Hepatitis C through blood transfusions or blood products in Northern Ireland at about 100, of whom approximately 50 had haemophilia. Reference was made to the Department of Health in London's "*standard response indicating that the Government does not propose to pay compensation since there was no question of negligence on the part of the NHS and that it believes that the most effective use of resources is to seek to improve the understanding, management and treatment of the disease*".

John Breen told the Inquiry that he passed on the line approved by Ministers in London and that "*The policy in Northern Ireland, as I understood it, was to follow the policy adopted in London.*" He felt it was premature to make any concessions in respect of compensation "*because the matter had not been firmly decided by the Department of Health in London.*"

An attempt was made by the Department of Health in mid 1995 to "*establish the views of the Territorial Health Departments*". A handwritten SHHD file note, undated but written after 9 May 1995, refers to the author having received phone calls from John Breen (and from Peter Davenport in the Welsh Office) regarding the issue of compensation for those infected with Hepatitis C. The note records that "*Both Wales and N.I. were concerned about the financial implications of what seems to be a marked softening in the DoH attitude towards compensation. Apparently the sum of £60,000 is being considered per case and*

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the Treasury have already made it clear that the funds must be found from within existing resources." A "*council of war*" with the Welsh Office and Northern Ireland Office had been agreed. The position of officials in Northern Ireland as communicated to the Department of Health in early June 1995 was that "*Officials' view is that it is difficult from point of view of equity to resist comparisons with HIV compensation. But this could mean a substantial drain on health resources. The views of Ministers have not been sought yet.*"

The response of the Welsh Office and, post devolution, the Welsh Assembly Government in the 1990s and 2000s to the position of people infected with hepatitis through blood and blood products largely echoed the approach taken by the Department of Health in London. David Hunt, who was the Secretary of State for Wales in the early 1990s, explained that the "*room for manoeuvre*" that he had in that role was "*in practice very limited in most instances, except at the margins of policy.*" As with Northern Ireland, ministers within the Welsh Office had little if any direct involvement in the decision-making that led to the initial payment to the Macfarlane Trust or to the further payment announced in November 1989; there is little evidence of Welsh Office involvement in the settlement discussions in the HIV haemophilia litigation; and the Welsh Office took its lead from the Department of Health on the question of financial support for those infected with Hepatitis C. The same position was maintained by the Welsh Assembly Government in the 2000s.

It is a sad commentary on these arrangements (in respect of infected blood) that no-one involved in health policy at the Welsh or Northern Ireland Office queried that policy following the decision in *A and Others v National Blood Authority* in 2001 – for this cast a very different light on the facts from that presented by the Department of Health in London.

In theory, devolution of health powers meant that Northern Ireland and Wales had more freedom but in practice, the Department of Health policy continued (largely) to be followed in the 2000s.

What has been said about the response of the government in England thus applies to Northern Ireland and Wales too – except for the added criticism that policy on infected blood was determined with a lack of curiosity as to whether the English position was actually justified.

7.8 The Government's Response to Calls for Compensation from 2020-2024

This chapter considers the calls for compensation since 2020 and the Government's response. It does so at a time when it is still not known how the Government intends to respond to the recommendations that have been made, save that the Victims and Prisoners Bill has at the time of writing reached the report stage and provides for the establishment of an Infected Blood Compensation Authority and on 30 April 2024 an amendment requiring the scheme to be set up within three months of the Bill receiving Royal Assent was accepted.

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On 13 July 2020 the Paymaster General Penny Mordaunt wrote to the Chancellor of the Exchequer, Rishi Sunak, on compensation: "*Following the stakeholder meeting in January, Minister* [Oliver] *Dowden wrote to the Prime Minister setting out agreed actions to address the most pressing issues of support, including consideration of a framework for compensation … I believe it to be inevitable that the Government will need to provide substantial compensation … I believe we should begin preparing for this now, before the Inquiry reports.*" The Paymaster General wrote again to the Chancellor on 21 September 2020. She repeated her expectation that the Inquiry would make recommendations about levels of financial support. It was, she said, "*inevitable that the Government will need to provide substantial compensation.*" She indicated that the costs were likely to be high and she firmly believed that the Government should "*begin preparing for this now – before the Inquiry reports.*" She said "*I cannot stress enough the urgency of taking long overdue action on financial support and compensation.*"

The question of compensation was not new in 2020. An awareness that compensation might be recommended was a central factor in the unwillingness of successive governments to establish a public inquiry.

Penny Mordaunt told the Inquiry that she would expect anyone in Government with a working knowledge of the infected blood scandal to understand that people were continuing to suffer and continuing to die – that this was not only a matter of historical injustice. One purpose of raising at that stage the "*inevitable outcome*" of compensation was so that the Treasury could start to make appropriate provision and so that all Government departments were "*aware of what is likely to need to happen and prepare for that.*" She wanted to give the Treasury "*some encouragement to grip the issue*".

There was no formal response to this letter but on 25 March 2021 she was able to announce that: "*To meet the Government's commitment to consider a framework for compensation, we can confirm our intention to appoint an independent reviewer to carry out a study, looking at options for a framework for compensation, and to report back to the Paymaster General with recommendations, before the Inquiry reports.*" This study would provide advice on "*potential compensation framework design and solutions which can be ready to implement upon the conclusion of the Inquiry, should the Inquiry's findings and recommendations require it.*" It was her expectation that the Government's response would be published and shared with the Inquiry so that the Inquiry would have the benefit of considering it.

Giving evidence to the Inquiry in May 2021 the then Secretary of State for Health Matt Hancock agreed that there was a moral responsibility on the Government to address the impact of what has happened to those infected and affected. He added: "*should the Inquiry's recommendations point to compensation, then of course we will pay compensation and Sir Robert Francis's Review on compensation is there in order that the Government will be able to respond quickly to that … what I can say to you is that we will respect the outcome of the Inquiry and if the Inquiry points to compensation, as opposed to a support scheme, in the future then the Government will pay compensation.*"

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Sir Robert Francis KC was appointed and delivered his report *Compensation and Redress for the Victims of Infected Blood – Recommendations for a Framework* on 14 March 2022.

The Paymaster General Michael Ellis, who had succeeded Penny Mordaunt, explained that: "*It is my intention to publish the Study and the Government response, in time for the Inquiry and its core participants to consider them before Sir Robert gives evidence to the Inquiry.*" On 22 March he gave the same message, and again on 31 March 2022, and on 27 April, that: "*It is my intention to publish the compensation framework study alongside the Government's response as soon as possible, and in sufficient time for the infected blood inquiry and its core participants to consider them before Sir Robert gives evidence to the inquiry.*"

Despite the Government making it clear, in these various statements, (a) that it would publish its response to Sir Robert's study at the same time as the study itself and (b) that it understood the importance for those infected and affected to be able to consider the Government's response before Sir Robert gave evidence to the Inquiry, on 7 June 2022 the Government published the study but **no** response from the Government to that study. What was said on this occasion by Michael Ellis was that: "*There is a great deal of complexity to the issues that the study covers and a wide range of factors to be taken into account in considering Sir Robert's recommendations. This analysis cannot be completed hurriedly but officials across government are focussing on this so that the government can be ready to respond quickly to the Inquiry's recommendations, as was intended when the study was commissioned.*"

On 9 June, the Paymaster General told the House of Commons that the Government was considering Sir Robert's recommendations, that he would update the House as the work progressed, and that "*Sir Robert will give evidence to the Inquiry on 11 and 12 July, so just a few weeks from now, and the Government will need to reflect very carefully on his evidence to the Inquiry in considering his study.*" In response to further questions, the Paymaster General said that Sir Robert's recommendations needed "*careful consideration*", which it would be "*remiss*" of the Government to "*rush*": "*It is most important that we are able to reflect on his evidence, which he is due to give in four or five weeks' time, and we will do so after that.*" The Government would, he indicated, "*want to hear what* [Sir Robert] *has to say. We will study it very carefully and will act as expeditiously as possible after that.*"

This statement would be reasonably understood as the Government indicating that it **would** respond to the compensation framework study once it had considered Sir Robert's oral evidence (on 11 and 12 July 2022).

Sir Robert gave evidence to the Inquiry on 11 and 12 July 2022. On 14 July Dame Diana Johnson MP reminded the Paymaster General that people infected had continued to die since the announcement of the Inquiry ("*Time is pressing*"). In response he assured her that the matter was being given "*expeditious consideration*" and that the Government would respond to Sir Robert's recommendations "*just as soon as possible.*"

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Despite many more parliamentary questions, over two years after Sir Robert delivered his study to the Government, people who are infected and affected still do not know the Government's response to his recommendations.

The Inquiry's First Interim Report was published on 29 July 2022. This recommended that an interim payment, of no less than £100,000, as recommended by Sir Robert, should be made without delay to all those infected and all bereaved partners.

The Government responded promptly to this recommendation, announcing on 17 August 2022 that interim payments of £100,000 would be made to infected individuals and bereaved partners.

In February 2023 the Inquiry stated that it would be publishing a second interim report, about the Compensation Framework Study by Sir Robert Francis KC. The Inquiry published that report on 5 April. The principal recommendation was that a compensation scheme should be set up "*now*" and should begin work "*this year*" (i.e. 2023). A further recommendation was that an interim payment should be paid "*to recognise the deaths of people to date unrecognised and thereby alleviate immediate suffering.*" This reflected the fact that "*some people have died as a result of infected blood and blood products without any payment being made in respect of their death, leaving bereaved parents, children or siblings who have suffered profound distress and loss which has to date been unremedied.*"

On 12 June 2023 UK, Scottish and Welsh Ministers, and the Northern Ireland Department of Health Permanent Secretary, met for the first time to discuss compensation. A joint communique noted agreement that working together to enable a response as soon as possible after the Inquiry concludes did "*not preclude earlier announcements as work progresses.*" There have, however, been no such announcements.

In July 2023 the Prime Minister told the Inquiry that the work was not concluded and no decisions had been made: the Government did not yet have options that were ready to implement on conclusion of the Inquiry. Jeremy Hunt, giving evidence in his capacity as Chancellor of the Exchequer, told the Inquiry that "*we are genuinely in a situation where no decisions have been made about the level of compensation or how it will be funded.*" He could not say where the funding would come from or what the timescales were. He did think that "*good progress has been made*" but there was more work to do.

The above narrative speaks for itself. It needs little commentary, beyond a brief highlighting of the chronology:

- The Government did not do what it said it would: publish its response to the Compensation Framework Study alongside the study itself and in advance of Sir Robert's evidence to the Inquiry.
- The Government then failed to publish its response after Sir Robert's evidence, despite saying that it would "*act as expeditiously as possible after that.*"

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- The Government has not yet (as at today) published any response to the Compensation Framework Study.
- Little appears to have been done before late 2022. The fact that the first cross – government meeting of senior officials took place in November 2022, that it was only decided in early 2023 to establish a DHSC team to undertake costs analysis, that the Small Ministerial Group met for the first time on 22 February 2023, and that the first ministerial meeting involving the devolved administrations was not until June 2023 have the appearance of working at a sluggish pace.
- The Government said it was planning to be ready to respond to compensation recommendations that it expected to arrive in mid and then autumn 2023. On that timescale, its work should now be complete.
- Such evidence as there is suggests that this is not the case and that key decisions may still remain to be made.
- At several stages Government has said that it would update Parliament with as much detail as it could as work progressed. It is a matter of regret to this Inquiry that the Government has found little to report.

The effect of what has happened is that the Inquiry's own consideration of compensation has not been able to be informed by the Government's response to the Compensation Framework Study, that the Government's response has (thus far) escaped the scrutiny of the Inquiry; and that those infected and affected have felt a lack of transparency and openness characteristic of what they have had to face, and have been fighting, for nearly half a century.

The rationale of waiting for this Report, as explained to the Inquiry, begs for a better explanation. This is not a case in which the Government is expecting a report that says everything was done as it should have been. The expectation of the then Paymaster General, Jeremy Quin, as at 25 July 2023 was that the full report would put the compensation proposals "*into further and – I fear in many ways – deeply upsetting context.*" He confirmed a month later in his oral evidence his expectation that the final report "*will unveil very, very significant issues that happened over many decades and should never ever have happened.*" Penny Mordaunt recognised in Parliament in October 2023 that people have suffered "*layer upon layer of injustice*". The Prime Minister has acknowledged that what has happened "*has been an appalling scandal … thousands of people … have suffered for decades, and they have suffered a layer of injustices at that … this is not just about historic wrongs, people are suffering and being impacted today.*" Despite this, and the Government's acceptance of the moral case for compensation in December 2022, the Government has insisted upon waiting for this Report, despite knowing that the Inquiry's Second Interim Report contains its full recommendations on compensation.

Campaigners and Parliamentarians have continued to press the Government to share information. Jeremy Quin suggested the final report "*will enable the Government to see*

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those recommendations in their full context" and that "*Being able to put the Government's response into the context of those findings is a useful and helpful thing to do in justifying our actions*". Jeremy Hunt expressed the view that it was "*responsible and right to the taxpayers, who are funding this, for Government ministers to see the full context of the horrific scandal that this was, before we make the final decision as to how the compensation will work.*" But when the Government knows, as it clearly does, that what happened was a terrible injustice, that people deserve redress, and that lack of redress perpetuates the injustice, then to delay, and thus deny, justice in order to await the "*full context*" seems hard to justify.

7.9 Commentary on the Government Response

This chapter seeks to pull together some of the threads and themes from the preceding chapters in order to answer the Inquiry's Terms of Reference.

The Terms of Reference of the Inquiry include whether there was a "*cover-up*". A better expression to convey what happened is "hiding the truth". Hiding the truth includes not only deliberate concealment but also a lack of candour: the retelling of half-truths such as the "no conclusive proof" line; and failing to tell people about the risks inherent in treatment or the alternatives to that treatment, that they had been tested for infection, or been used in research, or were suffering from a potentially serious and fatal disease.

Clinicians and the NHS

A number of individual witnesses who gave evidence, or provided statements, record that they were told by their doctors that the risks to them of their contracting non-A non-B Hepatitis were relatively unimportant. Some people who had bleeding disorders were told that the risk of AIDS was undoubtedly far less than the dangers of not being treated with concentrate. In both cases, the seriousness of what the patient was facing was underplayed. In an even greater number of cases, people were given no information whatsoever about the risks of viral transmission from transfusion, or from treatment with blood products. There is overwhelming evidence, from a large number of people, of differing backgrounds, different ages, and different ways of expressing themselves, to exactly this effect. When coupled with the evidence as to what was or should have been known about non-A non-B Hepatitis and the risks of AIDS, and what was, frankly, not yet known but was entirely possible, there can be no other conclusion save that the whole truth was not given to them. Clinicians, or civil servants, often did not in fact know: but they did not admit to this, and instead assumed a more comfortable "truth" which had no adequate basis. And for some people the very fact that they had been infected, or the means by which they had been infected, was not disclosed to them, sometimes for years.

The evidence before the Inquiry that the truth was concealed or suppressed in this sense and in these ways is overwhelming.

The chapter then considers three specific examples: the first involves the provision of information by a haematologist at the Cardiff haemophilia centre to journalist Susan Douglas,

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and the response of the Press Council to the subsequent publication of Susan Douglas' article; the second involves a deception perpetrated on a woman who had just given birth and who was reassured that blood was heat treated; the third is of a clinician withholding from the wife of a deceased patient the fact that her husband had been infected with HIV following treatment.

The NHS did not respond to the infection of thousands of people with HIV and hepatitis, through transfusion or treatment with blood products, by undertaking investigations, providing detailed explanations, making sincere apologies and doing everything that could be done to learn lessons. Instead, what is apparent is a defensive closing of ranks.

There have without doubt been individual apologies from clinicians that were heartfelt and sincere; and there has been, in this Inquiry, some insightful organisational self-reflection. But most apologies have never been accompanied by any admission of anything having been done wrong.

The response of government

Just as the NHS responded defensively, so too did successive governments. The Report has found that the government resolved against any form of compensation at an early stage. It wrongly described the infection of thousands of people with fatal viruses as the unavoidable adverse effects of medical treatment. It thought at the outset that no one could or should be held responsible and that nothing had been done wrong. It assumed, without listening to the patients themselves, that doctors and the NHS had done nothing wrong and that the risks had been explained. Financial and reputational considerations predominated.

Five features characterise the government response. First, when financial support payments have been agreed at different points – initially for people with haemophilia infected with HIV, then for people infected through transfusion, and later for people infected with Hepatitis C – this has been in response to intense parliamentary, media and/or public pressure. The second feature is the slow and protracted nature of the government response: decision-making has taken far too long. Third is that governments have generally sought to provide the least that they can, to limit expenditure on financial support, despite the recommendations of the Ross expert group in Scotland, and the Archer Inquiry. The fourth feature is that in the past any steps towards some form of recognition have been accompanied by an insistence that nothing had been done wrong. The fifth is that, although now accepting that wrongs were done, the Government does not yet appear to be clear as to what lessons it has already learned, or seeks to learn, from the history it now accepts.

Standing back, and viewing the response of the NHS and of government, the answer to the question "was there a cover up?" is that there has been. Not in the sense of a handful of people plotting in an orchestrated conspiracy to mislead, but in a way that was more subtle, more pervasive and more chilling in its implications. To save face and to save expense, there has been a hiding of much of the truth.

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This failure to bring the true facts to life has come partly from the inertia of groupthink; but partly, it must be recognised from instinctive defensiveness, to save face and to save expense. When thousands of families had their lives irrevocably changed, though, it should not have taken decades for the truth to come out. That is a collective failing of successive governments.

This Report has found that there was deliberate destruction of documents of relevance. It has found that the Self-Sufficiency Report published in 2006 was self-justifying and that its redrafting had the effect of hiding significant information. It has found that over decades successive governments repeated lines to take that were inaccurate, defensive and misleading. Its persistent refusal to hold a public inquiry, coupled with a defensive mindset that refused to countenance that wrong had been done, left people without answers, and without justice. This has also meant that many people who are chronically ill have felt obliged to devote their time and their energies to investigating and campaigning, often at great personal cost.

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Glossary for the Overview

ACTTD	Advisory Committee on Transfusion Transmitted Diseases
ACVSB	Advisory Committee on the Virological Safety of Blood
ALT	alanine transaminase
APPG	All-Party Parliamentary Group
AFP	alpha fetoprotein
AHG	antihaemophilic globulin
BPL	Blood Products Laboratory
BSE	bovine spongiform encephalopathy
CDC	Centers for Disease Control and Prevention
CBLA	Central Blood Laboratories Authority
CMO	Chief Medical Officer
CSM	Committee on Safety of Medicines
CDSC	Communicable Disease Surveillance Centre
DHSS	Department for Health and Social Security
DH	Department of Health
DDAVP	desmopressin
DAA	direct-acting antivirals
EIBSS	England Infected Blood Support Scheme
ELISA	Enzyme immunosorbent assay
EAGA	Expert Advisory Group on AIDS
FDA	Food and Drug Administration
GMC	General Medical Council
anti-HBc	Hepatitis B core antibody
HTLV-3	Human T-Lymphotropic Virus Type 3
KS	Kaposi's sarcoma
MFT	Macfarlane Trust
MOH	medical officer for health
MRC	Medical Research Council

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MP	Member of Parliament
MSP	Member of Scottish Parliament
MMWR	Morbidity and Mortality Weekly Report
NBTS	National Blood Transfusion Service
NCJDRSU	National Creutzfeldt-Jakob Disease Research and Surveillance Unit
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NSSC	National Support Services Committee
nvCJD	new variant Creutzfeldt-Jakob disease
NHSBT	NHS Blood and Transplant
NANBH	non-A non-B Hepatitis
DHSSNI	Northern Ireland Department of Health and Social Services
PFL	Plasma Fractionation Laboratory
PCP	pneumocystis carinii pneumonia
PUPs	previously untreated patients
PFC	Protein Fractionation Centre
PHLS	Public Health Laboratory Service
RIA	Radioimmunoassay
RTC	regional transfusion centre
RTD	regional transfusion director
Regpay	regular payments
SHOT	Serious Hazards of Transfusion scheme
SHHD	Scottish Home and Health Department
SNBTS	Scottish National Blood Transfusion Service
SEAC	Spongiform Encephalopathy Advisory Committee
CSM(B)	Sub-Committee on Biological Products
UKHCDO	UK Haemophilia Centre Directors' Organisation
vCJD	variant Creutzfeldt-Jakob disease
WHO	World Health Organization

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Chronology for the Overview

This brief chronology is provided to help readers navigate some of the time lines discussed in the Overview to the Report. It is not by any means comprehensive. The story told by this Report is very often of things not being done when they should have been. This chronology does not attempt to capture the dates of things that should have been done but were not: it is very difficult sometimes to give an accurate date for when a thing was not done.

1946	Dr William d'A Maycock noted that users of plasma "*must be told that it is a potentially lethal fluid which should be used with discretion.*"
July 1948	Establishment of the NHS, by which time it was known that transfusions carried a risk of post-transfusion hepatitis; that this was often a delayed complication; that hepatitis was transmitted by a virus; and that it could be fatal
1952	World Health Organization Expert Committee on Hepatitis recommended five measures to reduce risks (selection of donors, control of pool size, treatment of plasma, maintenance of records, reporting)
1965	Introduction of ALT testing of all blood donations in Germany
1965	Discovery by Dr Baruch Blumberg of the Australia Antigen (the virus that would subsequently become known as Hepatitis B)
1966	Dr Judith Pool discovered how to use cryoprecipitate for haemophilia treatment
February 1970	Publication of *The Gift Relationship* by Professor Richard Titmuss
1971-1972	Hepatitis B testing of donations and plasma for fractionation introduced in the UK
January 1973	The first grant of a licence for commercial factor concentrates by the Licensing Authority (for Hemofil; followed by the grant of a licence for Kryobulin in March 1973)
1974	Outbreak of hepatitis in Bournemouth haemophilia centre following the administration of Hemofil
August 1974	Report by Prince and others in *The Lancet* that an agent other than Hepatitis B was the cause of most cases of post-transfusion hepatitis and that it may play a role in the development of chronic liver disease (neither A nor B, hence Non-A, Non-B Hepatitis

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January 1975	Letter from Professor Garrott Allen to Dr Maycock warning of risks of US commercial concentrates
	Policy of UK self-sufficiency in blood products announced by Dr David Owen
May 1975	WHO advised self-sufficiency for all nations and use of voluntary non-remunerated blood donations
	The Licensing Authority granted a licence for Profilate
	Dear Doctor letter from the CMO for England advising that blood collections from prisoners could continue
December 1975	Broadcast of World in Action *Blood Money* programmes
1976	The Licensing Authority granted licences for Koate and Factorate
September 1978	Publication in The Lancet of *Percutaneous Liver Biopsy and Chronic Liver Disease in Haemophiliacs* by Dr Preston and others
7 February 1979	Chief Scientist of DHSS "*has informed the* [MRC] *that* [NANBH] *is being given a high priority by the Department*"
April 1979	Dr Peter Kernoff described NANBH as "*a serious disease with long-term consequences*"
September 1980	Glasgow Symposium into *Unresolved Problems in Haemophilia* considered the risks of NANBH
	Memo from Dr Diana Walford DHSS described NANBH as a form of hepatitis that could be "*rapidly fatal*" or "*can lead to progressive liver damage*"
June 1981	CDC (in USA)reported a cluster of cases of people suffering from immune system failure and PCP
December 1981	Report of same failure of immune system and opportunistic infections in intravenous drug users
March 1982	Possibility that infectious agent was the cause of AIDS had developed as a leading hypothesis in the US
16 July 1982	MMWR reported three cases of AIDS in people with haemophilia
	Dr Harold Gunson notified the DHSS of the possibility of AIDS being transmitted through blood
November 1982	Dr Craske's report to haemophilia doctors identified an infectious agent as the most likely of the possible causes of AIDS

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	Final approval given for the redevelopment of BPL
December 1982	MMWR reported case of baby infected with AIDS following transfusion (San Francisco baby case) and additional AIDS cases in people with haemophilia.
	In the Netherlands, the Central Laboratory of the Blood Transfusion Services starts to coordinate a response with the Netherlands Haemophilia Society, haemophilia clinicians and the Netherlands National Institute for Public Health and Environmental Protection, to avoid using factor concentrates where possible
January 1983	Alpha press release 7 January "*The evidence suggests, although it does not absolutely prove, that a virus or other disease agent was transmitted to them in the Factor VIII concentrate*"
	Editorial in New England Journal of Medicine 13 January "*The fact that haemophiliacs are at risk from AIDS is becoming clear*"
	Discussion about AIDS at 19 January meeting of Hepatitis Working Party
	Discussion about AIDS at Heathrow meeting of haemophilia doctors and others on 24 January
February 1983	Pupils at Treloar's began to be examined for "*stigmata of AIDS*"
7 March 1983	Dr Bruce Evatt (CDC) wrote to Professor Arthur Bloom that the AIDS epidemic was evolving "*with a frightening pace*"
24 March 1983	FDA made recommendations to pharmaceutical companies in US that they should not manufacture any product from plasma collected before this date from high-risk groups (Haitians, male homosexuals, IV drug users)
26 April 1983	Professor Bloom reported probable case of AIDS to CDSC of a young man treated at the Cardiff Haemophilia Centre
1 May 1983	*Mail on Sunday* article *Hospitals using killer blood*
3 May 1983	Beginning of the "*no conclusive proof*" line to take
4 May 1983	Professor Bloom's statement published by the Haemophilia Society that the "*cause of AIDS is quite unknown*" and that he was unaware of any proven case "*in our own haemophilic population*"
9 May 1983	Letter from Dr Spence Galbraith (CDSC) to Dr Field (DHSS) advising that all blood products made from blood donated in the US after 1978 should be withdrawn from use until the risk of AIDS transmission had been clarified

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13 May 1983	Special meeting of UKHCDO reference centre directors. Draw up guidance but do not yet circulate it.
20 May 1983	Isolation of a viral particle (LAV) (the viral agent causative of AIDS) by Dr Luc Montagnier and team in Paris.
June 1983	Recommendations from the Council of Europe to avoid wherever possible the use of large plasma pool products and to tell clinicians and patients about the risks of treatment and the possibilities of minimising the risks
	Letter to haemophilia centre directors on 24 June 1983 from Professor Bloom and Dr Rizza
13 July 1983	Meeting of the Biologicals Sub-Committee of the Committee on Safety of Medicine (CSM(B)) concluded that the importation of US concentrates should not be suspended
August 1983	Death of first person with haemophilia in UK from AIDS
September 1983	Introduction of first AIDS donor leaflet
17 October 1983	UKHCDO annual meeting at which Professor Bloom said that "*he felt that there was no need for patients to stop using the commercial concentrates because at present there was no proof that the commercial concentrates were the cause of AIDS.*"
10 December 1983	*British Medical Journal* article "*There is no evidence that any product, commercial or volunteer, is free from the risk of transmitting AIDS*"
23 April 1984	Press conference announcement that Dr Robert Gallo had found the virus causing AIDS (HTLV-3), and test would follow soon.
September 1984	34% of people with haemophilia tested for HTLV-3 are positive
October 1984	CDC announce heating factor 8 concentrate can inactivate HTLV-3
November 1984	Meeting of UK Transfusion Directors unanimous that a screening test for HTLV-3 must be developed as soon as possible
December 1984	UKHCDO meeting at Elstree, issue of AIDS Advisory Document
December 1984	After this, all Scottish factor 8 concentrate heat-treated (but not BPL concentrates as yet)
January 1985	First meeting of the Expert Advisory Group on AIDS
	DHSS wrote that there is a need to evaluate all the HIV/AIDS screening tests to see which is the most suitable
February 1985	Issue of second AIDS donor leaflet

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March 1985	All BPL concentrates issued had been heat-treated. First releases of 8Y concentrate
September 1985	BPL was now heat treating all its Factor 8 at 80 degrees for 72 hours ("8Y"). This inactivated both HIV and NANBH effectively. BPL produced only enough for a quarter of the needs of England and Wales
14 October 1985	Screening of blood donations for HIV introduced
April 1987	PFC issues Factor 8 that does not transmit NANBH
November 1987	Statement to Parliament that £10 million would be made available to the Haemophilia Society to administer payments to people infected with HIV
1988	Identification of the virus responsible for NANBH (Hepatitis C)
	Establishment of the Macfarlane Trust
4 April 1989	First meeting of the Advisory Committee on the Virological Safety of Blood
	Availability of test for Hepatitis C announced
November 1989	Announcement of additional funding for Macfarlane Trust
1 September 1991	Screening of blood donations for Hepatitis C introduced
February 1992	Announcement to extend ex gratia financial support to people infected with HIV through blood transfusion or tissue transfer
April 1992	Establishment of Eileen Trust
January 1995	Decision to undertake Hepatitis C lookback
October 1997	CMO statement that three people who had suffered from vCJD had been blood donors
1998	Launch of Better Blood Transfusion initiative
	Various measures in response to vCJD including leucodepletion
August 2003	Announcement of Hepatitis C payment scheme (Skipton)
February 2009	Publication of the Archer Inquiry Report
March 2011	Caxton Foundation set up
2017	Establishment of the four national support schemes in place of the Alliance House Organisations
July 2017	Announcement of a public inquiry

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July 2018	Inquiry terms of reference laid in Parliament
March 2021	Announcement of a Compensation Framework Study
March 2022	Compensation Framework Study submitted to government
October 2022	Interim compensation to people infected and bereaved partners
April 2023	Inquiry publishes Second Interim report and final recommendations on compensation
December 2023	Government accepted the moral case for compensation

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1.4 Lessons to be Learned

Introduction

It is clear from the first chapters of this Report onwards that most infections could and should have been avoided. It is clear that mistakes were made. The way in which institutions, and in particular the government, reacted to what had happened after 1985 was in many respects shameful. This should never happen again. The first step in deciding how best the mistakes of the past can be consigned to the past, and kept there, is to understand the lessons to be learned from what happened.

One of the lessons is that wishful thinking is all too easy and should be avoided.

It would be wishful thinking to suggest that because we can now see what combined to cause the greatest treatment disaster in the history of the NHS[28] and recognise steps that need to be taken to guard against it happening again, that something similar will not do so. When this Inquiry began it was thought certain that there would be future serious viral threats to be met. I had not realised how soon that would prove true in the form of COVID-19.

The focus of this Inquiry has been on a different viral threat: blood-borne infections. Blood inherently varies from person to person, and some of those variations are harmful. Every blood transfusion carries risks with it, which go beyond those risks inherent in breaking the skin in order to insert a transfusion line. Currently, transfusion-transmitted infection risks appear low but it remains essential to identify future threats transmissible through blood, and deal with them. Public health threats must be faced up to; doctors must be both alert to unfamiliar symptoms following transfusion, prompt in their reporting of them (in case they are emerging elsewhere in the UK too) and candid with their patients about any risks; and both the blood services and government should be ready to react quickly and effectively to new or emerging threats.

To ensure the greatest possible safety, we need to avoid complacency. There is no basis for assuming that threats are all in the past: but watchfulness and learning the lessons of what happened in the infected blood disaster are critical to this.

What, then, (in addition to avoiding wishful thinking and complacency) are these lessons?

28 Lord Robert Winston's famous description.

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Guiding principle: patient safety

The first, and most important lesson, is that the first, and paramount consideration should always be safety. What happened would not have happened if safety of the patient had been paramount throughout.

Clear examples of when observing this would have made a difference are when clinicians took the decision to give their patients (a variety of) factor concentrates as a matter of convenience (see the *Treloar's* chapter) despite both the theoretical and the demonstrable risks to which this led (see the chapters on *Hepatitis Risks 1970 and After* and the *Knowledge of the Risks of AIDS)*; the failure of regulation in 1973 in licensing products which the manufacturers made clear carried with them a real risk of hepatitis, and were made from donors who did "*not inspire confidence*"[29] – if safety had been paramount this should not have happened; and when it was acknowledged during the arguments about whether to introduce surrogate testing for non-A non-B Hepatitis (Hepatitis C) that if safety had been given the weight it should have had, there could be no dispute about the need to introduce the tests. They were not introduced.[30] Had they been, people would have been spared infections.

Risk

Risk needs to be understood better. Few, if any, treatments come without risk. All pharmaceuticals have side-effects. All medical procedures have side-effects. Doing nothing ("conservative treatment") may also have repercussions. The further lessons as to risk which emerge from the events examined by the Inquiry are these:

Understanding risk is critical in ensuring safety. Mistakes were made. What is to be avoided for the future are:

- Confusing **certainty** with whether there is a **real risk calling for a response**.
  - A risk is just that: a real possibility that something might happen. It is recognition of such a risk which first calls for a response. Certainty (or near-certainty) that the potential event will actually occur (or is starting to occur) is not required. Thus if there is credible evidence that a hurricane might be approaching the coast, there will be no certainty for some time that it will make landfall rather than change direction. But no-one should wait for 100% certainty before evacuating the coastal region. To wait until there is a certainty that it will make landfall and be destructive is to wait too long.
  - Allied to that, the **response should be prompt**. A lesson from the Inquiry is that to wait for more research to be done to identify more precisely the degree of risk,

29 Dr Duncan Thomas' observation set out in the chapter on *Regulation of Commercial Factor Concentrates*. Written Statement of Dr Duncan Thomas para 2.52 WITN6405001

30 See the chapter on *Hepatitis C Surrogate Screening*.

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or identify more closely the cause of it, but in the meantime to do nothing but wait until the research is concluded, is to take far too long.

- **A risk is a risk irrespective of whether further research might help to understand it (and how to fight it) better.**
  - The question should always be asked whether conducting research will enable the risk which is apparent to be met more easily, and in a better way: but waiting for the answer should not prevent measures to reduce that risk being taken in the meantime merely because the research has not yet been concluded. Instead of research leading to effective action, calling for more research has too often led to inaction. Examples are the repeated failure to grasp the nettle of surrogate testing for non-A non-B Hepatitis/Hepatitis C because it was said more studies needed to be done; the failures to conduct a lookback as soon as testing for Hepatitis C became universal, because repeatedly it was left for further consideration; and the search to identify more exactly what was causing AIDS to develop in patients, leading to a desire for "conclusive proof" (of, to be noted, exact cause and effect rather than the risk of AIDS, though the **risk** was clear beyond doubt).
- **A risk exists even if the mechanism by which the risk is created is unclear.**
  - So long as there is a real possibility that A causes B, there is no need to understand precisely how it does so before responding. When John Snow's research in the 1850s showed that the source of a cholera outbreak in Soho was associated with the use of the Broad Street pump, science did not yet understand the vibrio form bacteria which caused cholera. It did not need to do so in order for people to stop using the pump, and avoiding the illness which doing so brought. Science did not yet understand why: but so long as the effect was clear, people did not need to understand the mechanism of cause and effect in order to take protective measures. Tying these (and the countless similar examples provided by the history of epidemiology) to the Inquiry, when it was clear that the development of swollen lymph glands in people with bleeding disorders was associated with their use of factor concentrates it was unnecessary to understand precisely why this was before taking measures to reduce the risk. Whether concentrate overloaded the immune system by adding too many foreign proteins for it to cope; whether it transmitted an infectious particle; or whether it caused existing benign infections to reawaken and damage the immune system, the link was clear. Treatment with concentrate risked getting AIDS. It did not need a close understanding of cause and effect to show at least that.
  - In particular, the fact that there was no conclusive proof that the cause of AIDS was transmissible by blood and blood products did not mean that there was no evidence that it might not be happening.

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- **Avoid asking the wrong question.**
  - Allied to the wrongful search for certainty, the wrong question was asked in the approach to the risks caused by non-A non-B Hepatitis and AIDS.
  - There was sufficient evidence that there was a risk that non-A non-B Hepatitis caused chronic serious long-term consequences leading to cirrhosis, liver cancer and death. This risk did not cease to be a risk by clinicians or others preferring to think the disease was benign. They assumed the best. They used wishful thinking. They might have been right (had facts turned out otherwise) but that is beside the point. The proper approach to the risk was to assume the reasonable worst-case scenario until it was proven that it was not the case. A lack of evidence that chronic non-A non-B Hepatitis in time led disproportionately to advanced liver disease[31] was not evidence that it did not do so. No evidence of effect is not evidence of no effect.
  - A similar question arose in respect of the risk of AIDS. Given sufficient material to show there was a real risk, the right question to ask was whether there was any evidence or reason to consider that blood products were free of it?[32]
  - Instead of the wrong question – "Is there conclusive proof this is the effect?" – the right question – "Is there any conclusive proof that it isn't?" – should have been the one that was asked. Only in that way is safety satisfied.
- **Risk must not be confused with incidence.**
  - Whether an infection leads very quickly to symptoms, or whether it has an incubation period to be measured in years, is important in assessing the risk of it spreading. If it is known that there is a real possibility that symptoms will emerge from infections only after several months, or longer, it is a simple error to look around, see there are very few infections at present, and therefore think that the risk is low. What matters is what is being incubated while you are looking around at what has already emerged. Elsewhere in this Report the analogy is given of seeing only the tip of the iceberg.
- **If risk exists somewhere else in the world it could still be a threat here.**
  - The early response of the UK Haemophilia Centre Directors' Organisation ("UKHCDO"),[33] and Professor Arthur Bloom in particular, was to regard much of the problem of AIDS, and therefore of people with haemophilia contracting AIDS, as being an American problem. This led to a sluggish response to what turned out to be HIV.

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31 The Inquiry does not accept that this is an accurate understanding of the state of the evidence about non-A non-B Hepatitis before 1980, but the point is directed towards those who assumed the best because the worst could not be conclusively proved.

32 See the Commentary section in the chapter on *Knowledge of the Risks of AIDS*.

33 Later the UK Haemophilia Centre Doctors' Organisation.

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  - It is too easy to dismiss a disease as being limited to particular countries or parts of the world; if a disease is prevalent somewhere else in the world, it is likely to be only a matter of time before it is transmitted to, and then within, the UK, unless (that is) measures are taken in the light of the knowledge that it is elsewhere in order to prevent it taking hold here.

- **Risks should not be ignored because they are thought inevitable.**
  - In 1975, for instance, Professor Bloom described hepatitis as an inevitable consequence of therapy with factor concentrates. In truth, there was nothing inevitable about it. The likely incidence could have been reduced. Hepatitis transmission through blood and blood products was, eventually – but only eventually – almost completely eliminated. To regard something as inevitable is an excuse for inaction: regarding it in that way may comfort a clinician who prescribes a medication when their patient suffers symptoms as a result, but it does not help the patient or their safety. If a consequence happens so frequently as to be "inevitable" this should not be a cause for comfort, but should, rather, be regarded as a challenge to take action in order to reduce or remove the risk of it happening.
- **Healthcare professionals should take a reflective approach to risk.**
  - Thus, where it is considered that healthcare workers deserve protection against particular risks, so too do their patients unless there are very particular circumstances. There is evidence, for instance, of patients who had been ignorant of risks being approached by healthcare workers in what seemed to be Hazmat protection when they, the patients, had been unaware of any risk (or if they knew they had some infection, of the potential severity of it); at a time when some were saying to patients that non-A non-B Hepatitis was "nothing to worry about" healthcare workers often wore significant protection.
- Finally, though the goal must be to eliminate the risk completely, this may not easily be achieved: **reduction of risk is worthwhile even if full elimination of risk is not yet possible**.
  - As the US Institute of Medicine said:

> "*In a crisis, decisionmakers may become so preoccupied with seeking solutions that will dramatically reduce danger that they will fail to implement solutions that are less effective but are likely to improve public safety to some degree. Partially effective risk-reducing improvements … can save lives, pending the development of more efficacious safety measures. In order that the perfect not be the enemy of the good … Where uncertainties or countervailing public health concerns preclude completely eliminating potential risks,* [the authority] *should encourage, and where necessary*

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require, [the industry] *to implement partial solutions that have little risk of causing harm."*[34]

- There were effective means of reducing the risk from transfused blood by adopting surrogate testing. The reduction in risk would not eliminate all risk. However, a reduction – particularly in the case of those with a clinical need for only one or two units of blood – would be well worth having.
- Similarly, the fact that a first-generation blood screening test (either for HTLV-3, or, later, for Hepatitis C) might be superseded by a second-generation test was part of the reasoning for delaying the introduction of screening, so that if the second test proved better it could be used. However, the first-generation test would nonetheless have been effective even if not as good. The lessons of the past had not been learned – a different, and right, approach had been used in the 1970s when blood was first screened for Hepatitis B by a test, although it left more infected donations undetected than detected. It is clear that although better tests for Hepatitis B were to be anticipated in due course (and indeed arrived) the use of the first test nonetheless spared some patients from becoming infected. In the 1970s, therefore, there was no waiting until there was a better test. In the 1980s, by contrast, there was waiting. The difference in approach came from looking for perfection, rather than something which was merely good. The consequences are obvious in retrospect: they could and should have been obvious then, looking forward.

Delay

- One of the more significant lessons to be learned is the **need to minimise delay in response to a real risk of infection**. It is an obvious point that lives will be affected if there is delay in a response to potential infection.
  - There are two aspects to the delays which are described repeatedly in different chapters of this Report. First, there was a delay in recognising risk (aspects of which are discussed above). But, secondly, there were delays in response to those risks which were identified.
  - Thus, there was delay in the 1970s in responding to the risk posed by hepatitis in blood products. The delay was in providing the resource and encouragement needed to address the possibility of viral inactivation.
  - There were delays in making any change in treatment for bleeding disorders despite knowledge that factor concentrates posed a risk (even if not conclusively proved) to those who took them.

34 Leveton et al *HIV and the Blood Supply: An Analysis of Crisis Decisionmaking* 1995 pp240-241 JREE0000019

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- There was an unconscionable delay in the UKHCDO issuing guidance having considered the question of AIDS. It decided in May 1983 to do so, but no guidance document was issued until some six weeks later, and no further guidance was issued until December 1984. That was too long. In itself, it would (ironically) have achieved little if the first document had been published earlier since it was very much advice to "continue as before", advice which in itself demonstrated an unreasonable delay in engaging with the realities of what was unfolding.
- The introduction of screening tests for HIV in the blood was delayed, largely because of delay and uncertainties about the need for, and the process of, evaluation. If it had taken place earlier, lives would not have been put at risk as they were.
- There were delays in taking a decision about surrogate testing for non-A non-B Hepatitis, followed by a significant and substantial delay in introducing screening for Hepatitis C, followed by a four-year delay in conducting a lookback which ought to have accompanied the universal screening.
- There was delay in embracing the better use of blood by giving fewer transfusions or using safer alternatives, which meant many more people were infected with Hepatitis C (see the chapter on *Blood Transfusion: Clinical Practice*).

These are only some examples of what was seemingly systemic delay.

Where a safety measure is available which will reduce a risk to patient safety, it should generally be introduced without delay, and in particular without waiting for national coordination. There is of course a judgement to be made here: for the dangers of introducing a remedy that may cause more of a problem than it solves, and the implications which any cost will have on other desirable healthcare measures have to be balanced against the need for a quick adoption of it. An example was that when heat-treated Factor 9 concentrates were first considered for use in the UK, there were not unreasonable concerns that the nature of the treatment might lead to greater risks of thrombosis.[35] However, this judgement should be reached as quickly as reasonably practicable.

- **Protective measures should be introduced as soon as possible, even if only locally.**
  - Where a protective measure is to be introduced nationally there may be no good reason why it cannot be provided as soon as a region is able to introduce it: to wait until other regions or areas are in a position to introduce the same test is to work patient safety to the lowest common denominator. For instance, the overriding concern in waiting for a UK-wide introduction of blood screening for Hepatitis C was not patient safety. It should have been. Dr Huw Lloyd in Newcastle was

35 The good track record in their use in the US was persuasive of the case in their favour: but to ask the question, where it was reasonable to do so, was sensible. However, every effort should be made to avoid unreasonable delay.

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right to proceed with Hepatitis C screening in his region. The fierceness of the criticism to which he was unjustly exposed for having done so demonstrates that this lesson needed to be learned. (See the chapter on *Hepatitis C Screening*). Coordinated action (unless it is itself necessary for there to be safety) should come second to safety.

Decision-making

Decision-making suffered significantly from delay. Sometimes there was paralysis when there should have been a decision. Delays that occurred in relation to infected blood have already been described as "seemingly systemic". A large part of the reason for delays in decision-making was because part of the system involved a range of different advisory committees, discussing aspects of the same issues without having any executive power or mechanism for politicians to know what was being discussed, unless officials chose to brief them or they happened to ask a question that prompted proper briefing.

- **A range of committees considering essentially the same issues should be avoided.**
  - Paul Sartain, a core participant, asked the Inquiry to investigate "*paralysis in decision-making, accountability and responsibility*", drawing on his experience of being a civil servant to explain why it seemed entirely tenable, in his view, that there were problems with self-sufficiency and early award of compensation;[36] Professor Ian Hann called for a "*bit less democracy and a bit more guidance*".[37]
  - When it came to dealing with AIDS it was not until 1985 that an expert advisory group on AIDS was assembled. An overarching, truly influential committee reflecting expertise in different relevant disciplines should have been established much earlier: if it had been it could have avoided the problems of a number of committees, including the Biological Sub-Committee of the Committee on Safety of Medicines, taking decisions without the best available information.
  - That there were different committees considering aspects of the same issue led Dr Brian McClelland to describe decision-making (in relation to surrogate testing for non-A non-B Hepatitis) as "*going round in very small circles some distance away from the target*".[38]
  - There was a similar to-ing and fro-ing between committees when it came to whether, and more particularly when, there should be a lookback in respect of Hepatitis C.
  - Similarly, there was a paralysis of decision-making when it came to the redevelopment of the Blood Products Laboratory, essential to enable production

36 Written Statement of Paul Sartain para 119, para 121 WITN1013001
37 Professor Ian Hann Penrose Inquiry Transcript 6 May 2011 p53 PRSE0006021
38 Dr Brian McClelland Transcript 28 January 2022 p103 INQY1000178

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in the greater volume which would ensure a greater degree of self-sufficiency. Dr Diana Walford was right to describe this as "*unconscionable*".[39]

- **Openness and transparency can aid decision-making.**
  - Part of the problem creating the repetition in different bodies of discussion of closely related issues was the secrecy which some committees adopted, in particular the Committee on Safety of Medicines[40] and the Advisory Committee on the Virological Safety of Blood. It could leave people who had not been part of those meetings unsighted and prevented an open and transparent debate about crucial safety issues.
- **Forward planning could have reduced infection and saved lives.**
  - Some of what caused delay was caused by an absence of forward planning. Forward planning, looking a number of years ahead, is not only desirable but is likely to be essential where capital expenditure is to be anticipated.
  - Dr Robert Cummings said that one of the important features of a successful voluntary blood donor system is forward planning. His influence led to the timely redevelopment of the Protein Fractionation Centre in Edinburgh, which came on stream in the mid 1970s.[41]
  - By contrast, the Blood Products Laboratory in London suffered from a lack of planning ahead. Prescient voices (such as that of Dr Rosemary Biggs, who in 1967 was calling for better production facilities to meet foreseeable demand) were raised, but it nonetheless took until 1986 to achieve a satisfactory redevelopment at the Blood Products Laboratory. A failure to plan ahead meant that the development came too late to achieve self-sufficiency at a time when it would have mattered most for safety's sake. (It also cost more money for the Treasury buying commercial concentrates, and implementing stopgap solutions at the Blood Products Laboratory which were necessary because of the poor state to which it had sunk over time whilst unreconstructed: delay was a false economy).
- **Decisions to adopt policies, especially clinical policies and those relating to safety, need to be kept under review.**
  - Thus it was promised by the Committee on Safety of Medicines Biological Sub-Committee of 13 July 1983 that the decision not to suspend the importation of factor concentrates would be kept under review. Yet there is no sign that it was. An advisory group on hepatitis was set up in 1980. Despite that being a year

39 Dr Diana Walford Transcript 20 July 2021 p29 INQY1000137

40 In principle, there was good reason for commercial secrecy, but not otherwise. However, this was not the deliberate action of any member of the Committee on Safety of Medicines. It was thought that section 118 of the Medicines Act 1968 required complete confidentiality, and it was not realised that this was not the case until 1989.

41 See the chapter on *Self-Sufficiency*.

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in which the Department of Health and Social Security expressed particular concern about non-A non-B Hepatitis this group never discussed the topic until 1989 – and the context there was to decide when screening of donations might start. No one and no body appears to have monitored these failures to carry out promised reviews.

- **"Corporate memory" should be valued.**
  - Forward planning involves taking care not to repeat the mistakes of the past. It is apparent there has been no mechanism to ensure that there is a sufficient corporate memory in the Civil Service of why previous decisions were, or were not taken, and the facts that informed those decisions so the reasons could be understood.
  - Thus, though a number of witnesses were asked, none actually knew the facts underpinning a number of "lines to take" adopted in the 1990s: and when they slipped into what they preferred to believe, rather than taking an objective view of the past, they were supported by a degree of groupthink rather than by a true "corporate memory".
  - **Curiosity has a significant part to play in asking the right questions**, for civil servants but also for ministers who because of multiple responsibilities cannot be expected to assemble the facts themselves. Politicians of different political persuasions had largely failed to be sufficiently curious of the lines they were advised to take (because those lines had been adopted for so long that they had become customary) or to consider what legal cases had to tell them; by contrast, it is when some ministers have been more curious that the truth started to emerge

Questioning the status quo

It is often natural for people to become invested in the way in which they do things, so that they cease to question what is being done, and how. One of the lessons to be learned from the Inquiry is that **everyone has a responsibility for patient safety** – from the government, whether in the departments of health, or as responsible for the NHS, or as the licensing authority; the blood transfusion services; hospital trusts and boards; clinicians; plasma fractionators; those overseeing the system and practice of medicine; and those who are professional advisers, educators or representative bodies including the General Medical Council, and Royal Colleges. All have a part to play in safety.

- All must **beware of "sacred cows"** in relation to medicine and clinical practice.
  - For instance, haemophilia doctors, and the Haemophilia Society, became convinced (for good reason) of the correctness of the principle that domestic concentrates were better and safer than foreign imported concentrates. However, there is some evidence of clinicians becoming so convinced that they were safe (as opposed to "safer", which is not the same) that they would hear no criticism

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of domestic concentrates, nor conceive that they could possibly transmit serious infections. There is no doubt that they were safer: but so valued was the principle of voluntary non-remunerated blood donation that it tended to be thought that little harm would follow from using domestic concentrate.

– Undue reverence for the comparative safety of voluntary non-remunerated donor blood in the UK played a part in thinking, wrongly, that the increase in pool size, domestically, of plasma given by voluntary donors would be of little consequence. It was important to recognise the value of voluntary non-remunerated blood donation, but not so as to lose sight to its potential shortcomings.

– Blind respect for the voluntary donor principle was probably responsible for a slowness in asking groups who were at higher risk of transmitting infection not to do so. It was too easily assumed that each donor would be responsible enough not to come forward if feeling unwell. Accordingly, donor leaflets were slow in emerging; donor selection was weak; and screening of the donors (as distinct from screening of their donations) fought shy of being more searching.

Allied to the need to be wary of "sacred cows" is a need to **beware of becoming too tied to the status quo**: to the habits of practice.

– Importantly, there is a strong sense that haemophilia clinicians became very attached to factor concentrates during the 1970s, because of their much greater convenience of use and the extent to which the speed and ease of infusion permitted patients to enjoy a fuller life than they otherwise would have done (assuming no infection). They were thought of as miracle drugs. This in turn caused those using them to tend to be blind to their shortcomings, such that there was a reluctance to alter therapy when, in 1982 into 1983, it became clear that giving factor concentrates might cause AIDS in addition to non-A non-B Hepatitis.

– The faith placed in factor concentrates led to a reluctance to "go back in time" to using cryoprecipitate.[42]

– It led, also, to some downplaying of the impact cryoprecipitate had had on life expectancy. Cryoprecipitate, not factor concentrate, was responsible for the large increase in life expectancy during the late 1960s and 1970s. Though factor concentrate did have an impact, it was more modest than often portrayed.

– Strong incentives to maintain the status quo often exist, and require a strong countervailing force concerned with the safety of blood and blood products.[43] Here that force existed, but it was weak.

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42 Although it remained in use, and had been in extensive use until only some four or five years prior to the first intimations that AIDS might be transmitted by factor concentrates and continued to be used in other countries, which experienced lower incidences of AIDS among people with bleeding disorders as a result.

43 The US Institute of Medicine expressed an identical view in relation to the US experience with AIDS, but the words are as applicable in the UK as they were for the US. Leveton et al *HIV and the Blood*

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- **Disturbing the status quo.**
  - It is plain that for a minority condition (bleeding disorders) a system whereby funding for treatment was paid out of regional health authority budgets gave rise to problems. The reasons for this system owed more to a desire not to disturb existing arrangements than to think afresh about the problems they might cause.
  - The splintered nature of the blood service in England and Wales, though it was a service common to all regions, added to the difficulties in responding both to initiatives to increase plasma production, to decrease the use of whole blood and increase the use of red blood cells as a separate component, and most probably slowed the initial development of the Better Blood Transfusion initiative (see the chapter on *Blood Transfusion: Clinical Practice*).
  - The blood services wanted reform, and that reform to the system would have helped people with a minority condition at significant safety risk, and yet the system remained in place.

Consent and communication

- **Communication means listening:** It is more talking with, than talking to.
- **Care must be taken to communicate.**
  - Communication should have been much better – telling a patient what the professional as an expert clinician knows about (a) risk; (b) alternatives; (c) consequences; (d) the nature of any tests to be performed and what they might show of significance to the patient; (e) what the results of those tests have been; (f) in particular, informing the patient that they are infected, as soon as it is known that they are; and listening properly to what the patient has to say; hearing their worries and questions, and goals and preferences for treatment.
  - Communication about a treatment involving risk to the patient and potentially their family members should explain (a) that there is a risk; (b) how serious a risk it is; (c) what steps can be taken to avoid or minimise that risk, including what alternatives are available; and (d) whether it is unreasonable, or unreasonably difficult, to take those steps. The clinician should bear in mind that the question is not whether taking the steps to avoid or minimise risk is reasonable – the fact that a step could be taken to prevent or minimise the risk of harm means it should be taken unless it would be unreasonable not to do so. That is a more demanding standard than simply doing what is reasonable in the circumstances.
  - Communication of a diagnosis or test result should in the first instance be to the patient: the lesson to be learned is that dismay and distress is caused when there is communication to others before patients themselves are told personally –

Supply: An Analysis of Crisis Decisionmaking 1995 p110 JREE0000019

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there is evidence of GPs, receptionists, nurses, and even headteachers and pharmaceutical companies being told in advance of patients themselves.

- The likes of what happened at Treloar's to communicate the results of testing must never happen again. It was unacceptable for children at Treloar's to be told in batches of five, "*you have*, *you haven't*"[44] and be delivered the news of the presence or absence of a deadly disease, and then to be expected to return to class for the afternoon's education. Not at home. No parent. No counsellor. This is so appalling that the fact it happened could be used to show doctors in training that even clinicians, like Dr Anthony Aronstam, who portrayed a sympathy to the boys he treated yet behaved like this, may slip into conduct which is to be condemned.
- Similarly, the practice of a group meeting for people with haemophilia at which some were told they were infected, and others not, or were given to understand that if they wanted further information they had to ask for it (rather than be given it) shows that a degree of panic and confusion amongst clinicians can lead to a lack of sensitivity, and compassion.
- People given devastating, unexpected news, who were liable to feel the stigma of their infection(s) in the popular mind, were likely to require some psychological support.[45] The term "counselled" often appeared in medical records. At that time, it meant telling a person that they were infected, advising them of a reduced life expectancy, telling them they should not become pregnant or father a child, and advising them what not to do. There is very little evidence of professional psychological counselling.

• There can be **no proper consent without adequate communication**, in particular of the risks and alternatives, but also so that the care of the patient respects the patient's ownership of their own body and life.[46]

- Consent is not a matter of obtaining a tick or a signature on a sheet of paper, but a real process of information, discussion and co-decision.[47]
- Consultation with the people affected by a treatment decision, which goes beyond telling the individual what is to be done but amounts to a process of co-determination in which the patient is involved, is fundamental, for the evidence before the Inquiry shows the ill effects of it being absent.

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44 Adrian Goodyear Transcript 5 June 2019 p83 INQY1000014

45 I have dealt with this fully in the second report of the Inquiry, which is why it needs no further expansion here. Infected Blood Inquiry Second Interim Report 5 April 2023 INQY0000453

46 The autonomy of patients was stressed by the Inquiry's ethical experts. Expert Report to the Infected Blood Inquiry: Medical Ethics April 2020 INQY0000241

47 As is generally accepted now in medicine the process of treatment of a patient by a clinician is a collaborative process in which the patient makes the eventual decision.

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- It is a **mistake to assume that patients truly know and understand something**, **unless their treating clinician has actually told them** and in sufficient detail for them to deal with it.
  - The evidence was that too many clinicians assumed people with bleeding disorders knew of the risks of hepatitis or HIV because the Haemophilia Society would have told them, or the newspapers gave the information. This misunderstands the relationship, which is one in which the patient expects (and is entitled to expect) the person who is a clinical expert in **their** care to give information they can actually rely on to make decisions. The clinician has the power of expert knowledge, which the patient lacks: but the patient has the power of ultimate decision, which the clinician must not usurp.
  - Too many doctors assumed that a patient knew (from previous clinicians) of their infection status. The consequence when the false assumption became apparent was unnecessary distress.
  - Politicians and civil servants tended to assume that doctors would have told their patients of risks, tests being conducted, infective status, how their infections affected others, available treatments, and available support schemes. These assumptions should not have been made without evidence (ie asking patients).
  - Thus, Susan Deacon tasked an investigation on behalf of the Scottish Executive "*to examine evidence about the information given to patients with haemophilia in the 1980s about the risks of contracting HCV from blood products*"[48] and its conclusion was that: "*We accept that clinicians would have had available to them information about the general risks of blood-borne disease, including hepatitis, and that they would have been able to pass this information on to patients*",[49] which shows an assumption of communication without any actual evidence of it.
- **Communication should not be withheld or delayed because the message conveyed may be difficult.**
  - The weight of the evidence is overwhelming that patients were more often than not left unaware that they had been tested. This may have contributed to making it difficult for clinicians to tell patients they had tested positive for an infection, when they did not know that they had been tested. But, difficult as it may sometimes be, it is part of a clinician's duty to be able to deliver bad news to their patient, and to aim to do it sympathetically rather than by providing false reassurance.
  - To tell an adolescent they have two years to live, during which they may waste away, that they are likely to face social revulsion and repudiation even by those

48 Memo from Christine Dora to PS/Minister for Health and Community Care 21 January 2000 p2 SCGV0000170_071

49 Scottish Executive Health Department *Hepatitis C and heat treatment of blood products for haemophiliacs in the mid 1980s* October 2000 p13 GGCL0000010

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they regard as friends, that ideally they should share the information with no-one, and should avoid being sexually active, is not easy. But the adolescent has a right to know. Without delay. (See the chapters on *Treloar's*, *People's Experiences*, and *Haemophilia Centres: Policies and Practice*).

Candour between doctor and patient

Consent and communication both require candour.

- **Candour is essential in the relationship between clinicians and patients**. Both patients, in accepting treatment, and clinicians, in advising on it, are badly affected by its absence.
  - Advice as to risks, prognosis, potential treatments and their side-effects needs to be realistic.
  - Many witnesses report being told that non-A non-B Hepatitis was benign, when the truth was that though many doctors thought it would turn out to be, no-one knew for sure, and many others thought serious consequences would emerge over time.
  - Some were told that because they had tested HIV positive they would probably not suffer from AIDS (it was not necessarily unreasonable for individual doctors in the early stages of grappling with AIDS to think that the development of antibodies would be protective, but, again, no-one knew for sure, and most feared the worst).[50]
  - Most significantly, patients were told in 1983 and 1984 – wrongly – that there was very little risk and they should continue to take their factor concentrate treatment as before. Learning that the truth was otherwise has damaged the relationship with their clinicians, usually beyond repair, and caused a loss of trust in all doctors and the NHS – yet despite that patients with bleeding disorders had no option but to return for further treatment.
- **Meaningful counselling and specialist psychological support** is of real importance. A lesson from what occurred is that too little thought was given to providing it.
  - Good communication needs sensitivity. Witnesses have testified to the dehumanising way in which they were told – or, worse, it was implied without saying – that they were infected with HIV and/or hepatitis, or advised starkly that they should not have a child. This called for better communication: but it also highlighted the need for proper counselling to be available.

50 In particular, those conducting the tests, such as Dr Richard Tedder, did not think that in this instance the antibodies were protective. The degree of dismay with which individual clinicians viewed the results when they received them also suggests that many had few illusions about what a positive test implied.

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- Where information is being given by a clinician to a patient which it will be difficult for that patient to come to terms with, a good communicator should be alive to that fact. A thoughtful clinician should also realise that, however good they think they are with patients, there are others who have more training and experience than they do in handling the potential psychological consequences of life-changing bad news.

Candour and transparency between government and citizen

- **Care needs to be taken that presentation does not override substance.**
  - "Lines to take" are an example. Clear presentation of political issues is important to aid understanding in a democracy, and to enable proper debate. It should not, however, misrepresent the substance.
  - The unqualified line "no conclusive proof" is liable to be misunderstood by people who hear it. Trust, in the political system where it concerns healthcare, and the NHS, is essential. That trust is easily sacrificed. It needs honesty, openness and transparency if there is not to be a loss of trust which is harmful to patient care.
  - The line "the best available treatment in the light of medical knowledge at the time" has been shown by the evidence before this Inquiry to be wrong. When the line was used it was well known that the treatment had resulted in over a thousand people suffering from AIDS, and a substantially larger number from hepatitis. In the light of that, the line defied logic unless it could be based on carefully considered foundations of fact. But this was what the government was asking people to accept, with the implication that it had performed that careful scrutiny of the facts.
  - A perceived need to be on the right side of the media also led to Susan Deacon's office describing her meeting with the Haemophilia Society to discuss an investigation into aspects of Hepatitis C as "*a PR exercise*".[51]
- **Government should not be ashamed or embarrassed to admit that it does not know the true facts, if the truth is that it does not.**
  - Dealing with uncertainty in a system which values certainty of outcome is not easy. Civil servants draft letters for ministers; they prepare briefing documents and submissions, or contribute to them. By virtue of their position, they may feel that they **ought** to know. They need to be alert to the fact that their own sources may feel the same. Those sources may – and in the case of medicine and health often will – not be sure what is correct. It may be embarrassing to admit this. It is, however, even worse to volunteer a "fact" or "half-truth" when there is no proper factual basis for it; or to dress it up in misleading text. If exposed, the result is a

51 Email from Karen Jackson on behalf of First Minister to Sandra Falconer and others 23 September 1999 SCGV0000170_152

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loss of face, and – more importantly – a loss of trust by others in what is being said, because it may be no more accurate than the exposed half-truth. Worse still, the purpose of a governmental official or body asserting a fact is that others should be able to rely on it. Where the assertion was not accurate, they may have suffered as a result.

- Thus, the "no conclusive proof" line will have been heard as "no proof", equalling "the claim that concentrates transmit AIDS is baseless". Clinicians will have relied on this to continue treatment as before; patients will have relied on it to continue accepting that treatment.
- The initial draft of the "no conclusive proof" line had the important qualification that the evidence suggested that what had not yet been proved was indeed the case. The qualification was not used in public pronouncements.[52] There is no record of any civil servant querying this with a minister's office, and pointing out that the wording was capable of misleading. Yet honesty is the obligation of the Civil Service as a whole, not just individual civil servants.
- Other lines to take (see the chapter on *Lines to Take*) such as the "best treatment available" were offered without any who used it being aware of any proper factual basis for the words.

- **Citizens need to be trusted with the truth rather than misleadingly reassured.**
  - Government in a democracy should trust its citizens to know the facts which government knows, unless there is a proper reason for secrecy. Those facts should convey the unvarnished truth: government does not need to assume that its citizens need to be protected against bad news, or news that alerts them to a particular risk, for fear they may panic. Citizens need to be told, rather than reassured.
  - Thus the attempts at reassurance in respect of the risk of AIDS were misleading. If the messaging had been more faithful to the facts, from the start, then more protective action may have followed, and followed more quickly, with the result that fewer deaths and less suffering would have been caused.
- **Extravagant claims should not be made.**
  - An adult faced with advertising claims in the media is used to reacting to a claim that something is "the best" with cynicism and scepticism. Medical treatment is not selling a product; nor is government in the same position as an advertiser. More is to be expected of both. The lesson to be learned is that claims for near perfection, or that what was done to a patient could not have been improved on (it was simply "the best"), need to have a sound basis in fact if they are to be

52 See the chapter on *Role of Government: Response to Risk*.

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advanced. All of us would like our treatment from the NHS to be the best that there could be, but wishing it is not the same as being it.

- Too often civil servants drafted unqualified statements for their minister to make in public, when they deserved to be qualified. Too often they made statements ("the best available treatment") which required justification in fact, when no basis of fact has been identified to make the statement; or made statements in the same vein which strained the facts beyond reality.
- To say that testing for Hepatitis C was introduced at the first available opportunity was equally to overstate the fact: as the chapter on *Hepatitis C Screening* shows, the UK lagged well behind a large number of comparable countries, and a legal case had determined that it should have been introduced earlier.
- It destroys trust that there has to be a legal case to point out the lack of candour, as happened with references to the Irish payment scheme. Civil servants made or drafted statements (one example being claims about the basis of the Irish payment scheme for Hepatitis C sufferers) when government had been told of the true position, yet ignored this.
- Civil servants (and ministers) should be sure of the factual basis, especially where what is asserted is about long past events and prone to a malleable corporate memory, where bold claims are made.

- **Civil servants must ensure that the information given to ministers is accurate.**
- Civil servants in health departments may draw some of their information from what clinicians tell them; but **clinicians may draw some of their information from what civil servants say**. Care should be taken that the process does not lead to one statement justifying the next which in turn is used to justify the first.
- **Just as bad policy should never be implemented as a response to press coverage, good policy should not wait for media pressure before being given effect.**
  - It should not require lobbying and media pressure to build up before taking action.
  - The evidence tells us that the timing of government action often corresponded with the timing of media and lobbying pressure. The timing of the introduction of the Macfarlane Trust owed much to such pressures (see the chapter on the *Macfarlane Trust*).
  - Governmental approval of screening blood for HIV was accelerated by the knowledge of infections following transfusion when these were highlighted in the popular press.

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Involvement in a decision of those affected by it

- **People affected by decisions need to be involved in them.**
  - This is true not only in respect of their own medical treatment. It is necessary for any support schemes to involve the people affected by them. (See the chapters on the *Macfarlane Trust*, *Eileen Trust*, *Caxton Foundation*, *Skipton Fund* and *National Support Schemes*).
  - There is a fear, now, that the design of the compensation scheme to meet the recommendations made in the second report of the Inquiry may not involve those people whom it most centrally affects.
- Paternalism is misplaced. This is true not simply of clinical practice (see the report of the ethical experts to the Inquiry) but also true of those administering support and true of politicians.

Medical records

Ensuring that sources and routes of infection can be easily established, and therefore infections better dealt with, relies on a good record-keeping system. The evidence is that historically either accuracy was not achieved; or records which may well have been accurate were lost, damaged, or destroyed. Too many were not accessibly retained. It is doubtful that even today accuracy and sufficiency of medical records has been achieved. (See the chapter on *Medical Records*).

- **A patient needs to be able to access their records with ease**, both to correct any inaccuracy but also to ensure that they have ownership of the records which relate to them.
- **Any failure of record-keeping is likely to result in some loss of trust in the system** the records serve.
- It is important that records are accurate.
  - It is also important that they are complete (so far as potentially relevant information is concerned).

Though there are now procedures under data protection legislation for correcting records known to be incomplete or inaccurate they are often cumbersome and expensive if they involve eventual complaint to the Information Commissioner's Office, or legal action, so it may well be that these challenges will not disappear with electronic records, unless the general system is carefully designed.

- **There is no place for gratuitous comments in records.**

Records should be statements of what was found clinically. They are not occasions for clinicians passing personal comments about patients – records are meant to be read, later,

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and they are the patient's records, so making a personal comment which has nothing directly to do with the treatment given may lead to a lack of trust. If the comment is derogatory, it may cause offence; if, by contrast, it is complimentary of the patient's attitude, demeanour or character it may risk being seen as patronising. The remedy is to restrict what is written to that which is clinically relevant.

Public health and complacency

- **Complacency is the enemy of safety**. The chapter on *Public Health* shows how public health protections against communicable disease diminished in the 1970s to 1990s because it was wrongly assumed that communicable disease was no longer a problem as it had been in the past. There is a danger that complacency takes the place of active scrutiny, and allows risk to flourish into reality when it might otherwise be prevented from doing so.

Final words

Where things appear to have gone wrong, and safety has been compromised, an attempt should be made to learn the lessons as quickly as possible.

The approach of other industries to health and safety is instructive. Where there is a serious accident on construction sites or in industry, the Health and Safety Executive are likely to investigate. Where there is a near miss between airliners, or a part of the plane falls off in flight, as well as when there is a tragedy, there is always an investigation. When the Aberfan disaster took place, there was an inquiry. When the Piper Alpha oil rig exploded, it was followed by an inquiry. The purpose is not so much to attribute blame (though that may follow) but to learn the lessons of the past, to prevent something similar happening, or happening as badly, in the future.

So far as infected blood is concerned, the need to learn lessons has been clear throughout the evidence: when the Bournemouth outbreak of hepatitis occurred in 1974, said to be Hemofil-related, a study followed but it is not clear that lessons were learned more generally.

- When it became apparent in the mid 1980s how many people had suffered serious illness as a result of their treatment with blood or blood products by the NHS, there was little apparent effort to establish precisely why that was, and to learn the lessons for the future.
- It is most likely the case that practices have changed as a result, and significant improvements have been made in haemovigilance and blood safety. So too, if belatedly, viral inactivation (of the infections in central focus) has been achieved in blood products; and it may be that experience of HIV infections informed the approach which was taken to meet what was for some time only a theoretical risk that vCJD could be transmitted through blood.

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- Nonetheless, in the other industries mentioned the approach has been systematic. The need was for a similar systematic approach to events such as described in this Report so that lessons which might improve patient safety could be learned. Part of such a system is to hold a public inquiry. People who were infected or affected by blood or blood products have said they wanted to know what lessons are to be learned. There has not been a systematic approach to identify them, until now.

There are several lessons to be learned from what happened, and why; and also from the way in which we as a nation responded to what had happened. It is helpful to recap what should have been a shorter chapter, had there not been so many lessons to learn. In conclusion, a summary of the principles of approach which should be adopted is set out in the chapter on *Hepatitis C Surrogate Screening*. Though they were expressed in relation to that particular chapter, they summarise central themes which have run through most aspects of the Inquiry and feature in chapter after chapter. They bear repeating.

(1) First and foremost, patient safety should have been the paramount, guiding principle.

(2) Second, a search for certainty can be, and in this case was, an enemy of achieving progress.

(3) Third, risks to public health need to be addressed with speed, consistency, and an objective look at such evidence as there is without making unjustified assumptions.

(4) Fourth, what aids the process is a clear structure for decision-making. Instead of effective decision-making here, there was "decision paralysis".

(5) Finally, cost, though a relevant factor, should not be the starting point. Patient safety should be.

Sadly, these principles were honoured more in the breach than in the observance.

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1.5 Recommendations

Introduction

In the light of all the evidence available to the Inquiry, and the submissions made to it, I have a number of recommendations to make. There is a danger in inquiries making too many recommendations: it becomes difficult to see whether action is truly being taken to avoid the errors of the past being repeated. Of the many recommendations which might have followed, therefore, this Report will concentrate upon a small number. I acknowledge that some participants may regret that I may not have chosen one which is their particular concern. Some of the lessons to be learned which were set out in the previous chapter *Lessons to be Learned* might also have resulted in additional recommendations made formally by the Inquiry. This should not, however, prevent anyone from applying the lessons identified there, avoiding in future the mistakes which have been identified, and using the content of that chapter as a basis for taking further action, and does not diminish the importance of learning those lessons.

1. Compensation

My principal recommendation remains that a compensation scheme should be set up now.

The Government accepted the moral case for compensation in December 2022 and my recommendations for compensation were made in the Inquiry's Second Interim Report of 5 April 2023.[53]

2. Recognising and remembering what happened to people

The scale of what happened, famously and accurately termed "*the worst treatment disaster in the history of the NHS*", requires recognition and a tangible reminder for future generations. Too many people have lived for too long in the shadows of infected blood. Society needs to show that it now sees what happened to them in its proper light.

Such public recognition involves a formal act of apology from those who had responsibility for what happened, and for failures of response to it. This should be meaningful: an apology on its own will be thought hollow if it does not give sufficient detail as to what the apology is for. It may not be enough (for example) for the Government, or NHS bodies, to say that they apologise for the suffering which has happened. This is an apology, true, but unless more is said, there is insufficient recognition in the words "we apologise" that the suffering is the result of errors made, wrongs done, and delays incurred – first in respect of what happened and why, and second in respect of what then happened by way of organisational response. There have (rightly) been said to be "*three components of full apologies: affect*

53 Hansard parliamentary statement on Infected Blood Inquiry 15 December 2022 p2 COLL0000022, Infected Blood Inquiry Second Interim Report 5 April 2023 INQY0000453

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(regret, remorse), affirmation (admission of fault), and action (compensation, reparation). Expressing sorrow or regret, whilst an important part of the healing process, is at best a partial apology."[54]

An apology should not only give some detail as to what is being apologised for, but to be understood by those to whom it is addressed as sincere and meaningful, it should lead to action. Compensation is part of this. Setting up a compensation scheme and making compensation payments this year, including interim payments as recommended in the Inquiry's Second Interim Report, would be a powerful statement underpinning the sincerity of an apology.

It is so obvious that an apology should be given that the risk of it being seen as given because it was formally recommended might detract from the force of the apology. I have not therefore listed it below, because though I expect one I do not think I need to say any more about it than I have.

In order to provide the public recognition and tangible reminder that is so obviously required, there should be a suitable national memorial. Funds have already been raised in Scotland with a view to there being such a memorial there. I recommend that a steering committee be formed to decide what memorials should be provided, and where, at public expense.[55] Essential voices which should be heard amongst the members of such a steering committee are people who have been infected and affected. The membership should reflect all routes of transmission; it will necessarily contain representatives of the governments of the nations of the UK. The memorial has to be meaningful, and its position appropriately prominent to act as a proper memorial and focus for those who survive, and for people who have been or are carers or who have been bereaved by infection, as well as being capable of being a public reminder.

I recommend that there should also be a memorial dedicated specifically to the children infected at Treloar's school. The memorial should be agreed with those who were pupils at Treloar's and should also be funded at public expense.

Funding should be made available for a biannual networking/support event for those infected and affected, to be organised by a working party of similar composition to the memorial steering committee, save that, although government will no doubt need to have input as to the overall funding, any government representatives should only be part of the working party at the invitation of the other members. Funding should be for a period of at least three events after the publication of this Report.[56] One of the aspects of the operation of the Macfarlane Trust which many found helpful was that in its first few years it organised

54 Quick *Duties of Candour in Healthcare: The Truth, the Whole Truth and Nothing but the Truth?* Medical Law review 2022 p11 RLIT0002448. Professor Oliver Quick quotes the words of Professor Gijs van Dijck as having "*neatly summarised*" the proposition.

55 Though there should remain a place for public subscription by those individuals or organisations who wish to contribute or who already have done so for a memorial in Scotland

56 This recommendation was put forward to the Inquiry by the clients of Collins solicitors and is similar to one put forward by the clients of Leigh Day solicitors for a forum where people can continue to meet virtually and in-person and share their experiences. Submissions on behalf of the core participants

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occasional weekend events which brought registrants of the Trust together. Though there was little professional psychological support given at the time, many have said that they valued the mutual support given by these. The time that people have been able to spend meeting others who have been similarly affected at, and in the margins of, the Inquiry, has also been important to many. The opportunity to stay in contact remains important now, since a large number of people who have been impacted by what happened otherwise live in isolation.

The working party may wish to consider the suggestion made by Collins Solicitors on behalf of their clients that such an event could "*usefully be combined with a public presentation/ update as to the ongoing process of providing compensation and implementing the other recommendations.*"[57]

Accordingly, I recommend:

2. Recognising and remembering what happened to people

(a) A permanent memorial be established in the UK and consideration be given to memorials in each of Northern Ireland, Wales and Scotland. The nature of the memorial(s), their design and location should be determined by a memorial committee consisting of people infected and affected and representatives of the governments. It should be funded by the UK government.

(b) A memorial be established at public expense, dedicated specifically to the children infected at Treloar's school. The memorial should be such as is agreed with those who were pupils at Treloar's.

(c) There should be at least three events, approximately six months apart, drawing together those infected and affected, the nature and timing of which should be determined by a working party as described above, facilitated by some central funding.

3. Learning from the Inquiry

The previous chapter *Lessons to be Learned* draws attention to a number of lessons which are not necessarily intuitive. They are starkly obvious to anyone who has read the rest of the Report, but few people in training for a career in medicine may take that opportunity. A very real danger is that the lessons of the past are forgotten when a fresh history is being made in the years to come, and only then, after another disaster, are remembered. All those responsible for medical education should take steps to ensure that those "lessons to be learned" which relate to clinical practice do indeed become part of every doctor's

represented by Collins Solicitors December 2022 p202 SUBS0000063, Recommendations on behalf of the core participants represented by Leigh Day 17 June 2022 pp22-23 SUBS0000003

57 Closing Submissions on behalf of the core participants represented by Collins Solicitors December 2022 p202 SUBS0000063. Initial submissions on behalf of the Core Participants represented by Collins Solicitors on non-financial recommendations June 2022 p5 SUBS0000015. They had in mind that the minister then responsible should give this, since it would underline the apology.

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training. However, it is above all the hard and awful facts of what happened that doctors need to understand so that the errors are not repeated. A package of training materials, with excerpts from oral and written testimony would underpin what can happen in healthcare, and must be avoided in future.

It has been pointed out by Christine Braithwaite, director of standards and policy at the Professional Standards Authority for Health and Social Care, that:

> "*We have noted in the course of our work that once a review or inquiry is complete, usually after publication, that the secretariat tends to be disbanded. The publication of an inquiry's findings, conclusions and recommendations can bring to light information that others may need to act on. In particular, professional regulators may want to obtain information to help them identify people described anonymously in a report, if there is evidence that calls into question their conduct or competence. This becomes challenging if a review/inquiry team is no longer operational. An example of this is the review into failings at Shrewsbury and Telford Matenity Services*[58] *which reported* [in March 2022]".[59]

The real problem here is access to the material which an Inquiry will have considered in the course of drawing its conclusions, and making its recommendations. Christine Braithwaite's words are a powerful reason for ensuring that the key documents considered by the Inquiry remain available and accessible at no cost to any person who wishes to access them. The material uncovered by the Inquiry (as will be seen by the copious references throughout this Report) underpins conclusions about safety and "next steps", and though maintaining it in a usable form will not be without some cost, it is a small price to pay if by doing so the cause of future patient safety can be advanced. Accordingly, I recommend that the Inquiry website is maintained with full functionality online. Thus I recommend:

3. Learning from the Inquiry

(a) The General Medical Council, and NHS Education for Scotland, Health Education and Improvement Wales, Northern Ireland Medical and Dental Training Agency and NHS England, should take steps to ensure that those "lessons to be learned" which relate to clinical practice should be incorporated in every doctor's training.

(b) They should look favourably upon putting together a package of training materials, with excerpts from oral and written testimony, to underpin what can happen in healthcare, and must be avoided in future.

(c) The Inquiry website is maintained online.

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58 Ockenden Report – Findings, Conclusions and Essential Actions From the Independent Review of Maternity Services at The Shrewsbury and Telford Hospital NHS Trust 30 March 2022 WITN7523009

59 Written Statement of Christine Braithwaite para 12 WITN7523001

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4. Preventing future harm to patients: achieving a safety culture

The account in the chapters of this Report sets out the history of a failure to focus on risk, a failure to put safety first, a failure to listen to voices advising a different course. It also contains a history of systemic failures – a large number of committees, advisory bodies and working groups, many of which seemed partly to cover the same ground as each other, and lacking executive power or sufficient status to demand the ear of those who did have that power. It describes widespread failures of record keeping. The recommendations which follow thus arise out of the Inquiry's Terms of Reference – but it is noticeable that similar failings have been identified throughout healthcare in other inquiries and suggest a wider problem still.

In the NHS there are three particular aspects which demand action:

- First, **changing the culture**, such that safety is embedded as a first principle, and is regarded as an essential measure of the quality of care. Though performance, efficiency, and expense are all important, it should be the safety of care in any health institution that is the aspect in which all its staff take particular pride.
- Second, a **more rational approach to regulation and safety management**, resolving the problems created by the current systems for trying to deliver safer care: which are fragmented, overlapping, confusing, and poorly understood.
- Third, **ensuring a coherent approach to data** – for patients to whom that data relates, and by a body (preferably just one, but if more than one is necessary, then as few as possible) which, with the appropriate consent of the patients concerned, can make use of that data to help identify threats and trends, and better inform protection for others.

To understand the link between these three, it is important to recognise: first, that there have, over the last five decades, been multiple high profile failures of care which have themselves been the subject of earlier public inquiries and recommendations;[60] and second, that it has long been pointed out that the regulatory framework for the NHS is overly complex and disjointed. Thus, for example, in 2002 Professor Kieran Walshe argued that "*Current regulators vary widely in their statutory authority, powers, scope of action, and approach. The resulting mosaic of regulatory arrangements is highly fragmented and some roles are duplicated.*"[61]

60 There is a useful snapshot of some of these inquiries in the period up to 2001 in: Walshe and Higgins *The use and impact of inquiries in the NHS* British Medical Journal 19 October 2002 pp1-2 RLIT0002403. Some of the more recent inquiries, such as the inquiry into the Mid Staffordshire NHS Foundation Trust, are referred to in the main text of this chapter.

61 Walshe *The rise of regulation in the NHS* British Medical Journal 20 April 2002 p2 RLIT0002387. In 2016 the chief executive of the Nuffield Trust argued that "*oversight from so many different bodies creates the potential for confusion and the risk of the 'problem of many hands', in which accountability is distributed and it is not clear who is responsible for key actions.*" Edwards *Burdensome regulation of the NHS* British Medical Journal 20 June 2016 p1 RLIT0002413

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By 2019, it was revealed just how much further this fragmentation and duplication had gone when Professor Charles Vincent and others set out in an attempt (for the first time) to describe and understand what body regulated what process within the NHS in England, to what extent, and with what powers. Their study showed that there were then over 126 organisations which exercised some regulatory influence on NHS provider organisations. Three were national overseeing bodies; 18 were statutory regulators. They commented:

> "*The multitude of organisations that are simultaneously involved in various types of activities overseeing healthcare is striking … There is no reason to think that all these organisations should do exactly the same thing, but the variability in approach and overlapping functions suggest that there is no overall integrated regulatory approach … Evidence of overlapping responsibilities, duplication, practical challenges in coordinating regulatory compliance and providing assurance have been extensively documented.*"[62]

There seems an inevitability about the conclusion that:

> "*The regulatory system of the NHS has evolved rather than been designed and is not fully understood even by professional regulators and it is almost impossible for the general public to navigate the system. Regulation is important and the actions of thoughtful and well-intentioned regulatory organisations have the potential to improve health service standards. However, the overall impact of the regulatory system hinders the effectiveness of regulatory actors and can be challenging for NHS providers detracting from safety and quality improvement initiatives.*"[63]

If safety is to be regulated properly, it needs to be easy for an ordinary user of the system to know to whom they can express any concerns they may have about it, who will take up their cause, and what they can expect from them. At the same time, those who are busy working within the system, especially those in leadership roles or on the boards of hospital trusts and health boards, need to have clarity as to what, precisely, is expected of them.

Yet, so far as England is concerned, the Parliamentary and Health Service Ombudsman,[64] Rob Behrens, as recently as 17 March 2024 drew attention (amongst other matters) to the difficulties of navigating the regulatory system. He also saw another problem caused by the current system – he is quoted as saying that there are now "*too many regulators in the health service – too many bodies doing roughly the same thing – [and] they're not sufficiently joined up, which means that decisive action which should be taken isn't taken, because ministers aren't getting one voice about what should happen.*"[65]

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62 Oikonomou et al *Patient safety regulation in the NHS: mapping the regulatory landscape of healthcare* BMJ Open 9 July 2019 pp6-8 RLIT0001735

63 Oikonomou et al *Patient safety regulation in the NHS: mapping the regulatory landscape of healthcare* BMJ Open 9 July 2019 p8 RLIT0001735

64 Each of the four nations has its own ombudsman: the others are the Scottish Public Services Ombudsman, Public Services Ombudsman Wales and Northern Ireland Public Services Ombudsman.

65 The Guardian *NHS ombudsman Rob Behrens: 'There are serious issues of concern'* 17 March 2024 p2 RLIT0002366

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The Professional Standards Authority for Health and Social Care, which has a remit to oversee the statutory regulators of health professionals (including the General Medical Council and the Nursing and Midwifery Council which respectively regulate doctors and nurses across the UK)[66] pointed out that "*the Paterson, Cumberlege, and Ockenden reports describe a fragmented system with patient safety concerns falling through the gaps and the patient voice being lost*"[67] in its report "*Safer care for all*" published in September 2022. The Professional Standards Authority concluded that "*The health and social care safety system, of which inquiries and reviews are an integral part, is made up of a complex jigsaw of institutions. Each has a specific remit, and no single body is tasked with ensuring that together they create an effective safety system that protects patients and service users.*"[68] The Authority considers that there is a problem with:

> "*Harm and risk of harm going unaddressed because:*
>
> - *patients and service users are not listened to*[69]
> - *data is not collected*
> - *information/ intelligence/ data is held in the wrong place and/or not shared with the appropriate bodies*
> - *the extent of a risk is not identified because bodies are not pooling their intelligence/data*
> - *trends that can only be spotted by taking a bird's-eye view are not identified*
> - *a joined-up response is required but none is forthcoming as a result of remit apathy ('not my responsibility') and/or lack of accountability for joint working.*"[70]

The solution proposed by the Professional Standards Authority for Health and Social Care was that there should be a Safety Commissioner in each nation with an overarching role

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66 The remit of the Professional Standards Authority for Health and Social Care encompasses the statutory bodies that regulate health professionals across the UK, and the statutory body that regulates social workers in England.

67 Professional Standards Authority for Health and Social Care *Safer care for all: Solutions from professional regulation and beyond* September 2022 p6 RLIT0001837

68 Written Submission of Professional Standards Authority January 2024 p1 RLIT0002406

69 The examples given were Mid Staffordshire, Cumberlege, and Morecambe Bay. These inquiry and investigation reports are as follows: Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry RLIT0001757, First Do No Harm: The report of the Independent Medicines and Medical Devices Safety Review RLIT0001379, The Report of the Morecambe Bay Investigation WITN7523007

70 Written Statement of Christine Braithwaite para 11 WITN7523001. Christine Braithwaite identified a lack of candour with patients and families (giving as examples Bristol, Mid Staffordshire, Morecambe Bay, Cumberlege – two of which predated the statutory duty of candour becoming law); and gave examples of inquiries which had shown that data was not shared or acted upon (Paterson, Cumberlege, Shrewsbury and Telford). Written Statement of Christine Braithwaite para 15 WITN7523001. The other inquiry and investigation reports are as follows: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995: Learning from Bristol July 2001 DHSC5030766, Report of the Independent Inquiry into the Issues raised by Paterson February 2020 WITN7523006, Ockenden Report – Findings, Conclusions and Essential Actions From the Independent Review of Maternity Services at The Shrewsbury and Telford Hospital NHS Trust March 2020 WITN7523009

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focussed on ensuring that the various bodies charged with protecting the public work together as an effective system, rather than as a collection of disparate institutions and activities. In its view, the remit should not simply be limited to medicines and devices, for this was likely to add a further layer of complexity to an already fragmented system – what it saw as needed was an overall, independent, transparent body concerned with all aspects of patient safety.[71]

There is now a Patient Safety Commissioner for England. Dr Henrietta Hughes began her role with effect from September 2022. However, her role is by statute one in relation to the safety of medicines and medical devices, not overall patient safety. She nonetheless was able to say in a report on her first 100 days that it was clear from what she had been told by patients, healthcare professionals and senior leaders that "*the focus of the health service is on productivity, operational performance, and financial control. Medicine is industrialised when it needs to be humanised. As well as asking 'What's the matter with you?' we should be asking 'What matters to you?' so that healthcare is personal, meaningful, and safer.*"[72]

There is provision, too, in Scotland for a Patient Safety Commissioner.[73] In Scotland the powers are not focussed on medicines and medical devices, but being "*Independent of Government and the NHS and accountable to the Scottish Parliament, the commissioner will have complete freedom to consider or investigate any issue they believe to have a significant bearing on patient safety in healthcare, and will be able to hear from patients and their families as well as gather information from healthcare providers, to inform their work.*"[74] The Act establishing this post became law on 7 November 2023.[75] It has yet to be seen how this works in practice, though on the face of it the remit provides for a wider responsibility than that of the English equivalent.

Simplification of the structures by which safety is promoted or supervised with the NHS is (obviously) highly desirable. One means of moving in this direction would be a coherent safety management system which those who work within the NHS and the patients whose choices of treatment inform healthcare can buy into.[76]

There is little time to waste. Dr Henrietta Hughes, Patient Safety Commissioner in England, said in the report reflecting on her first 100 days in post that "*It is clear that the culture is getting worse and unless leaders set out a strategic intention to listen and act, we are*

71 Professional Standards Authority for Health and Social Care *Safer care for all: solutions from professional regulation and beyond* September 2022 p14 RLIT0001837, Written Statement of Christine Braithwaite para 18, para 40 WITN7523001

72 Patient Safety Commissioner *100 Days Report* 2 February 2023 p2 RLIT0002394

73 There are presently no plans for a Patient Safety Commissioner in Northern Ireland. On 27 February 2024 the Minister for Health and Social Services in Wales stated he had no plans to introduce such a role in Wales. Senedd Cymru answer given on 27 February 2024 RLIT0002458

74 Law Society of Scotland *Patient Safety Commissioner Bill passes final stage* 28 September 2023 RLIT0002428

75 Patient Safety Commissioner for Scotland Act 2023 RLIT0002436

76 Written Statement of Dr Rosie Benneyworth paras 34-40 WITN7689001, Written Statement of Dr Rosie Benneyworth WITN7689012. Dr Benneyworth is chief executive officer of the Health Services Safety Investigations Body.

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heading straight back to the days of Mid Staffs and other health scandals, severe harm, and death."[77] Over a year has passed since then.

Similarly, on 26 March 2024 Patient Safety Learning (a charity and independent voice for improving patient safety) published a report entitled *We are not getting safer: Patient safety and the NHS staff survey results.* This considered the NHS Staff Survey 2023 for England, and saw in it a need to raise awareness of the urgency of action to create a patient safety culture.[78]

The culture will not change unless candour is ensured as best we can.

The duty of candour

On 6 December 2023 the Lord Chancellor Alex Chalk announced to Parliament that the Deputy Prime Minister Oliver Dowden had that day signed what was to be known as the "Hillsborough Charter" on behalf of the Government. The Charter had been proposed by Bishop James Jones, former Bishop of Liverpool, in his report on the Hillsborough disaster, entitled *The patronising disposition of unaccountable power*.[79] Alex Chalk acknowledged in his response on behalf of the Government that it had taken too long for the Government to respond.[80]

Bishop James Jones had written:

> "*The experience of the Hillsborough families demonstrates the need for a substantial change in the culture of public bodies. To help bring about that cultural change, I propose a charter drawn from the bereaved families' experiences and made up of a series of commitments to change – each related to transparency and acting in the public interest.*"[81]

There are six undertakings in the charter. Apart from the first (which relates to a public tragedy of the kind which happened at Hillsborough) all are applicable to the subject of this Report. They are:

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77 Patient Safety Commissioner *100 Days Report* 2 February 2023 p3 RLIT0002394

78 Amongst its findings in relation to this survey were: "*Turning to questions on clinical safety, the responses to this year's survey show that the percentage of staff who feel secure raising such concerns is now at a five-year low. We note that it is difficult to imagine that such figures in other safety critical industries, where the consequences of incidents may also be serious injury or loss of life, would be deemed acceptable*" and that "*Overall, the results in this section of the survey are a clear indication that we remain far away from the NHS vision of creating a patient safety culture throughout the health service.*" Patient Safety Learning *We are not getting safer: Patient safety and the NHS staff survey results* 26 March 2024 p4, p11 RLIT0002386

79 The report had been produced six years earlier. The Right Reverend James Jones *The patronising disposition of unaccountable power: A report to ensure the pain and suffering of the Hillsborough families is not repeated* 1 November 2017 COLL0000025

80 Hansard parliamentary statement on Hillsborough: Bishop James Jones Report 6 December 2023 p2 RLIT0002396

81 The Right Reverend James Jones *The patronising disposition of unaccountable power: A report to ensure the pain and suffering of the Hillsborough families is not repeated* 1 November 2017 p13 COLL0000025

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> "*2. Place the public interest above our own reputation.*
>
> *3. Approach forms of public scrutiny … with candour, in an open, honest and transparent way, making full disclosure of relevant documents, material and facts. Our objective is to assist the search for the truth. We accept that we should learn from the findings of external scrutiny and from past mistakes.*
>
> *4. Avoid seeking to defend the indefensible or to dismiss or disparage those who may have suffered where we have fallen short.*
>
> *5. Ensure all members of staff treat members of the public and each other with mutual respect and with courtesy. Where we fall short, we should apologise straightforwardly and genuinely.*
>
> *6. Recognise that we are accountable and open to challenge. We will ensure that processes are in place to allow the public to hold us to account for the work we do and for the way in which we do it. We do not knowingly mislead the public or the media.*"[82]

This is aimed at organisations: the language ("*we*" and "*our*") is that of the organisation which signs up to the charter, as the UK Government and a number of other organisations (including the police forces in England and Wales) have done. In responding, Alex Chalk said that Bishop James Jones had made it clear that he wanted to "*help bring about cultural change*" through commitments to change "*related to transparency and acting in the public interest.*"[83]

The Hillsborough report and charter derived from a disaster of a very different kind from that which has been the subject of this Report. However, in both there have been allegations of cover-up, and a lack of frankness or desire to tell the truth, a hiding of documents, and a making of assertions for which there was no proper basis in fact – or which, as likely to be read, would in practice be misleading.[84] Bishop James Jones' approach applies with equal force to disasters in the health context, which are likely to arise out of a series of individual experiences revealing some systemic or individual failing.[85]

Recommendations of previous inquiries to change the culture

It is a sad fact that very few inquiries into aspects of the health service or parts of it have ended without recognition that the culture needed to change. Over the past 50 to 60 years there have been several inquiries, of different types – but nearly all have had some such recommendation.

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82 The Right Reverend James Jones *The patronising disposition of unaccountable power: A report to ensure the pain and suffering of the Hillsborough families is not repeated* 1 November 2017 p13 COLL0000025

83 Hansard parliamentary statement on Hillsborough: Bishop James Jones Report 6 December 2023 p2 RLIT0002396

84 See the detail throughout the full Report.

85 Such as the Shrewsbury and Telford Hospital Review, the Bristol Royal Infirmary Report and the Shipman Report.

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An example is that of the Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995, optimistically entitled *Learning from Bristol*. Recommendations made by the Bristol Inquiry included:

> "*To promote a new culture within the NHS: a three-way partnership of respect, honesty and openness between:*
>
> *– NHS and public;*
>
> *– professionals and patients; and*
>
> *– professionals and professionals.*"

Thus:

> "*– The patient must be at the centre of everything which the NHS does …*
>
> *– There must be openness and transparency in everything which the NHS does …*
>
> *– The safety of patients must be the foundation of the NHS's commitment to the quality of its services;*
>
> *– Sentinel events, that is, errors, other adverse events, and near misses, which occur during the care of patients, must be seen as opportunities to learn, not just as reasons to blame.*"[86]

The Bristol Report emphasised the need for change in culture. It also recognised that there was a link between candour and safety. Being open and transparent about a "*sentinel event*" enables possible shortcomings to be treated as an opportunity to improve the quality (that is, the safety) of the NHS.[87] In short, candour is not simply a matter of ensuring trust as between patient and professional, or between both patient and professional on the one hand and the organisation of which the professional is part on the other. It is a matter, more importantly still, of ensuring safety for the future.

Following both the Bristol Royal Infirmary Inquiry report, and *An organisation with a memory* (a study by the Chief Medical Officer of England's expert group on learning from adverse events in the NHS),[88] a National Patient Safety Agency was proposed. One was set up in 2002, and was absorbed into NHS England in 2012. Professor Ian Kennedy had envisaged that it would keep a national database of sentinel events, and anticipated that the culture he proposed should contribute to sentinel events being identified.[89]

When Sir Robert Francis KC reported in the Mid Staffordshire NHS Foundation Trust public inquiry, he noted that the National Patient Safety Agency had however not been alerted to

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86 The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995: Learning from Bristol July 2001 pp444-445 DHSC5030766

87 The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995: Learning from Bristol July 2001 p270 DHSC5030766

88 Department of Health *An organisation with a memory: Report of an expert group on learning from adverse events in the NHS* 2000 RLIT0002440

89 Professor Kennedy chaired the Bristol Inquiry. The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995: Learning from Bristol July 2001 pp368-372 DHSC5030766

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the concerns which he exposed in his Report. He recommended, as recommendation 12 that "*Reporting of incidents of concern relevant to patient safety, compliance with fundamental standards or some higher requirement of the employer needs to be not only encouraged but insisted upon. Staff are entitled to receive feedback in relation to any report they make, including information about any action taken or reasons for not acting.*"[90]

I shall come back to the words "*not only encouraged but insisted upon.*"

The existing statutory and professional obligations of candour

Regulations were made in the year following the Mid Staffordshire report.[91] These were the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.[92] They cover England. Regulation 20 is headed "*Duty of candour*". It provides that "*(1) Registered persons must act in an open and transparent way with relevant persons in relation to care and treatment provided to service users in carrying on a regulated activity.*" (A *"registered person"* means, in relation to a regulated activity, a person who is the service provider, and thus includes NHS trusts; "*regulated activity*" includes treatment by the NHS of a patient; a patient is a "*service user*" for these purposes.) Regulation 20 continues: "*(2) As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a registered person must*" (in summary):

(a) notify the patient that the incident has occurred and provide them with reasonable support;

(b) give them an account of all the facts the registered person knows about the incident at the time to the best of its knowledge;

(c) say what further enquiries the registered person believes are appropriate;

(d) include an apology (though not necessarily an admission of liability); and

(e) record the notification in a written record to be kept securely by the registered person.[93]

With the exception of the provision of reasonable support, it is an offence not to comply, though the health service body has a defence if it proves that it took all reasonable steps and exercised all due diligence to prevent the breach that occurred.[94]

At the centre of this regime is a "*notifiable safety incident*" which is defined as:

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90 The report was now just over ten years ago, itself being just over ten years after the Bristol report. This recommendation followed from facts set out in chapter 2 of his report. Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry Volume 1: Analysis of evidence and lessons learned (part 1) February 2013 p246 DHSC5113232

91 The statutory authority for these was under the Health and Social Care Act 2008.

92 Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 SI 2014 No. 2936

93 Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 Regulation 20 (2) and (3) RLIT0002451

94 Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 Regulation 22 RLIT0002451

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> "*any unintended or unexpected incident that occurred in respect of a* [patient] *during the provision of* [treatment] *that, in the reasonable opinion of a health care professional, could result in or appears to have resulted in (a) the death of the service user* [the patient]*, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition or (b) severe harm, moderate harm or prolonged psychological harm to the service user*".[95]

It appears from a number of the submissions made to me that some core participants were not aware that a duty of candour existed, and in particular were unaware of the terms in which it is expressed.

The duty of candour is imposed upon the health service body, not upon an individual health care professional. (Although the word "*candour*" is used in the regulation as a heading, and it is not defined, the substance of what is meant by candour in this context appears from regulation 20, the material parts of which are set out above.)

However, so far as individual doctors, nurses and midwives are concerned, there is also a duty which may have practical consequences for them if breached. The General Medical Council and the Nursing and Midwifery Council regulate the professional standards expected of any doctor, nurse or midwife. It is unprofessional for such a person to behave without candour towards a patient. The professional obligation of a health professional is to put the patient first. That means putting self-interest to one side; it means being frank, as well as open and transparent.[96]

The Care Quality Commission has issued guidance which sums up the position: "*Both the statutory duty of candour and professional duty of candour have similar aims – to make sure that those providing care are open and transparent with the people using their services, whether or not something has gone wrong.*"[97]

It would be helpful if after the words "*open and transparent*" were added the words "*and forthcoming*": it is all very well to be open and transparent when asked by a patient about an event. It may be another thing to volunteer to the patient the question the patient might have asked, and its answer, had the patient only realised that something which the professional understood to have gone wrong had done so, even though the patient was ignorant of it. Candour is more than being open and transparent, valuable though both qualities are.

In circumstances where a patient has suffered harm or distress, the General Medical Council and Nursing and Midwifery Council express the duty as being to "*explain fully and promptly*

95 Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 Regulation 20 (8) RLIT0002451

96 See the GMC's guidance Good Medical Practice January 2024 paras 45-46 RLIT0002452, the NMC's guidance The Code October 2018 para 14 RLIT0002453; and their joint guidance Openness and honesty when things go wrong: The professional duty of candour June 2015 RLIT0002454

97 Care Quality Commission *Regulation 20: Duty of candour* June 2022 p2 RLIT0002426

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what has happened and the likely short-term and long-term effects": this in effect equates to being forthcoming.[98]

Health is a devolved issue. The text thus far has concentrated upon the position in England – though the General Medical Council and Nursing and Midwifery Council have a UK wide remit.

The Scottish Government introduced a statutory duty broadly similar to that in England, for NHS bodies, in 2018, under the Duty of Candour Procedure (Scotland) Regulations 2018. As is the case south of the border, the duty rests on organisations, not individuals.[99]

The Duty of Candour Procedure (Wales) Regulations 2023[100] establish an equivalent duty in Wales, requiring NHS organisations in Wales to be open and honest with service users receiving care and treatment in the event of a "*notifiable adverse outcome*".[101]

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98 Though in the joint guidance (2015, predating the guidance using the word "*fully*") on "*Openness and honesty when things go wrong: The professional duty of candour*" the obligation is expressed differently – "*You should share all you know and believe to be true about what went wrong and why, and what the consequences are likely to be.*" The effect is similar.

As to "near miss" incidents, the guidance says:

"*21. … You must use your professional judgement when considering whether to tell patients about near misses. Sometimes there will be information that the patient needs to know or would want to know, and telling the patient about the near miss may even help their recovery. In these cases, you should talk to the patient about the near miss, following the guidance in paragraphs 11–17.*

22. Sometimes failing to be open with a patient about a near miss could damage their trust and confidence in you and the healthcare team. However, in some circumstances, patients may not need to know about an adverse incident that has not caused (and will not cause) them harm, and to speak to them about it may distress or confuse them unnecessarily. If you are not sure whether to talk to a patient about a near miss, seek advice from your healthcare team or a senior colleague." GMC *Openness and honesty when things go wrong: The professional duty of candour* June 2015 RLIT0002454

99 The Organisational guidance says that:

"*The organisational duty of candour procedure is a legal duty which sets out how organisations should tell those affected that an unintended or unexpected incident appears to have caused harm or death. They are required to apologise and to meaningfully involve them in a review of what happened.*

When the review is complete, the organisation should agree any actions required to improve the quality of care, informed by the principles of learning and continuous improvement.

They should tell the person who appears to have been harmed (or those acting on their behalf) what those actions are and when they will happen.

The duty of candour procedure provisions reflect our commitment to place people at the heart of health and social care services in Scotland.

We recognise that when unexpected or unintended incidents occur during the provision of treatment or care, openness and transparency is fundamental. This promotes a culture of learning and continuous improvement."

Duty of Candour Procedure (Scotl248and) Regulations 2018 RLIT0002455, Organisational Duty of Candour guidance March 2018 WITN7671005

The Scottish Public Services Ombudsman has reported 12 cases between March 2021 and December 2023 which have included issues about the duty of candour not being fully observed.

100 National Health Service, Wales The Duty of Candour Procedure (Wales) Regulations 2023 WITN5712003

101 It applies "*if the care we provide has, or may have contributed to unexpected or unintended moderate or severe harm, or death*". A Summary of the Duty of Candour Procedure states:

"On first becoming aware that the duty of candour applies, the NHS must notify the service user or a person acting on their behalf. This contact should be 'in person', which means by telephone, video call or face to face.

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Northern Ireland consulted on introducing a statutory duty in 2021. The responses are currently being analysed. Legislation is not yet in place. The reasons for calling for a statutory duty given by John O'Hara QC (now Mr Justice O'Hara) in his report of The Inquiry into Hyponatraemia-related Deaths resonate with experience elsewhere:

> "*The reticence of some clinicians and healthcare professionals to concede error or identify the underperformance of colleagues was frustrating and depressing, most especially for the families of the dead children … It should not have been so. Health service guidance for 25 years and more has repeatedly recommended transparency and openness in the interests of the patient. This has proved inadequate to the problem which is why this Report must recommend a statutory duty of candour in Northern Ireland.*"[102]

Between them, the legislative duties of candour cover healthcare organisations; the professional duties and professional regulators cover individual healthcare professionals – but there remains a gap. Though there are some in leadership roles in NHS Trusts and health boards who are subject to professional duties as doctors or nurses, and though it may rightly be said that organisational duties have ultimately to be performed by individuals, there are many leaders who are as yet subject to no individual accountability for candour within their organisation.

Recent developments

When Alex Chalk responded to Bishop James Jones' charter, he said that the Government intended to conduct a review of the effectiveness of the duty of candour for health and social care providers. He said this was "*In response to recent concerns about openness*".[103] The review is intended to consider:

> "*1. To what extent the policy and its design are appropriate for the health and care system in England.*
>
> *2. To what extent the policy is honoured, monitored and enforced.*

The purpose of the 'in person' notification is to offer an apology, provide an explanation of what is known at that time, offer support, explain the next steps and provide point of contact details.

The service user or person acting on their behalf will be sent a letter within five working days, confirming what was said in the 'in person' notification.

The NHS will undertake an investigation to find out what happened and why, and how we can prevent it from happening again.

This will take place according to the NHS Wales 'Putting Things Right' Procedure.

The named point of contact provided as part of the Duty of Candour procedure will give you more information about this process and what happens next.

If you do not want us to contact you, or if you would prefer someone to act on your behalf, please let us know and we will make the necessary arrangements."

A service user guide to The Duty of Candour p2 RLIT0002446

102 The Inquiry into Hyponatraemia-related Deaths Report January 2018 p28 RLIT0002450

103 Hansard parliamentary statement on Hillsborough: Bishop James Jones Report 6 December 2023 p3 RLIT0002396, UK Home Office *A Hillsborough legacy: the government's response to Bishop James Jones' report* 13 December 2023 pp41-42 RLIT0002429

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3. To what extent the policy has met its objectives."[104]

It is to be noted that it does not grapple with how well known the duty is to the wider public: if some participants in this Inquiry were unaware there was such a duty, this indicates that the architecture of the NHS is difficult for individual users of it to navigate.

On the same day as Alex Chalk responded, to Parliament, the Parliamentary and Health Service Ombudsman for England, Rob Behrens, said:

> "*I have long called for closer openness and transparency when things go wrong in the NHS. The duty of candour was intended to reinforce this. However, a decade after its introduction, our Broken Trust report into avoidable deaths in the NHS found that the duty is not always implemented as it should be and called for a full review to assess its effectiveness … Despite it being a statutory duty to be open and honest when things go wrong with a patient's care, I know from the cases we investigate that this doesn't always happen. Patients and their families deserve better.*"[105]

What the *Broken Trust* report had found was that "*the physical harm patients experienced was too often made worse by inadequate, defensive and insensitive responses from NHS organisations when concerns were raised.*" One of the four broad themes of failings leading to avoidable death was the failure to listen to the concerns of patients or their families.[106]

The *Broken Trust* report went on to say:

> "*We also looked at the further harm – sometimes called compounded harm – that happens when families, who have already experienced the devastating consequences of losing a loved one, try to understand what has happened but are met with a poor response from NHS organisations. We identified several factors which contribute to compounded harm:*
>
> - *a failure to be honest when things to wrong*
> - *a lack of support to navigate systems after an incident*
> - *poor-quality investigations*
> - *a failure to respond to complaints in a timely and compassionate way*
> - *inadequate apologies*
> - *unsatisfactory learning responses.*"[107]

104 Department of Health and Social Care *Duty of candour review: terms of reference* December 2023 pp4-5 RLIT0002425. The announcement said the review would be published in spring 2024 but a call for evidence was only opened in April 2024, with an indication that the review will be published "*this year*". Duty of candour review 16 April 2024 RLIT0002456

105 Parliamentary and Health Service Ombudsman *Ombudsman Rob Behrens comments on DHSC review into duty of candour* 6 December 2023 p2 RLIT0002424

106 Parliamentary and Health Service Ombudsman *Broken trust: making patient safety more than just a promise* June 2023 p8 WITN7706002

107 Parliamentary and Health Service Ombudsman *Broken trust: making patient safety more than just a promise* June 2023 p8 WITN7706002

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This is not just an English perspective. The Ombudsman in Wales published a report *Groundhog Day 2: An opportunity for cultural change in complaint handling?* in June 2023. The report described "*A lack of openness and candour*", "*clear evidence of maladministration or service failure not identified during local investigations*", "*A lack of objective review of clinical care and treatment*", and recorded that "*Sometimes, the individual clinicians who have delivered the care are involved in complaints responses.*"[108]

Over 20 years after Bristol, and over ten since Mid Staffordshire, it appears from this that too little has changed. This demonstrates how difficult it can be to change culture.

Professor Kennedy rightly observed that "*Cultural and institutional change takes time and can be slow, requiring patience and forbearance.*" Nonetheless, he anticipated that changes in the culture would follow the implementation of the recommendations he made. He had seen the recommendations as forming an interlocking whole.[109] It is a sad indictment of the system's ability to effect a change of culture over such a long timescale that the same concerns continue to surface. The concerns discussed above have been recognised in inquiry after inquiry. They have led to a strengthening of whistleblower protection, have led to a statutory duty of candour upon health service bodies in England, Scotland and Wales, have led to stern warnings from the Parliamentary and Health Service Ombudsman – but have not yet effected a change in culture.

Speaking up

In England, the role of the Freedom to Speak up Guardian was created in response to recommendations made in Sir Robert Francis KC's report "*The Freedom to Speak Up*".[110] There are now 1,000 such guardians across England, reporting through a National Guardian to the Secretary of State for Health and Social Care. This system aims to encourage a listening culture, in which people working in the health service feel free to speak up.[111]

As to whistleblower protection, the Public Interest Disclosure Act 1998 introduced provisions into the Employment Rights Act 1996 to protect a "worker" from any detriment in their employment as a result of their making a disclosure of a kind covered by the Act.[112] This

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108 Ombudsman Wales *Groundhog Day 2: An opportunity for cultural change in complaint handling?* June 2023 p15, p17 RLIT0002447

109 The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995: Learning from Bristol July 2001 p444, p446 DHSC5030766

110 Francis *Freedom to Speak Up: an independent review into creating an open and honest reporting culture in the NHS Report* 11 February 2015 RLIT0002459

111 There are Confidential Contacts as part of the Scottish Speak Up Network and the Scottish Public Services Ombudsman has taken up the role of the Independent National Whistleblowing Officer in Scotland. Healthcare organisations in Wales have a Speaking Up Safely Board Champion who is independent and an executive director as Speaking Up Safely Executive Lead.

112 What is covered is: "*information which, in the reasonable belief of the worker making the disclosure, is made in the public interest and tends to show one or more of the following–*

(a) that a criminal offence has been committed, is being committed or is likely to be committed,

(b) that a person has failed, is failing or is likely to fail to comply with any legal obligation to which he is subject,

(c) that a miscarriage of justice has occurred, is occurring or is likely to occur,

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includes the disclosure of information tending to show that "*the health or safety of any individual has been, is being or is likely to be endangered.*" It is thus capable of covering the "*sentinel events*" (as Professor Kennedy in Bristol described them), and "*notifiable safety incidents*" or "*notifiable adverse outcomes*" as described in the regulations establishing the duty of candour in the health service. The disclosure is to be made to specified classes of people, depending on the circumstances.

Whistleblowers are recognised as capable of providing a valuable service. The protection given to them consists of ensuring they do not suffer a detriment for making the revelations which they do. However, the system is one in which it is almost assumed that, but for the Act, a whistleblower would otherwise be subject to blame. It is that cultural assumption which most needs to be addressed. What most needs to be valued[113] is ensuring that reporting near misses ("*sentinel events*") as well as harmful acts is prized, so that we may learn how to avoid them next time a similar situation occurs.

If a culture of learning from mistakes and near misses is to work most successfully, and if being frank and forthcoming is to be regarded as essential for patient safety then it is insufficient for me simply to add the voice of this Inquiry to an increasingly long list of those which have asked for a change of culture, but have failed to achieve it.

Something more is required if culture is to change.

There are, in my view, two aspects which are vital if culture is to change. They are "insisting upon the reporting of concerns" on the part of those in a leadership role, and the better organisation of the systems dealing with safety across healthcare.

(d) that the health or safety of any individual has been, is being or is likely to be endangered,

(e) that the environment has been, is being or is likely to be damaged, or

(f) that information tending to show any matter falling within any one of the preceding paragraphs has been, is being or is likely to be deliberately concealed."

Employment Rights Act 1996 Section 43B(1) RLIT0002435. The Act applies to Scotland, Wales and England: there are near identical provisions in an Order in Council applicable to Northern Ireland.

113 Current legislation may be seen as being complex, giving a protection in carefully delineated circumstances, which are dealt with under the provisions of Part IVA of the Employment Rights Act 1996 (ss 43A – 43L). The provisions are rightly directed at the particular circumstances that call for protection (including that the disclosure must be of information, as opposed to allegation or opinion; that the whistleblower must have a "*reasonable belief*" that the disclosure is in the public interest and that the information they are revealing "tends to show" that there has been a "*relevant failure*" – ie a criminal offence; a breach of legal obligation; a miscarriage of justice; a danger to health and safety of an individual; damage to the environment or related to a deliberate attempt to conceal any of these matters; and that information relating to any of the above has been, or is likely to be deliberately concealed. The information must in the first instance be given to the whistleblower's employer (or other responsible person as defined by s.43C). It is unnecessary for present purposes to give more detail, save to say that the legislation is not simple, and may seem to be focused more on the acts and behaviour of the whistleblower than on the direct protection of a person from harm, or other people in a similar situation in future from potential harm.

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Insisting on the reporting of concerns

I said I would return to the words which Sir Robert Francis used in recommendation 12 of his report into the Mid Staffordshire Trust. "*Reporting of incidents of concern relevant to patient safety … needs to be not only encouraged but insisted upon.*"[114]

Andrew Bragg, who was infected by treatment under the NHS and is a chemical engineer and chartered scientist by background, has a lifetime of experience working with high hazard chemicals – substances that could, in his words "*seriously impact both our employees, our neighbours and people who use* [them]".[115] He has worked with regulation all his life. It is worth quoting part of what he had to say to the Inquiry:

> "*So every time I have been with the NHS I have been a professional observer of organisational systems. So I have been looking at how the medical teams who are treating me are functioning. It is not always a very pretty picture. So there are lots of examples of where – – poor team working, poor communication, unsystematic working, working from memory – – so lots of boxes which, in my business, we would not accept but seems to be fairly routine in the Health Service. The type of things I'm looking for is not really specific to my industry. There are lots of industries where you face complex challenges which potentially put lives at risk. So the chemical industry, oil and gas industry, offshore, nuclear industry, aviation, building complex structures. In all of these, managing risk, managing personal safety, managing the safety of third parties is absolutely the core of what you do. But I see very little of that thinking in the NHS.*
>
> *So, how do we end up so good at this and perhaps NHS not so good? Well, we have external regulatory drivers that keep us honest. So in the UK we have the Health and Safety Executive. So they are responsible for managing safety for all businesses, operations in the UK. So if we have an instance or an accident which results in serious harm or death, we will be externally audited in a very rigorous way and all our failings will be exposed and we will be expected to put it right and make sure it never happens again. We also have external inquiries, like this one.*"[116]

I do not propose a culture in which there is no blame, but rather one where the blame falls in the right place. To take Andrew Bragg's example of the aviation industry. The expectation is not that people who are concerned with the safety of an airliner are blamed when fault occurs,[117] but that they are blamed for not taking steps to bring to attention their concerns that it might do so. Rather than seeing a whistleblower as needing protection from

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114 Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry Volume 1: Analysis of evidence and lessons learned (part 1) February 2013 p246 DHSC5113232

115 Andrew Bragg Transcript 17 January 2023 p164 INQY1000266. He worked for ICI, and today works as a global sustainability and regulation manager; he has been a lead auditor.

116 Andrew Bragg Transcript 17 January 2023 pp166-167 INQY1000266

117 The principle is stated broadly in the text, but there will be some occasions on which blame will necessarily follow eg where there has been a serious neglect of duty.

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retribution which would otherwise follow, the culture should be one in which the reporting of the concerns of which Sir Robert Francis speaks is recognised as a human, professional and statutory duty. The duty is to report matters which it is reasonable to think may have an adverse impact on patient safety. A failure to do so, when the substance of what might be reported is known to one or more people, but has not been reported by them, may be regarded as a breach of professional duty,[118] and might usefully underpin the statutory duty of candour. However, the duty also rests on those to whom a report is made. In the case of someone in a leadership role, they may choose to escalate a report, resolve it, or deal with it as appropriate, but in any case they should consider it properly. A failure to give the report proper consideration should be regarded as culpable.[119] Further, if any action in this context is deserving of disciplinary action by the employer it is failing to speak up, or failing to act on a report, rather than regarding a whistleblower as a maverick, or as a "tell-tale".

Incentivising change

A failure to check or tighten bolts on an aircraft wing may not lead to a crash – but it could constitute a near miss. Reporting that it has happened is valued. In the mining industry, the use of canaries in cages was largely superseded by the role of a "deputy"[120] whose job it was to ensure the mine was safe[121] before a shift began, and tell underground workers to leave the moment there was information that suggested there was a risk it might not be. This initially Victorian development to protect workers has been credited as a principal reason why the UK coal mining industry was one of the safest. Industry dealing with offshore safety; the handling of hazardous chemicals, aerospace, maritime, and nuclear power enterprises systematise safety checks, and highlight cases where they may not have been performed. These industries have each adopted a safety management system. The NHS has not.

Speaking up about a "sentinel event" (or, in terms used by Healthcare Improvement Scotland, a "significant adverse event", in Northern Ireland "serious adverse incident" or in England and Wales "patient safety events" or incidents) is a first stage. Andrew Bragg submitted that there should be a statutory responsibility to report, formally, when one has

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118 See for example the GMC's Good Medical Practice ("*You must act promptly if you think that patient safety or dignity is, or may be, seriously compromised*" and "*If patients are at risk because of inadequate premises, equipment or other resources, policies or systems, you should first protect patients and put the matter right if that's possible. Then you must raise your concern in line with your workplace policy and our more detailed guidance on Raising and acting on concerns about patient safety.*") GMC *Good medical practice* came into effect 30 January 2024 para 75 RLIT0002452. See also the GMC's guidance Raising and acting on concerns about patient safety which stipulates that "*All doctors have a duty to raise concerns where they believe that patient safety or care is being compromised by the practice of colleagues or the systems, policies and procedures in the organisations in which they work. They must also encourage and support a culture in which staff can raise concerns openly and safely*" GMC *Raising and acting on concerns about patient safety* 12 March 2012 para 7 RLIT0002457

119 Some reports may be misunderstandings, but even then misunderstandings may be shared, and it may be useful to put them right. The duty on the person to whom a concern about a sentinel event is reported should arise only if that person is identifiable as an appropriate person to whom to make such a report.

120 Later, a Regulation 12 manager.

121 From fire, flood, gas, movement of the strata, and collapse in particular.

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occurred should be required of all employees within the NHS, including those who are not medical or nursing professionals.[122] The second stage is investigation and review, to see what if any action is desirable. The third is implementation of the actions it is thought will be effective to prevent recurrence. The fourth is audit – to check that the action appears to be having the anticipated effect. Each step needs to be taken and logged: the data should be collated nationally, as Professor Kennedy suggested in his report on Bristol.[123]

Since 2003/04, the NHS in England has collated patient safety incident records uploaded from local risk management systems. NHS England now collects over 2.3 million patient safety incident records each year, which can lead to National Patient Safety Alerts.[124] NHS Wales uses Datix Cymru to gather data on all patient safety incidents, including near-misses.[125] Northern Ireland's system is called the Datix Risk Management system.[126] Healthcare Improvement Scotland has had a database of all category 1 significant adverse event reviews since 2020 and work is underway to standardise adverse event data reporting in Scotland.[127]

Where an individual is responsible for something going wrong that was, or might have been, harmful, they should not usually be blamed for "owning up" (for that enables patient safety to be better achieved), but they should certainly be blamed if they keep silent.

The existing professional duties of candour in healthcare are good starting points, so far as those currently subject to such duties are concerned. However, others who are not covered by these obligations should be subject to reciprocal duties. Reporting concerns about the healthcare being provided, or the way it is being provided, where there reasonably appears to be a risk that a patient might suffer harm, or has done so, is critical to realising risks, and

122 Andrew Bragg Transcript 17 January 2023 p175 INQY1000266. Following his submission the Inquiry gathered written statements from organisations with roles in patient safety including:
Healthcare Improvement Scotland: Written Statement of Lynsey Cleland WITN7671001
NHS Wales: Written Statement of Judith Paget WITN5712002
Department of Health in Northern Ireland: Written Statement of Peter May WITN7461007
DHSC: Written Statement of William Vineall WITN4688083

123 The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995: Learning from Bristol July 2001 p465, p447 DHSC5030766. Professor Kennedy hoped that the changes he was recommending would lead to a change in the culture: "*Perhaps the most significant change we call for is one which does not attract a specific Recommendation. This is the change which is needed in the culture of the NHS. We see changes to that culture as being a product of the Recommendations as a whole. If the Recommendations are implemented, changes in the culture will follow.*" His steps included a duty of candour, regulation, assurance and a national reporting system: matters which are reflected in these recommendations too. These remain important. Now, some of those most centrally involved with patient safety in England are exploring the contribution that a safety management system could bring in addition (see the discussion in the text): it would add significantly to the "*whole*" which Professor Kennedy envisaged.

124 Written Statement of Dr Aidan Fowler para 18, paras 32-42 WITN7717001. The devolved administrations are observers on an external stakeholder panel when National Patient Safety Alerts are issued and have access to the data and analysis generated in support of an Alert.

125 Written Statement of Judith Paget para 9 WITN5712002

126 Written Statement of Peter May para 3.1 WITN7461007

127 Written Statement of Lynsey Cleland para 19, para 23 WITN7671001

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improving safety. It should be considered a serious disciplinary matter on the part of the person in authority to whom a report of a sentinel event is reported not to consider it adequately.

The need to ensure that people in leadership roles have a duty resting upon them individually as leaders is further underpinned by observations of the Independent Neurology Inquiry in Northern Ireland in 2022, which became a statutory inquiry during the course of proceedings and reported (in respect of doctors who exercised leadership roles, as well as administrators) that: "*Medical professionals were ... apprehensive in raising a concern about the practice of a colleague or querying discrepancies that arose, which did not directly touch upon the welfare of their own patient. It was clear that senior managers were too often reluctant to manage doctors and were easily deflected by the raising of any clinical dimension to an issue of concern. Correspondingly, many doctors who took on a management role were accustomed to operating collegially and consensually and found the responsibilities of management did not easily fit into that extant culture*."[128]

In short, this would make whistleblowing an obligation: but more than that, it would make the person to whom a report of a sentinel event is made, accountable for what is then done in response to it. It entrenches the principle that safety is the responsibility of all. It makes patient safety a hallmark of quality care. In effect, it gives teeth to the duty of candour in healthcare.

Accountability of leadership

On several occasions during the course of the Inquiry witnesses were asked what could be done to change the culture of the NHS. Many inquiries had suggested a culture change was needed. None had achieved this.

The answer given by Professor Sir Jonathan van Tam was "*leadership*". The exchange went like this:

> *"Q: … how do you best incentivise candour and openness in the organisations which you lead and, for that matter, in the NHS?*
>
> *A: ... it boils down to a set of personal values and it boils down to me as a leader, in whatever position I am in an organisation, insisting of the people who report to me, and who are also in leadership positions, insisting on certain standards and insisting upon responsibility and accountability. And insisting, in their reports, on the same and building from the very top to the bottom an insistence on quality ... I don't think this is something that can be created by a mission statement or a set of wonderful principles that are ... framed in every office in the building. I think it has to be about lived relationships and about, if you're in a position of leadership, your expectation directly of the people who report to you, and your insistence that they have the right to expect the same all the way down the system. Of course at different levels with different things that they are responsible for at different*

128 Independent Neurology Inquiry Report June 2022 p21 RLIT0002449

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> *levels in the system, but that kind of built-in ownership and accountability for what they do.*"[129]

Lord Evans of Weardale, then chair of the Committee on Standards in Public Life, emphasised the central importance of leadership in his foreword to a report in January 2023: *Leading in Practice: A review by the Committee on Standards in Public Life*.[130]

Rob Behrens identified a "*cover-up culture*" from his experience as Parliamentary and Health Services Ombudsman over the last seven years. Asked how such a culture can be ended he is quoted as saying that: "*First of all, you have to recognise that it* [a cover-up culture] *exists and secondly you have to make leaders accountable for how the culture operates*". He added that ministers, NHS bosses and the boards of NHS Trusts need to be much more proactive.[131]

Since culture is identified by seeing the way in which people behave and react, it is not something that can necessarily be directed from the top. However, it is generally true that leadership sets the tone for an organisation. It can establish the parameters within which those who work for the organisation operate. It can indicate the approach which it is acceptable to take to those whom the organisation serves, fellow workers, and third parties.

The seven principles of public life identified by Lord Nolan 30 years ago include leadership.[132] Accountability is another. Rob Behren's words encapsulate four more – objectivity, and integrity, in recognising the problems with an existing culture; openness and honesty in admitting to it. The first principle – selflessness – may also have a part to play, by not seeking to retreat into defensiveness, which is another way of describing actions which put self-interest ahead of those of others.

The importance of leadership and the possibility it can make a difference is real. An individual duty of candour, and a duty to record, and give proper consideration to reports of concerns made by healthcare staff to those in leadership roles should be provided for, enforceable first as a requirement of the job, and second underpinned by secondary legislation.

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129 Professor Sir Jonathan Van-Tam Transcript 18 November 2022 pp67-68 INQY1000265

130 He said: "*Senior leaders must ensure that values are understood and embedded into all aspects of how their organisations operate – from the way leaders communicate with employees, to the priority given to developing good decision-making, to the approach taken to recruitment and performance management. While the tone from the top is critical, leadership matters throughout an organisation. Leaders at all levels have a fundamental role in exemplifying and helping their teams live up to the Principles in their day-to-day behaviours.*" He did however caution that "*From the evidence we have heard, it is clear that there is no single right way to embed an ethical culture in organisations, but a range of possible approaches and measures*", although it was clear that an ethical culture did not happen by accident. Committee on Standards in Public Life *Leading in Practice: A review by the Committee on Standards in Public Life* January 2023 p4 RLIT0002399

131 The Guardian *NHS ombudsman Rob Behrens: 'There are serious issues of concern'* 17 March 2024 RLIT0002366. He told the Inquiry: "*Defensive cultures are a product of defensive leadership, so the behaviour of senior leaders is critical in creating an open, transparent environment where patient safety is prioritised.*" Written Statement of Rob Behrens para 19 WITN7706001

132 Lord Nolan *Standards in Public Life: First Report of the Committee on Standards in Public Life* May 1995 p18 RLIT0001795

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Organisation of a safety management system

The steps identified above require a body (preferable to one person,[133] since safety requires team effort; though having an individual in every healthcare organisation who has a designated responsibility for safety[134] can be part of the system) to oversee a safety management system, to collate reports and build a picture of the challenges to safety within the health services across the UK and the measures that are needed to meet them.

Why is the status quo not enough? The answer is that despite the focus on patient safety, there are still recurring safety risks and serious incidents in healthcare. This can be seen in repeated concerns in the last decade such as in the Morecambe Bay Investigation (Kirkup, 2015),[135] *First Do No Harm: The report of the Independent Medicines and Medical Devices Safety Review* (The Independent Medicine and Medical Devices Safety Review, 2020),[136] the Ockenden review of maternity services at Shrewsbury and Telford Hospital NHS Trust (Ockenden, 2020);[137] and *Reading the signals: Maternity and Neonatal Services in East Kent Report* (Kirkup, 2022).[138] These investigations and reports have identified similar problems to those which this Inquiry has laid bare: not only a problematic culture, which does not put patient safety first; but too many bodies, with no one having an overall role with executive power or central influence; too much fragmentation leading to a confusion of approach and paralysis of decision-making.

Dr Henrietta Hughes, the Patient Safety Commissioner for England, gave evidence that "*Overall, the patient safety landscape has arguably become too cluttered and is too confusing from the point of view of patients … Reorganisations also inherently present short term inefficiencies and delay.*"[139]

In *First Do No Harm*, Baroness Cumberlege wrote in the opening letter to the Secretary of State:

> "*We have found that the healthcare system – in which I include the NHS, private providers, the regulators and professional bodies, pharmaceutical and device manufacturers, and policymakers – is disjointed, siloed, unresponsive and*

133 The Professional Standards Authority suggested that coordination be achieved by a commissioner with an overarching role focussed on ensuring that the various bodies charged with protecting the public work together as an effective system. Though I am not averse to this, it might be better that there be a commission with one head. Professional Standards Authority for Health and Social Care *Safer care for all: solutions from professional regulation and beyond* September 2022 pp84-87 RLIT0001837

134 Provided that care is taken that this does not lead to other health professionals thinking that safety is not their problem too.

135 Kirkup *The Report of the Morecambe Bay Investigation* March 2015 WITN7523007

136 First Do No Harm: The report of the Independent Medicines and Medical Devices Safety Review 8 July 2020 RLIT0001379

137 Ockenden Report – Findings, Conclusions and Essential Actions From the Independent Review of Maternity Services at the Shrewsbury and Telford Hospital NHS Trust 30 March 2022 WITN7523009

138 Kirkup *Reading the signals: Maternity and neonatal services in East Kent – the Report of the Independent Investigation* October 2022 WITN7523008

139 Written statement of Dr Henrietta Hughes para 36 WITN7328004

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> *defensive … The system is not good enough at spotting trends in practice and outcomes that give rise to safety concerns."*[140]

In mid October 2023 the Health Services Safety Investigations Body ("HSSIB") published a report about safety management systems for healthcare. The report said:

> "*An overall systems approach is needed – that is, one that encompasses all aspects of healthcare including non-clinical services, which can have a significant impact on patient safety. For example, a whole-system approach should consider auxiliary services such as decontamination services, facilities management or healthcare engineering. Currently, this may not be the case in healthcare. HSSIB* [Health Services Safety Investigations Body] *highlighted the importance of other services and parts of the healthcare system that may have a significant impact on patient safety and will need to be included in an overall systems approach."*[141]

The report described the essentials of safety management systems: "*An SMS* [safety management system] *is a proactive and integrated approach to managing safety. It sets out the necessary organisational structures and accountabilities and will continuously be improved. It requires safety management to be integrated into an organisation's day-to-day activities. There is no one-size-fits-all SMS*". The report detailed that it involves:

(a) *"**safety policy** – establishes **senior management's commitment** to improve safety and outlines responsibilities; defining the way the organisation needs to be structured to meet safety goals*

(b) ***safety risk management – which includes the identification of hazards (things that could cause harm) and risks** (the likelihood of a hazard causing harm) and the assessment and mitigation of risks*

(c) ***safety assurance – which involves the monitoring and measuring of safety performance** (eg how effectively an organisation is managing risks), the continuous improvement of the SMS, and evaluating the continued effectiveness of implemented risk controls*

(d) *safety promotion – which includes **training, communication and other actions to support a positive safety culture** within all levels of the workforce."*[142]

In summary:

> "*The purpose of an SMS is to ensure that an industry achieves its business and operational objectives in a safe way and complies with the safety obligations that apply to it. However, it is not just a paper-based or electronic system specifically*

140 First Do No Harm: The report of the Independent Medicines and Medical Devices Safety Review 8 July 2020 pp3-4 RLIT0001379

141 Health Services Safety Investigations Body *Investigation report: Safety management systems – an introduction for healthcare* 18 October 2023 p11 RLIT0002398

142 Health Services Safety Investigations Body *Investigation report: Safety management systems – an introduction for healthcare* 18 October 2023 p3 RLIT0002398. Emphasis added.

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> *developed for demonstrating compliance with regulatory frameworks. Instead, an SMS should be a dynamic set of arrangements which grows in maturity and develops as the industry evolves.*"[143]

The HSSIB recommended that "*NHS England explores, and if appropriate, supports the development and implementation of safety management systems (SMSs) through an SMS co-ordination group. This should be in collaboration with regulators, relevant arm's length bodies and national organisations, academics, patient representatives and safety leaders from other safety-critical industries.*"[144]

This is consistent with Andrew Bragg's submission discussed above that there should be a systemised approach to safety, as there is in other safety critical industries.

The Patient Safety Commissioner for England is strongly supportive of the work the HSSIB is leading, looking at how recommendations are made to the healthcare system and moving towards an agreed set of principles that national organisations and office holders (such as the Patient Safety Commissioner) with the power to make safety recommendations can sign up to – but cautions that it has to start from a detailed "*gap analysis of the current landscape*", and a danger that one body might be a recreated National Patient Safety Agency which, as noted, was absorbed into NHS England in 2012, and might be seen as the preserve of "*highly specialised 'experts' … in contrast to high reliability organisations in other sectors with SMSs, where safety is seen as the responsibility of everyone from the CEO downwards.*"[145]

The National Director of Patient Safety for NHS England told the Inquiry that "*it is right to ask what more the NHS could do in this space and what more we could learn from other industries … Understanding how SMSs might be conceived and applied in a healthcare setting is an integral step for informing further policy developments.*"[146]

The Professional Standards Authority for Health and Social Care also agrees with Andrew Bragg's view that there is a need for a body to check that the healthcare safety system is operating effectively, and that serious review findings are implemented.[147]

In summary, a powerful consensus has been building over the last three years that an appropriate safety management system is needed for healthcare in England.

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143 Health Services Safety Investigations Body *Investigation report: Safety management systems – an introduction for healthcare* 18 October 2023 p3 RLIT0002398

144 Health Services Safety Investigations Body *Investigation report: Safety management systems – an introduction for healthcare* 18 October 2023 p5 RLIT0002398

145 Written Statement of Dr Henrietta Hughes para 28, paras 30-31, para 35 WITN7328004

146 Written Statement of Dr Aidan Fowler para 18, paras 48-49 WITN7717001

147 Written Statement of Christine Braithwaite para 13 WITN7523012. The statement does, though, draw attention to some of the differences between aviation safety, where for instance planes can be grounded, and the NHS which has variable staffing, less predictable demand, where critical decisions need to be made fast, conditions may vary from shift to shift and there are multiple variables in the nature of diseases and conditions. Written Statement of Christine Braithwaite paras 11-12 WITN7523012. See also Andrew Bragg's submission: Andrew Bragg Transcript 17 January 2023 pp167-170 INQY1000266

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Dr Rosie Benneyworth of the HSSIB has set out the next steps towards this – first, investigating accountabilities for patient safety across organisational boundaries,[148] then considering how NHS staff and patients could be involved in an integrated safety management system.

In Scotland, Healthcare Improvement Scotland scrutinises and assures the quality of NHS services in Scotland but does not regulate them.[149] There is no equivalent organisation elsewhere in the UK.[150] It recognises "*the combined strength of the respective skills and expertise that each of the organisations with a role to play in safety and quality of care in Scotland currently bring, but also understand the vital importance of these organisations working together to share, consider and respond to intelligence about health and care systems, as demonstrated by our membership of the Sharing Intelligence for Health & Care Group (SIHCG) and the secretariat support we provide for this.*"[151]

The NHS Wales Executive has developed a National Quality Management System that integrates quality and safety intelligence with performance to provide "*a rounded picture of organisations which can be used as an early warning*".[152]

In Northern Ireland it is the Department of Health that manages the Serious Adverse Incident process, working jointly with the Public Health Agency.[153]

Patient records

Because moves are already under way to give patients greater access to their own records, that development in itself needs no recommendation from this Inquiry. However, the digital initiatives in England, Scotland, Wales and Northern Ireland are still works in progress, and this Inquiry is in a position to provide a unique perspective on aspects of process and outcome which may assist in achieving what patients will value most about the new landscape which is being formed. A repeated lesson from the Inquiry has been a sidelining of what patients have had to say.

148 A report is due for publication in October 2024. Written Statement of Dr Rosie Benneyworth WITN7689012

149 Established in 2011 as a Health Body, constituted by the National Health Service (Scotland) Act 1978, as amended by the Public Service Reform Scotland Act 2010 and the Public Bodies (Joint Working) Act 2014. While Healthcare Improvement Scotland is not a special health board, it may be grouped with NHS special health boards in terms of Scottish Government initiatives such as shared services.

150 Written Statement of Lynsey Cleland paras 5-6, WITN7671001. The approach of the NHS Wales Executive is described by their chief executive. Written Statement of Judith Paget para 4, paras 14-15 WITN5712002. The position in Northern Ireland is set out by the Permanent Secretary in the Department of Health. Written Statement of Peter May paras 3.1-3.3 WITN7461007

151 The position of Healthcare Improvement Scotland is: "*We would have a strong interest in any proposals to further strengthen the safety of the health and care system in Scotland, but believe that detailed consideration needs to be given to the existing landscape, including the proposals for a Patient Safety Commissioner, in order to ensure that any new arrangements are evidence-based and do not inadvertently duplicate, complicate or dilute existing provisions.*" Written Statement of Lynsey Cleland paras 30-31 WITN7671001

152 Written Statement of Judith Paget para 14 WITN5712002

153 Written Statement of Peter May paras 3.1-3.3 WITN7461007

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The message delivered generally to the Inquiry is one of deep concern about the failings of NHS record keeping to date. It is important for there to be faith in the new system. There should accordingly be a formal audit of the success of the system, as operated in each of the four health administrations, by the end of 2027, which reports in a public forum as to its level of success in the percentage of the population who are (a) able to access their medical records online; (b) able to identify any corrections that need to be made to the data which has been recorded in their records, and can succeed in any reasonable case in securing those corrections; and (c) satisfied that they have sufficient control over the use of their data for purposes beyond their immediate treatment such as for research. It should also measure and report the degree of confidence which health professionals have in the degree of detail, accuracy and timeliness of any record they enter, and be able to assess that little material which should be recorded has been omitted. It should evaluate how far the savings in time which are identified in the Government strategy have been achieved in England, and whether all the national governments' digital initiatives have met their objectives and can be shown (on balance) to have improved the safety of patient care.

Because so many people who were infected trace their infections back to events which happened some time before they were diagnosed, the destruction policies of many health bodies have meant they are no longer are able to see, by looking back through their records, what was recorded as having happened, and be able to show to others (if necessary) what it led to in earlier years. Patients have a medical past which may help to inform diagnosis and treatment options today: where diseases may incubate over long periods, and attendances at medical centres may be sporadic, this may be important to them. Destruction policies should therefore be kept under review.

Professor David Armstrong drew attention in his evidence to problems caused because of a lack of interoperability of the digital systems currently in use in hospitals, both as between many hospitals, and as between hospitals and GPs.[154] There is plainly a danger that the systems to be adopted in England, Scotland, Wales and Northern Ireland may not be capable of interoperability, which could affect patient care given the regular movements of populations within the UK, and the resultant risks of gaps in personal health records (and the consequences of those risks).

The above analysis, considered in the light of all the material the Inquiry has reviewed, leads me to make the following recommendations:

4. Preventing future harm to patients: achieving a safety culture

(a) Duty of candour

(i) A statutory duty of candour in healthcare should be introduced in Northern Ireland.

154 Professor David Armstrong Transcript 14 September 2022 pp141-145 INQY1000240. Professor David Armstrong is professor of medicine and sociology at King's College London.

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(ii) **The operation of the duties of candour in healthcare in Scotland and in Wales should be reviewed, as it is being in England, to assess how effective its operation has been in practice. Since the duty was introduced in 2023 in Wales, the review there need not be immediate, but should be no later than the end of 2026.**

(iii) **The review of the duty of candour currently under way in England should be completed as soon as practicable.**

(iv) **The statutory duties of candour in England, Scotland, Wales (and Northern Ireland, when introduced) should be extended to cover those individuals in leadership positions in the National Health Service, in particular in executive positions and board members.**

(v) **Individuals in leadership positions should be required by the terms of their appointment and by secondary legislation to record, consider and respond to any concern about the healthcare being provided, or the way it is being provided, where there reasonably appears to be a risk that a patient might suffer harm, or has done so. Any person in authority to whom such a report is made should be personally accountable for a failure to consider it adequately.**

Success in implementation will be measured by the extent to which there is an increase in the number of reports made of near miss incidents to the designated data collector; and a decline in the number of widespread or significant healthcare failures.

(b) Cultural change

(i) **That a culture of defensiveness, lack of openness, failure to be forthcoming, and being dismissive of concerns about patient safety be addressed both by taking the steps set out in (a) above, and also by making leaders accountable for how the culture operates in their part of the system, and for the way in which it involves patients.**

(c) Regulation

(i) **That external regulation of safety in healthcare be simplified. As a first step towards this, there should be a UK wide review by the four health departments of the systems of external regulation, with the aim of addressing all the points made earlier in this Report and in other reports since 2000.**

(ii) **That the national healthcare administrations in England, Northern Ireland, Scotland and Wales explore, and if appropriate, support the development and implementation of safety management systems ("SMS"s) through SMS coordination groups (as recommended by the HSSIB), and do so as a matter of priority.**

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Success in implementation will be measured by the percentage of patients who know to whom they can express any concerns they may have about safety, who will take up their cause, and what they can expect from them. At the same time, it will be measured by the extent to which those who are busy working within the system, especially those in leadership roles, have clarity as to what, precisely, is expected of them, from whom. It should also be measured by a reduction in avoidable harm from both errors and systemic issues.

(d) Patient records

(i) Before the end of 2027 there should be a formal audit, publicly reported, of the extent of success of digitisation of patient records in each of the four health jurisdictions of the UK, measuring at least the levels of patient access to their personal records, their ability to identify and correct apparent errors in them, their interoperability, and the confidence of health professionals in the detail, accuracy and timeliness of any record they enter, and that little material which should be recorded has been omitted. Next steps should be identified.

(e) Consideration should be given by the national healthcare administrations in England, Scotland, Wales and Northern Ireland, to further coordination of their approaches particularly to ensure that patterns of harm, or trends, are identified and any response which for the sake of patient safety would be better coordinated than left to each individual administration can collaboratively be agreed and implemented.

5. Ending the defensive culture in the Civil Service and government

A duty of candour on civil servants and ministers

The Inquiry has a particular perspective to bring to the debate about whether to extend the duty of candour, on which the Lord Chancellor Alex Chalk said the Government was keeping related duties and obligations under review: "*we will not rule out taking further action if it is needed.*"[155] The chapter on *Lines to Take* lays out clearly the consequences of civil servants and ministers adopting lines to take without sufficient reflection, when they were inaccurate, partial when they should have been qualified, had no proper evidential foundation, ignored findings made by courts which were inconsistent (or flatly contradictory of) the lines adopted, or made unrealistic claims that treatment had been the best it could be. The commentary to that chapter reflects how:

155 Hansard parliamentary statement on Hillsborough: Bishop James Jones Report 6 December 2023 p3 RLIT0002396

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> "*In relation to Hepatitis C, Ministers took on faith what civil servants said; civil servants took on faith what the files said. No one stood back and reflected. No one asked questions – could this really be right? How could the best treatment available lead to the infection of so many?*"[156]

It records how a "*line, which was wrong from the very outset, then became entrenched for around twenty years: a dogma became a mantra. It was enshrined. It was never questioned.*"[157] "Lines" are particularly important because they are set out to express underlying policy and, especially when in place over many years, then affect or hinder the development of new policies.

In respect of three of the "lines to take", the consequences are described as cruel:

> "*The cruelty, for those infected and affected, of hearing, over and over, that they had received the best treatment available, that testing had been introduced as soon as possible, that they had been inadvertently infected, should not be underestimated.*"

The use of the lines contributed to delay in there being a public inquiry; it almost certainly meant that those infected and affected did not get the financial and psychological support they would otherwise have received; it contributed to a loss of trust in the health service and in the ability of government to understand and respond to genuine concerns and complaints.

In the light of findings such as are concentrated in the chapter on *Lines to Take*, the Inquiry has a particular perspective on how the existence of a clearer, more emphatic, duty of candour among civil servants might have altered the nature of the government response. It might have avoided compounding the suffering which had already occurred.

I doubt that the last word has yet been said on whether a statutory personal duty of candour should be introduced across the Civil Service. No one can sensibly dispute that people in public life should observe basic moral principles: they are as applicable to government ministers and officials as they are to clinicians.[158] The principles of public life may have

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156 See the chapter on *Lines to Take*.

157 See the chapter on *Lines to Take*.

158 As was clear from the evidence of the expert group on Public Health and Administration, the attributes of integrity, honesty, objectivity and impartiality form the bedrock upon which the Civil Service was built; and ministers were expected to behave with objectivity, openness and honesty, even before Lord Michael Nolan articulated those principles as part of the seven principles of public life. Public Health and Administration Expert Panel Transcript 3 October 2022 pp6-9 INQY1000251. Expert Report to the Infected Blood Inquiry: Public Health and Administration August 2022 pp8-12 EXPG0000048. The Seven Principles of Public Life are:

1. Selflessness (requiring holders of public office to act solely in the public interest)
2. Integrity
3. Objectivity
4. Accountability
5. Openness
6. Honesty
7. Leadership

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become known as the Nolan Principles in 1995,[159] but they articulate what was already well understood, and went beyond the "*basic moral principle of our society that we should tell the truth*."[160] Yet they did not prevent what the chapters on the government response describe. I said in the chapter *Lines to Take* that it is ironic that these Nolan principles were articulated in their present form at a time when for six years an over-confident line with no proper evidential foundation had been repeated by civil servants, adopted by them as having the status of a "given" through a form of groupthink, and was to go on being used repeatedly. It is more than ironic: it shows that without statutory underpinning the principles of Lord Nolan and the Civil Service Code are not in themselves sufficient to prevent this happening.

It must be a concern that unless a duty of candour "has teeth" it might similarly be broken in future; and it is my concern that unless I draw attention to this I shall not be fulfilling my duty of making appropriate recommendations to the Government.

In addressing how best patient safety in future can be ensured in healthcare, and what "teeth" might be effective in achieving the long sought-after change of culture, I have proposed that leaders should be made accountable for failures of candour in their organisations; that no blame should fall on those who admit to making honest mistakes, or to a "near miss", but instead on those who hide them (either in themselves or others), and that reliable data will enable a proper record so that leaders and the public are informed accurately about progress towards safer care.

Though the Civil Service does not itself deal directly with patient care, its actions, and those of the ministers it supports can compound any failures of care, especially where they do so by expressing mistaken, inadequate, or ill-considered views of the facts, or simply by delaying responses to concerns or fresh information. Taking a wider view, there is a duty to the public served by civil servants: citizens deserve honesty rather than ill-placed defensiveness.

Dame Una O'Brien, who was formerly Secretary to the Bristol Inquiry and later Permanent Secretary at the Department of Health and Social Care, and thus worked in a part of the Civil Service closely linked to the issues arising in this Inquiry, wrote an article in April 2023, entitled "*Silence is not golden: The civil service must enable a 'speak-up' environment*". In it she described the problem which led to the title of the article – "*will I be heard respectfully without negative consequences? The policies and procedures might look polished and inviting, but sometimes, especially in the civil service, a culture of hierarchy and dismissiveness can cause us to hold back.*" She pointed to the examples of "*Sue Gray's report regarding No.10: 'Some staff had witnessed or been subjected to behaviours at work which they had felt concerned about but at times felt unable to raise properly*'" and to "*the Foreign Affairs Committee's report on the withdrawal from Afghanistan, where they point to the absence of an adequate process for officials to express concerns about policy without fear of damaging their careers.*" Both showed that (despite the Civil Service Code and Nolan

159 Lord Nolan *Standards in Public Life: First Report of the Committee on Standards in Public Life* May 1995 RLIT0001795

160 The words of Professor Kennedy in his 1980 Reith Lectures *Unmasking Medicine* Transcript 26 November 1980 p3 RLIT0000620

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Principles) people found it difficult to express concerns. She then turned to the "*mature good practice*" of the nuclear and airline industries for inspiration as to the best way of addressing this. Her solution was, as it had been in those industries, to develop "*systems that counter deference and encourage staff at all levels to speak up with concerns.*" She thought that part of achieving this was "*leadership*", and a culture of trust and respect.[161]

What she says echoes what the Inquiry has found of the period leading up to today; and the solutions she suggests for the Civil Service are consistent with mine for healthcare: ensure the accountability of leadership, and put blame not on those who raise concerns, but on those who knowing of a matter of concern do not then raise it or who ignore concerns raised.

In the House of Lords debate on whether to accept an amendment to the Victims and Prisoners Bill which proposed a statutory duty of candour, the following exchange took place. Baroness Brinton asked the Parliamentary Under-Secretary of State, Lord Bellamy, "*there is an issue about the personal duty of candour that changes behaviour. Does he recognise that?*" His answer was: "*Yes, the Government recognise that up to a point. What we are discussing is the right way to get there. The Government are not convinced that this statutory amendment is the right way.*"[162]

It is plain that the objective of those who support a statutory duty is the same as those in government who do not – that there needs to be a change of culture to one which values personal candour and rejects defensiveness. The question is what best achieves this.

Part of the view of the Government has been that the introduction of an independent advocate for victims of major incidents will go a considerable way in addressing what might otherwise be achieved by enacting a statutory duty of candour. The addition of an independent advocate to support victims of a major incident is indeed valuable. The Bill regarding the role of independent advocates has, at the time of writing, not yet reached the statute book. As currently drafted, it is very much a supportive one, in effect to act as a knowledgeable intermediary, in response to a "*major incident*". The independent advocates will have no powers themselves to investigate; nor powers to require the provision of, or even to see, documents. It is difficult to see that the role would have made a material difference to the way in which governments reacted to what had happened to infect people through blood and blood products. It is not at all easy to see that it would have encouraged a more reflective approach within the Civil Service, or a more curious approach from ministers.

It is unlikely that the role, important and valuable though it is, will have any significant part in achieving the culture change which is needed to prevent a future recurrence of the apparent deafness and defensiveness of government to concerns about what had happened to cause infections by blood and blood products.

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161 Civil Service World *Silence is not golden: The civil service must enable a 'speak up' environment* 6 April 2023 RLIT0002432

162 Hansard debate on Victims and Prisoners Bill 26 February 2024 pp5-6 RLIT0002433

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I well understand that a duty of candour cannot be drafted so widely as to oblige each individual civil servant of whatever rank to consider separately in the aftermath of a major incident whether they need to disclose a document they have seen or information of which they are aware. This would, as Lord Bellamy suggests, be unworkable.[163] Government is entitled to formulate its policy in a "safe space" if it is to work effectively. However, those in a leadership role (as opposed to more junior civil servants) are well placed to know what documents and information may and should be disclosed without encroaching on such a safe space.

Equally, a duty should not be so limited as to apply only when concerns have developed so far as to lead to an inquiry, or to a claim by way of judicial review, or a court case.

If and when, however, serious concerns are raised with or come to the attention of government departments (as they were in relation to infected blood) there is a very real place for a statutory requirement of candour to bite. This will first and foremost place requirements on those who lead – for they should be accountable by statute for the honesty, objectivity and completeness of what is said by them, or given to ministers to say. They should be responsible too for ensuring that a candid response is forthcoming, which should draw attention to any document or reliable information reasonably to be regarded as relevant to the concern being raised telling not just the truth, but **the whole truth**, and nothing but the truth. Those in a department who are not themselves in a leadership role should be obliged to tell those to whom they report of any concern they have that a response (or proposed response) is lacking or inaccurate – and to record that they have done so.

I have recommended that those in leadership positions in the health service, who would not otherwise be within the scope of a statutory duty of candour, should be made subject to it, and made accountable for their personal handling of concerns about the safety of healthcare amongst those they lead. Recognition of a corresponding duty of leaders in the Civil Service is also recommended.

The duty of ministers is to be properly reflective, curious and prepared if need be to be critical of advice. What they say should, of course, be candid (subject to overriding issues of public interest) but they also have a role in helping to ensure that Government as a whole is candid.

It follows that I recommend that:

5. Ending a defensive culture in the Civil Service and government

(a) The Government should reconsider whether, in the light of the facts revealed by this Inquiry, it is sufficient to continue to rely on the current non-statutory duties in the Civil Service and Ministerial Codes, coupled with those legal duties which occur on the occasions when civil servants and ministers interact with courts, inquests and inquiries, as securing candour.

163 Hansard debate on Victims and Prisoners Bill 26 February 2024 p5 RLIT0002433

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(b) If, on review, the Government considers that it is sufficient to rely on the current non-statutory duties in the Civil Service Code, it should nonetheless introduce a statutory duty of accountability on senior civil servants for the candour and completeness of advice given to Permanent Secretaries and Ministers, and the candour and completeness of their response to concerns raised by members of the public and staff.

(c) The Government should consider the extent to which Ministers should be subject to a duty beyond their current duty to Parliament under the Ministerial Code.

6. Monitoring liver damage for people who were infected with Hepatitis C

In February 2020 at the end of the hearings with the expert groups I said:

> "*I would like to draw the attention publicly now of NHS England and hospital trusts and boards throughout the country to the fact that the need for specialist treatment by professionals who have a special understanding of infected blood and blood products has not gone away, now that there is greater success in treatment of the underlying conditions, that there is a need to ensure that the standards of follow-up of those who have cleared Hepatitis C but have been left with a compromised liver are maintained in accordance with what the experts have set out this week*".[164]

One of the most important issues to participants in relation to their treatment is their ability to access monitoring and follow up care for Hepatitis C (and related symptoms and conditions) after they achieve sustained virological response ("SVR"). This arises because of their very reasonable anxieties about the harm long-untreated Hepatitis C may have done to their bodies. Even if "cured", in the sense that the disease process itself is no longer active, it has left an increased risk of developing end-stage liver disease or liver cancer if they had developed fibrosis or cirrhosis before treatment.[165] Witnesses told the Inquiry that they had simply been discharged from any ongoing care or monitoring following achievement of SVR. Currently there is no consistent clinical practice, and some patients receive no clinical surveillance.

The prognosis and progression to cirrhosis and hepatocellular cancer is variable as between patients,[166] with the major factor determining any long-term impact being the degree of liver fibrosis at the time the person's Hepatitis C PCR test became negative.[167] That has treatment and monitoring implications. Although there is evidence that treatment intervention, even at

164 Sir Brian Langstaff Transcript 28 February 2020 pp177-178 INQY1000054

165 Hepatitis Expert Panel Transcript 26 February 2020 pp173-181 INQY1000052, Expert Report to the Infected Blood Inquiry: Hepatitis January 2020 p58, pp67-68 EXPG0000001

166 Expert Report to the Infected Blood Inquiry: Hepatitis January 2020 p30 EXPG0000001

167 Expert Report to the Infected Blood Inquiry: Hepatitis January 2020 p58 EXPG0000001

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late stages of fibrosis, will change the risk of liver failure dramatically, successfully treated patients still carry risks of progressing to cirrhosis.[168] Further, evidence from Scotland has shown that after successful treatment, the risk of cancer fell but did **not** return to normal after a three year period.[169] The extent to which SVR is associated with a reduction in the risk of Hepatitis C-related damage (note, this is a reduction, not an eradication) depends on the time Hepatitis C has been left to progress untreated and to what extent fibrosis or cirrhosis has already occurred. There is thus a long term risk of those infected by NHS treatment – the vast majority of whom were left untreated for years or even decades – developing liver cancer even for those who have not reached liver failure.[170] Liver cancer is such that surveillance is crucial for identifying it at an early stage. The tumour is "*very variable … and some patients despite screening may be diagnosed at a late stage, even though they've been undergoing tests.*"[171]

It is possible in theory for HCV to "*reactivate*" following immunosuppression, for example associated with cancer treatment, if the assumed SVR did not in fact amount to full clearance of the virus. "*You can think you have got rid of a virus infection in a human host and then you do something to them and if there is any residual virus it may reactivate.*"[172] Though confirmed as a theoretical possibility in the Expert Report to the Infected Blood Inquiry: Virology (Hepatitis Supplementary), which also confirms that there is "*no perfect test to establish* [complete eradication]" of Hepatitis C it should be noted that the Expert Group says that rates of recurrence are very low (if it has not occurred within 12 weeks of finishing therapy) and it is rare after 24 weeks.[173]

In the chapter on *Access to Treatment*, I recorded the recommendations of Professor Michael Makris. These relate to people with an inherited bleeding disorder infected with Hepatitis C, but they are equally applicable to those who have been infected by transfusion. He recommends that those who are infected, including those who have successfully cleared the virus, should be reviewed by a liver specialist at least once. He explains that many of the patients with bleeding disorders treated over the last 35 years, especially prior to the last decade, will have been treated through haemophilia centres rather than by an hepatologist. Studies have shown that successful Hepatitis C treatment does not eliminate the risk of liver-related complications in persons with infected bleeding disorders. Due to higher baseline risk, incidence was higher after direct-acting antivirals than interferon-based SVR – since people were being treated later.[174]

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168 Hepatitis Expert Panel Transcript 26 February 2020 pp96-97 INQY1000052

169 Hepatitis Expert Panel Transcript 26 February 2020 pp96-97 INQY1000052

170 Expert Report to the Infected Blood Inquiry: Hepatitis January 2020 p56 EXPG0000001, Hepatitis Expert Panel Transcript 26 February 2020 pp170-171 INQY1000052

171 Hepatitis Expert Panel Transcript 26 February 2020 p119 INQY1000052

172 Professor Richard Tedder Transcript 14 October 2022 p75 INQY1000256

173 Only 1 out of 384 patients suffered a recurrence 60 weeks after completing therapy. Expert Report to the Infected Blood Inquiry: Virology (Hepatitis Supplementary) December 2022 pp8-9 EXPG0000131

174 Written Statement of Professor Michael Makris WITN4033023. See the chapter on *Access to Treatment*.

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He recommends that patients with advanced fibrosis or cirrhosis are entered into an hepato-cellular screening programme, with six-monthly ultrasound scans and regular hepatology follow-up to detect early signs of liver failure because "*The chances of success in the treatment of hepatocellular carcinoma depends on how early it is diagnosed, so every attempt should be made for early identification.*" He notes that "*If surveillance is required, there should be a named doctor/team responsible for making sure it takes place on time*" and that those with an inherited bleeding disorder who have had Hepatitis C should be seen by a consultant hepatologist, rather than a more junior member of staff.[175]

I said in the course of the hearings, and repeat here, that given the particular complexities infected people with inherited bleeding disorders present, and a need to have some understanding of the historical context, I agreed with what Professor Makris was saying.

In respect principally of people infected with Hepatitis C as a result of transfusion, the participants represented by Leigh Day[176] recommended in essence what Professor Makris had set out. Since I consider their recommendations to be justified by the evidence, my recommendations use their words as my own, with the addition of two further points.

The first is point (v) to accord with Professor Makris' recommendations in respect of the involvement of a consultant hepatologist.

The second reflects the commentary at the conclusion of the section on *Treatment of Hepatitis C* in the chapter on *Access to Treatment*, where I said that: "*The consistent delivery of appropriate follow-up monitoring is a legitimate concern. For this reason, I recommend that those bodies responsible for commissioning hepatology services in each of the home nations should publish the steps they have taken to satisfy themselves that the services they are commissioning meet the particular needs of this group of people harmed by NHS treatment, including those with bleeding disorders whose treatment for Hepatitis C was not managed by hepatologists.*"

I therefore recommend:

6. Monitoring liver damage for people who were infected with Hepatitis C

(a) All patients who have contracted hepatitis via a blood transfusion or blood products should receive the following care:

(i) those who have been diagnosed with cirrhosis at any point should receive lifetime monitoring by way of six-monthly fibroscans and annual clinical review, either nurse-led, consultant-led or, where appropriate, by a GP with a specialist interest in hepatitis

175 Written Statement of Professor Michael Makris p4 WITN4033023. See the chapter on *Access to Treatment*.

176 This was a group which consisted largely of those who had been infected by transfusion, the majority of whom were infected by Hepatitis C. Final Submissions on behalf of Leigh Day Participants 16 December 2022 pp202-203 SUBS0000059. This is consistent with the advice of the expert group on hepatitis. Expert Report to the Infected Blood Inquiry: Hepatitis January 2020 pp67-68 EXPG0000001

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(ii) those who have fibrosis should receive the same care

(iii) where there is any uncertainty about whether a patient has fibrosis they should receive the same care

(iv) fibroscan technology should be used for liver imaging, rather than alternatives

(v) those who have had Hepatitis C which is attributable to infected blood or blood products should be seen by a consultant hepatologist, rather than a more junior member of staff, wherever practicable

(vi) those bodies responsible for commissioning hepatology services in each of the home nations should publish the steps they have taken to satisfy themselves that the services they are commissioning meet the particular needs of the group of people harmed by NHS treatment

7. Patient Safety: Blood transfusions

The measures taken to reduce the risk of transmission of infection by the blood services have greatly changed the risk-profile of blood transfusion. The majority (>80%) of reports to the Serious Hazards of Transfusion scheme ("SHOT") are now due to errors or mistakes in the clinical transfusion process. The biggest risks are receiving the wrong blood (either the wrong component is transfused or specific requirements are not met), receiving too much blood too quickly and developing transfusion associated circulatory overload ("TACO"), or not receiving blood quickly enough (blood delays).

Shared decision making and consent in clinical transfusion practice was recommended by the Advisory Committee on the Safety of Blood, Tissue and Organs ("SaBTO"), by NICE in their blood transfusion guidance (and supported, in Scotland, by Realistic Medicine) yet successive audits, including a recent audit against the NICE Quality Standards, has demonstrated less than universal compliance.

Though NHS hospitals and staff continue to be under exceptional pressure, perhaps never more so than over the past few years, most of these are systems errors preventable with the right processes, knowledge and training as well as implementation of enhanced electronic clinical systems which promote and support best practice in the laboratory and at the bedside.

Professor Cheng-Hock Toh, chair of the National Blood Transfusion Committee, asked readers of the *British Medical Journal* the question "*How can we ensure that the right patient gets the right blood at the right time*?" He summed up his answer by saying "*Preventing ... avoidable harm is not difficult – it needs clear leadership and resolve to make the right decisions to use blood effectively and for the right blood to be transfused in a timely manner.*"[177]

177 Cheng-Hock Toh *How can we ensure that the right patient gets the right blood at the right time?* British Medical Journal 23 October 2023 RLIT0002235

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What he says resonates with the evidence there has been before the Inquiry, and leads to six improvements which will help to avoid harm.

The first is in respect of how best to avoid blood transfusions which though very safe indeed (nowadays) nonetheless always come with risks, some of which, as of now, may be unknown.

Tranexamic acid

There is a substantial body of evidence which shows that patients who receive tranexamic acid[178] have significantly less life-threatening bleeding, major bleeding or bleeding into a critical organ within the 30 days after treatment. There is no difference in the risk of unwanted thrombosis. Large surgical trials have shown that tranexamic acid resulted in a lower incidence of postpartum haemorrhage amongst patients undergoing caesarean section, and a lower incidence of haemorrhage resulting in re-operation among patients undergoing cardiac surgery.[179]

Its use is supported by NICE. In 2015 NICE issued a guideline recommending that tranexamic acid be offered to adults undergoing surgery who are expected to have at least moderate blood loss; and that tranexamic acid be offered to children undergoing surgery as well, if they are expected to have at least moderate blood loss (ie greater than 10% blood volume). Tranexamic acid is not expensive. There is strong evidence that it is clinically effective and that its use will reduce mortality and costs. Yet it was noted that clinical opinion was that usage might have been as low as 10%-20% at that point.[180]

It became a NICE quality standard in December 2016.[181] By 2021 a national comparative audit showed that 67.5% of eligible surgical patients were given tranexamic acid, though potentially all were eligible to receive it.[182] It appears there is a NICE quality standard that is not being well implemented.

Patients at risk of a blood transfusion could have been offered it too, and in Professor Roberts' view should have been. He said: "*if I had surgery and woke up to find I'd received blood and I hadn't been given tranexamic acid, I'd be really annoyed …*"[183] So he and Professor Mike Murphy (of NHSBT and professor of blood transfusion medicine at the University of Oxford) formed an ad-hoc group with representation from the Royal College of Surgeons of England, the Royal College of Anaesthetists and the Royal College of Physicians, and "*we wrote an editorial and said ... the status quo isn't adequate and we're going to try and*

178 Tranexamic acid prevents the natural process of clot breakdown, allowing the clot to stay in place. The body is therefore more likely to clot successfully, to stem bleeding.

179 Devereaux et al *Tranexamic Acid in Patients Undergoing Noncardiac Surgery* New England Journal of Medicine April 2022 RLIT0001825, Professor Ian Roberts Transcript 10 November 2022 pp70-79 INQY1000259

180 NICE Guideline on Blood Transfusion 18 November 2015 p10, p22 RLIT0001793

181 NICE Quality standard on Blood Transfusion 15 December 2016 RLIT0001794

182 NHS Blood and Transplant *2021 National Comparative Audit of NICE Quality Standard QS138* February 2022 p9 WITN7001061

183 Professor Ian Roberts Transcript 10 November 2022 p86 INQY1000259. Professor Roberts is a professor of epidemiology at the London School of Hygiene and Tropical Medicine.

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change things, and we made some suggestions of what we think needed to be done and we are still in the process of trying to carry those things out."[184]

They have recently pointed out that the 2023 audit of the NICE Quality Standards for Blood Transfusion produced nearly identical results to the 2021 audit.[185] The actions thus far taken have been ineffective, despite the Royal College of Surgeons (England) and the Royal College of Anaesthetists having highlighted its use, and aimed to ensure that "*consideration of tranexamic acid use*" is included in the safe surgery checklist of all NHS hospitals.[186]

The National Medical Director of NHS England, Stephen Powis, wrote in 2022 to Trust medical directors recommending the wider use of tranexamic acid to reduce bleeding in surgery.[187]

Professor Toh, wrote in the *British Medical Journal* as chair of the National Blood Transfusion Committee:

> "*The number of deaths related to blood transfusions has more than doubled since the covid-19 pandemic and the Serious Hazards of Transfusion group reports that these numbers have not returned to pre-pandemic levels, remaining at or above 35 deaths per annum since 2020.*
>
> *This is deeply concerning but not entirely surprising in an overstretched NHS, yet immediate and sustainable improvements are achievable. Firstly, we must effectively reduce blood loss and unnecessary use of blood. A huge body of evidence supports use of tranexamic acid to reduce major surgical bleeding by 25%, thus avoiding unnecessary blood use. Tranexamic acid is an inexpensive drug championed by UK Medical Royal Colleges*".[188]

He also said: "*leadership by integrated care boards in standardising and benchmarking transfusion performance between hospitals could deliver better patient blood management. This would save lives and avoid disastrous 'never events' in transfusion.*"[189]

184 Professor Ian Roberts Transcript 10 November 2022 pp87-88 INQY1000259

185 Letter from Professor Murphy, Professor Roberts and Professor Toh to Sir Brian Langstaff 1 November 2023 p2 WITN7310003, NHS Blood and Transplant *2023 National Comparative Audit of NICE Quality Standard QS138* February 2024 p14 RLIT0002421

186 Letter from Professor Murphy and Professor Roberts to Sir Brian Langstaff 16 November 2022 p2 WITN7310002

187 Cheng-Hock Toh *How can we ensure that the right patient gets the right blood at the right time?* British Medical Journal 23 October 2023 p1 RLIT0002235

188 Cheng-Hock Toh *How can we ensure that the right patient gets the right blood at the right time?* British Medical Journal 23 October 2023 RLIT0002235

189 Cheng-Hock Toh *How can we ensure that the right patient gets the right blood at the right time?* British Medical Journal 23 October 2023 RLIT0002235

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I recommend that:

7. Patient Safety: Blood transfusions

(a) Tranexamic acid

(i) In England Hospital Transfusion Committees and transfusion practitioners take steps to ensure that consideration of tranexamic acid be on every hospital surgical checklist; that hospital medical directors be required to report to their boards and the chief executive of their Trust as to the extent of its use; and that the board report annually to NHS England as to the percentage of eligible operations which have involved its use. If the percentage is below 80% or has dropped since the previous year, this report should be accompanied with an explanation for the failure to use more tranexamic acid and thereby reduce the risk to patient safety that comes with using a transfusion of blood or red blood cells.

(ii) In Scotland, Wales and Northern Ireland offering the use of tranexamic acid should be considered a treatment of preference in respect of all eligible surgery.

(iii) Consideration be given to standardising and benchmarking transfusion performance between hospitals in order to deliver better patient blood management.

The recommendations which follow closely follow recommendations suggested by the NHSBT in their closing submissions. Though in the way they are formulated, they relate (necessarily) to England, I note that the Welsh Blood Service "*agrees and endorses the comprehensive submissions and recommendations now advanced to the Inquiry by NSHBT ... in Wales, headways is already being made in areas which overlap some of the recommended actions, as a result of the Welsh-specific NHS Wales Blood Plan ... WBS will consider with care whatever recommendations the Inquiry makes, with a view to building on those improvements which have already started.*"[190] The Northern Ireland Blood Transfusion Service "*earnestly awaits Sir Brian's recommendations to explore further ways in which to deliver improved and enhanced care to its service users.*"[191] The Scottish National Blood Transfusion Service has developed its own similar approach. In 2021 it set out a 5-year plan. The strategy comprises three main strategic goals: Education, Communication and Data & Quality Improvement.[192]

190 Closing submissions of the Welsh Blood Service 15 December 2022 p2 SUBS0000049

191 Closing submissions of the Northern Ireland Blood Transfusion Service 16 December 2022 p23 SUBS0000051

192 In overview, these are:

Education: to continue to educate and develop a workforce to deliver person centred care with the key focus on the safe, effective and appropriate use of blood for patients in Scotland

Communication: between team members and the transfusion network to promote and share initiatives in clinical transfusion practice

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Review of progress towards the Transfusion 2024 recommendations

In 2019 in England a plan – *Transfusion 2024* – set out key priorities for clinical and laboratory transfusion practice for safe patient care across the NHS for the next five years. It was based on the outcomes of a symposium in March 2019, organised by the National Blood Transfusion Committee and supported by NHS England and NHS Improvement. The key priorities were set out under four headings in a table – Patient Blood Management, Transfusion Laboratory Safety, Information Technology, and Recommendations for further research and development – each with a number of specific actions to be taken.[193] Progress needs to be maintained – first by publicly assessing progress across the first five years, and determining what the next steps should be, including whether a further five year plan is merited.

I recommend:

(b) Progress in implementation of the *Transfusion 2024* recommendations be reviewed, and next steps be determined and promulgated; and that in Scotland the 5 year plan is reviewed in or before 2027 with a view to determining next steps.

The responsibility for this in England is that of NHS England, shared with the National Blood Transfusion Committee, the Royal Colleges (as appropriate), and NHSBT.

Transfusion laboratories

Transfusion laboratory safety is one of the key priorities expressed in *Transfusion 2024*. Though transfusion is in general conducted very safely, there are still hazards, to which SHOT draws attention in its annual reports. Most transfusion-related complications arise from mistakes in hospital transfusion laboratories.[194] Thus in 2020, 323 such complications were reported; in 2021, 266; and in 2022, the latest year for which there is a report, 296.[195]

Clinical and laboratory teams can function optimally only if adequately staffed and resourced. Inadequate staffing levels have been a common feature to which other inquiries into NHS incidents have drawn attention. They include the Mid Staffordshire Inquiry;[196] the Paterson

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Data and quality improvement: to use the unique opportunity of Account for Blood (AfB) and the Scottish Transfusion Epidemiology Database (STED) along with other healthcare datasets and dashboard capabilities to set and monitor key performance indicators and care quality indicators which continually improve clinical transfusion practice.

SNBTS Transfusion Team 5-year Strategy pp27-28 March 2021 WITN7300016

193 Allard et al *Transfusion 2024: A 5-year plan for clinical and laboratory transfusion in England* Transfusion Medicine 2021 pp2-4 WITN7001031. The seminar in March 2019 is discussed in the chapter *Blood Transfusion: Clinical Practice*.

194 Annual SHOT Report 2021 p77 SHOT0000032

195 Annual SHOT Report 2020 p73 SHOT0000031, Annual SHOT Report 2021 p77 SHOT0000032, Annual SHOT Report 2022 p73 SHOT0000033

196 Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry February 2013 RLIT0001925

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Inquiry;[197] the Ockenden Review;[198] and an inquiry into avoidable deaths and failures of care in sickle cell patients (*No One's Listening*).[199] Compliance with UK Transfusion Laboratory Collaborative ("UKTLC") standards has been accepted by the MHRA, and UK Accreditation Service as evidence to support their inspections for laboratories: the UKTLC has concluded that a significant proportion of the errors were most probably related to issues of information technology, staff education, staffing levels, skill mix, training and competency issues.[200]

This material leads me to recommend, as the NHSBT suggests that I should, that:

(c) Transfusion laboratories should be staffed (and resourced) adequately to meet the requirements of their functions.

Training in Transfusion Medicine

The Inquiry has heard evidence that clinicians, particularly those without expertise in the blood transfusion field, lack sufficient training. Historically, this has led to inappropriate use of transfusion; most notably transfusion where it is unnecessary.[201]

In a context where risks inherent in blood and blood components can never be nil, it is important that inappropriate use of transfusion is avoided. In addition, avoidable errors in relation to blood transfusion remain.[202] All staff likely to be involved in blood transfusions need to have basic knowledge of blood components, indications for use, alternative options where available, risks, benefits, possible reactions, and management. In addition, such staff need to have the skills to improve patient outcomes in respect of transfusion and reduce health inequalities by involving patients in their own care and ensuring that any care takes into account the needs of patients as individuals.

NHSBT recommends that reducing risks to patients' safety in this respect involves haematology training, transfusion training, and education on the Better Blood Transfusion initiative.[203]

SNBTS says that the LearnBloodTransfusion e-learning programme started in 2004, and until recently was used throughout the UK. In Scotland it is mandated that all those in clinical

197 Report of the Independent Inquiry into the Issues raised by Paterson February 2020 RLIT0001926

198 Ockenden review summary of findings, conclusions and essential actions 30 March 2022 RLIT0001927

199 No One's Listening: An Inquiry Into The Avoidable Deaths and Failures of Care for Sickle Cell Patients in Secondary Care RLIT0001928

200 Chaffe et al *UK Transfusion Laboratory Collaborative: minimum standards for staff qualifications, training, competency and the use of information technology in hospital transfusion laboratories 2014* Official Journal of the British Blood Transfusion Society 29 October 2014 RLIT0002437. The UK Transfusion Laboratory Collaborative was formed in 2006 in response to 30-40% of all wrong blood events reported to SHOT originating in hospital transfusion laboratories. It involves all major transfusion organisations in the UK.

201 See the chapter *Blood Transfusion: Clinical Practice*.

202 For example, see the 2022 SHOT report: *Annual SHOT Report 2022* SHOT0000033

203 In her Written Statement Dr Miflin described some of the work that NHSBT already does in respect of training in blood transfusion at the postgraduate level. Written Statement of Dr Gail Miflin paras 1480-1488 WITN0672006. See also Closing Submissions of NHSBT 16 December 2022 para 17.43 SUBS0000062

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transfusion practice complete the Safe Transfusion Practice module within the first few weeks of starting work in a Scottish hospital and compliance is monitored by the hospital transfusion committee. The SNBTS transfusion team signpost the modules to be completed by each staff group. NHSBT has now developed an alternative e-learning programme Blood Transfusion Training.[204]

I recognise that the content of training is carefully considered by those bodies whose principal concern it is. However I recommend (as invited to do by NHSBT):[205]

(d) That those bodies concerned with undergraduate and postgraduate training across the UK of those people who are, or intend to be, working in the NHS ensure that they are adequately trained in transfusion, that the standards by which sufficiency of training is measured are defined, and accountability for training in transfusion be defined.

Implementing SHOT reports

Acting on reports of near-misses and serious events is part of the tapestry of haemovigilance. The MHRA, SHOT and the National Blood Transfusion Committee now between them provide a complete picture on haemovigilance in the UK. The role and work of SHOT has been set out in evidence by Professor Bellamy.[206] He said, in compelling evidence, that mandating reporting to SHOT would help, because:

> "*we know that there is a large level of underreporting … It simply isn't credible that years go by when no hospital has a near miss … I think for near misses, there is a tendency not to report things. But if you want a system which is robust, which is going to stop the real harm from taking place, you're not going to do that by waiting until that real harm occurs. You need to recognise the patterns beforehand. You need to recognise the behaviours, the practices, the systems errors, which lead to those near misses because it's only if you get rid of all the near misses that you're going to stop the eventual actual event from happening.*"[207]

In his statement he explained that "*reporting … to the MHRA is mandatory for actual serious adverse events and reactions, but reporting to SHOT, for example, near-misses, is 'professionally mandated' but not legally mandatory, but forms part of clinical governance*

204 para 241 SUBS0000044. SNBTS also worked with the territorial health boards through the Scottish National Blood Transfusion Committee ("SNBTC") and Haematology and Transfusion Scotland Network to develop a Scottish National Transfusion Record ("NTR") in July 2022, which guides clinicians through the consent process with a Transfusion Associated Circulatory Overload ("TACO") checklist.
NHS Lothian Transfusion Education and Training: Blood Transfusion procedure outlines the transfusion education and training requirements of staff members involved in any stage of the transfusion process. (November 2023)

205 Closing Submissions of NHSBT 16 December 2022 paras 17.41-17.43 SUBS0000062

206 Written Statement of Professor Mark Bellamy WITN7312001, Professor Mark Bellamy Transcript 16 November 2022 p182 INQY1000263. Professor Bellamy is chair of the SHOT steering group.

207 Professor Mark Bellamy Transcript 16 November 2022 pp64-65 INQY1000263

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arrangements for Trusts and Health Boards … although SHOT and MHRA use an integrated reporting portal".[208]

He thought that mandating NHS trusts and health boards to have a designated person in place to report haemovigilance matters might be possible. If such a post were not mandated, he feared that what would then be an optional position could be an early victim of cuts.[209] Professor James Neuberger was "*very much in favour*" of legally mandating reporting, and said that having someone statutorily responsible would be a "*very useful start.*"[210]

As I comment in the chapter on *Blood Transfusion: Clinical Practice*:

> "*all three of Professor Bellamy, Professor Neuberger and Dr Cave thought more reporting should be encouraged; all agreed that near-misses should be identified (indeed, the reasoning articulated for this by Professor Bellamy is compelling), and differed only on whether the effect of mandating a 'responsible person' to ensure proper haemovigilance reporting would be to incentivise others to think of reporting or lead to them thinking that it was someone else's responsibility … for my part I think that mandating trusts and health boards to have a responsible person in place, as a first step, together with a regularly audited professional requirement on doctors who are responsible for giving transfusions to include in their report not only that a transfusion was given (recording the identifiers of the unit(s)) but stating why it was given would be more likely to underpin the importance of haemovigilance than water it down.*"

SHOT is a professionally independent body making recommendations to improve blood safety to all organisations involved in blood transfusion. Reporting to SHOT is "*professionally mandated*". Thus, among other mechanisms, the regulatory framework operating around implementation of SHOT report recommendations should similarly be professionally mandated and monitored by healthcare regulators. This will produce a requirement for implementation within a system which has an in-built monitoring framework. This must not absolve healthcare providers of a separate obligation to monitor the implementation of the recommendations. In the submission of NHSBT it nonetheless retains an appropriate flexibility for good reasons and an appropriate risk assessment.[211]

I recommend:

(e) That all NHS organisations across the UK have a mechanism in place for implementing recommendations of SHOT reports, which should be professionally mandated, and for monitoring such implementation.

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208 Written Statement of Professor Mark Bellamy para 33 WITN7312001. He said "*the existing regulations are a little bit too flimsy and nebulous, whereas what is laid out for the MHRA reporting scheme and the BSQR* [Blood Safety and Quality Regulations] *is absolutely clear.*" Professor Mark Bellamy Transcript 16 November 2022 pp65-66 INQY1000263

209 Professor Mark Bellamy Transcript 16 November 2022 pp66-67 INQY1000263

210 Professor James Neuberger Transcript 16 November 2022 pp66-67 INQY1000263

211 Closing Submissions of NHSBT 16 December 2022 para 17.34 SUBS0000062

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Establishing the outcome of every transfusion

It is likely to be of significant importance to establish the outcome of every transfusion. If this had been achieved at the time of the principal events described in the Report, it seems likely that alarm bells would have rung sooner; that infections would have been detected (clinically, if they could not be established by existing tests) and advice to patients have been better informed, more quickly.

Scotland started developing the system "Account for Blood" in 2008 and it was in use from 2010. The database now covers 95-98% of blood transfusions in Scotland. The Scottish Transfusion Epidemiology Database uses the patient data from the Account for Blood system and links it with hospital inpatient records.[212] SNBTS worked with the territorial health boards through the Scottish National Blood Transfusion Committee and Haematology and Transfusion Scotland Network to develop a Scottish National Transfusion Record in July 2022, which guides clinicians through the consent process with a Transfusion Associated Circulatory Overload (TACO) checklist. The current aim, as part of a 5 year plan is to better understand the demand for blood components and how demand changes over time.

Outside Scotland the outcomes for recipients of blood components are not easily known without a national or clinical audit. *Transfusion 2024* has been mentioned above. It includes development of a system of "vein-to-vein" tracking. The plan notes that implementation of these significant schemes would be subject to finding the funds to do so.[213] However, NHSBT submits that having robust systems to understand the outcomes of people undergoing transfusion of blood components, coupled with one that allows clinical audit and research, should be an aim of the NHS. This is likely to be best achieved using the IT systems currently being developed, which have appropriate interfaces between existing systems.[214] Furthermore, if it is done correctly it should allow NHSBT to manage the blood stocks throughout the system and for experts to audit the appropriate use of blood components using simple tools of analysis rather than large complex time-taking audits, thus in itself leading to a greater likelihood of a better use of blood.[215]

I am told that the recording of, and access to, information concerning transfusion is currently difficult in the NHS in England. The lack of integration between various records is an important limitation which hampers patient access to information, and limits the ability of the blood service to undertake tracing, audit and root cause analysis.[216] Thus, a framework within existing systems should be established for proper recording of outcomes for recipients of blood components.

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212 Closing Submissions of SNBTS 16 December 2022 paras 242-245 SUBS0000044

213 Allard et al *Transfusion 2024: A 5-year plan for clinical and laboratory transfusion in England* Transfusion Medicine 2021 p3 WITN7001031

214 Simply trying to take data out of many existing systems into a new registry would be fraught with data transfer risks and potential errors and would be extremely difficult to set up and costly to maintain.

215 Closing Submissions of NHSBT 16 December 2022 para 17.57 SUBS0000062

216 Closing Submissions of NHSBT 16 December 2022 para 17.58 SUBS0000062

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Though this recommendation is focused on the blood services in England, the outcomes which are reported should be of interest to the WBS, NIBTS and SNBTS. The latter recommends the implementation of enhanced electronic clinical systems which promote and support best practice at the bedside as a major plank in preventing avoidable systems errors from harming patients. It is important that resources continue to be allocated to improve these further – and to ensure that insofar as those systems provide information on outcomes from transfusion the detail is shared, possibly through SHOT, with the other blood services of the UK.

I recommend:

(f) Establishing the outcome of every transfusion

(i) That a framework be established for recording outcomes for recipients of blood components. That those records be used by NHS bodies to improve transfusion practice (including by providing such information to haemovigilance bodies).

Success in achieving this will be measured by the extent to which the SHOT reports for the previous three years show a progressive reduction in incidents of incorrect blood component transfusions measured as a proportion of the number of transfusions given.

(ii) To the extent that the funding for digital transformation does not already cover the setting up and operation of this framework, bespoke funding should be provided.

(iii) That funding for the provision of enhanced electronic clinical systems in relation to blood transfusion be regarded as a priority across the UK.

8. Finding the undiagnosed

When doctors become aware that patients received a blood transfusion prior to 1996[217] they should immediately be offered a test for Hepatitis C (if they have not already had one). There may be limited opportunities in the usual interactions between patients and their GPs for it to be found out in normal practice that a given patient had ever had a transfusion in the past, if it is not already known. However, the opportunity arises when a new patient is registered at a practice. They should then be asked, as a matter of routine, if they had a transfusion before 1996 and, if they say they have, should be offered the opportunity of a precautionary blood test. There need be no alarm for the patient about this: rather, the offer should instil confidence that their safety is being protected by the doctor, and a substantial majority of previously untested patients may expect the reassurance of a negative test. However, if the test is positive (as it is likely it will be in some cases) then treatment with

217 The reasons for picking this date are that it is reasonably possible that some infections may have occurred from blood transfusions after universal screening was introduced in September 1991, and it was in 1996 that SHOT effectively began.

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direct acting antivirals may follow.[218] This requirement would also have the effect of raising awareness in general practice about Hepatitis C and thereby reduce the number of people diagnosed very late, some of whom have given evidence to this Inquiry.

I recommend:

8. Finding the undiagnosed

(a) When doctors become aware that a patient has had a blood transfusion prior to 1996, that patient should be offered a blood test for Hepatitis C.

(b) As a matter of routine, new patients registering at a practice should be asked if they have had such a transfusion.

9. Protecting the safety of haemophilia care

Peer review of haemophilia centres

Audits of practice are more often than not conducted internally in hospital Trusts and health boards: if shortcomings are identified, that leads to discussions and agreement as to the steps necessary to overcome them; these steps are then implemented; and then whether and how far those steps have been successful in remedying the original shortcomings is assessed. Audit of a specialist centre which is not conducted internally, but by a clinical team from other centres is probably better described as "peer review".

A practice of peer review of haemophilia centres by haemophilia consultants from other centres has grown up since 1991 (in Northern Ireland and Scotland) and in England and Wales (1992/93), and has been refined over time. Consultant specialists help to identify service gaps against the service specification adopted at the time. Over the years since then, this too has evolved. A national service specification for haemophilia and related conditions has been developed and published.[219]

Peer review not only helps a centre to be better assured it is adopting "best practice", or identifies where it may be falling short, but it can highlight matters of growing concern across the country. Thus, the last peer review reported inequity in the quality of care provided

218 The Statistics Expert Group compared the age-sex bands for EIBSS claimants in England against their statistical estimates for the number of people infected with Hepatitis C through transfusions and identified three groups who appear to be underrepresented:
- people born 1975-1984 who had a transfusion as a child (at best a quarter of the number estimated feature as claimants)
- people born 1965-1974 who had a transfusion (only a third of the number estimated feature as a claimant)
- women born 1945-1964 who had a transfusion around childbirth (just over half the number estimated feature as claimants)

Expert Report to the Infected Blood Inquiry: Statistics (Supplementary) July 2023 p9 EXPG0000132

219 The Haemophilia Alliance *A National Service Specification for Haemophilia and other Inherited Bleeding Disorders* February 2006 HSOC0020872

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because of inconsistency in the provision of key staff groups especially in physiotherapy and psychosocial care.[220]

Three institutional core participants (UKHCDO, the Scottish Territorial Health Boards, and the Belfast Health and Social Care Trust) support auditing and peer review: technically, the professional assessment, against standards, of the organisation of healthcare processes and quality of work, with the objective of facilitating its improvement. The primary aim is to ensure the care provided is both safe, and of the highest quality, and that shortfalls in provision are identified. In particular, in a small specialty such as haemophilia, this enables best practice to be maintained across the UK.

However, peer review is defeated if the recommendations made as a consequence of the review are not implemented. Accordingly, I recommend:

9. Protecting the safety of haemophilia care

(a) That peer review of haemophilia care should continue to occur as presently practised, with any necessary support being provided by NHS Trusts and Health Boards; and

(b) That NHS Trusts and Health Boards should be required to deliberate on peer review findings and give favourable consideration to implementing the changes identified with a view to ensuring comprehensive, safe, care.

(c) A peer review of each centre should take place not less than once every five years.

Networks for haemophilia care

Most haemophilia centres only have a small number of dedicated specialists, since bleeding disorders are relatively rare. It can be all too easy for these small numbers to lead to a degree of isolation amongst specialists, or to create difficulties in facilitating discussion of haemophilia care during the course of busy practices, especially since these often involve other aspects of haematology. The Scottish Territorial Health Boards have found it particularly useful for there to be regional networks of clinicians providing regular forums for case and policy discussions. These networks are arranged so that they include patient involvement in policy discussions.[221]

At the moment, Scottish haemophilia centre directors meet every two months, and constitute such a network: patient input to the forums comes via the Scottish Inherited Bleeding Disorder Network.[222]

220 *Overview Report of the Inherited and Acquired Haemophilia and other Bleeding Disorders Peer Review Programme* May 2020 p5 RLIT0001937

221 Closing submissions of the NHS Scotland Territorial Health Boards pp112-113 SUBS0000058

222 Closing submissions of the NHS Scotland Territorial Health Boards p113 SUBS0000058

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To an extent, such networks already exist informally elsewhere, and with some support from the Haemophilia Society and UKHCDO. However, discussion in a multidisciplinary format, involving patients, would help to prevent one or two voices having a disproportionate influence on care over others. As the history revealed by the Inquiry has shown, the influence of one or two voices can (and did in 1983/84) have a damaging effect on the safety of patient care: the moderating effect of wider discussion, the involvement of patients, and of other clinical disciplines should help to avoid this being repeated in future.

Accordingly, I recommend that:

(d) The necessary administrative and clinical resources should be provided by hospital trusts and boards, integrated care boards, and service commissioners to facilitate multi-disciplinary regional networks to discuss policy and practice in haemophilia and other inherited bleeding disorders care, provided they involve patients in their discussions.

Recombinant factor products

In the submissions made by participants represented by Collins solicitors[223] it is indicated that people with severe von Willebrand disorder are still being treated with plasma-based factor products. I recommend (adopting wording used by the Scottish Territorial Health Boards, who also favour this proposal)[224] that, across the UK:

(e) recombinant coagulation factor products should be offered in place of plasma-derived ones where clinically appropriate. Service commissioners should ensure that such treatment decisions are funded accordingly.

National haemophilia database

There is no doubt that a database of the type which the National Haemophilia Database ("NHD") constitutes should be maintained. It helps to track the occurrence of disease, its prevalence, and clinical outcomes (in particular, mortality over time). It helps to identify needs as yet unmet in order to plan future therapeutic and organisational arrangements. Such a registry was recommended by the European Association of Haemophilia and Associated Disorders in 2008;[225] and is thought to be especially important for pharmacovigilance and planning of care including budget allocation.

It has been of considerable benefit to the Inquiry to have seen the figures and been supplied with data kept and collated by the NHD. Though there have historically been uncertainties about some of the data, and concerns about the way in which the data was collected, it has

223 Submissions on behalf of the core participants represented by Collins Solicitors p202, p222 SUBS0000063

224 Submissions on Recommendations of the NHS Scotland Territorial Health Boards p7 SUBS0000006

225 Colvin et al *European principles of haemophilia* Haemophilia 21 November 2007 HSOC0021039

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nonetheless represented a reliable means of showing trends in care and outcome in some detail. It is thus useful for historical research where that is needed.

Individuals may opt out of their data being used for research should they wish to do so: those who do **not** opt out are included in the UK National Haemophilia Research Registry, which may be used for observational research (the identity of patients is not disclosed for this purpose).

The UKHCDO, which runs the NHD, is a charity. Its members are NHS consultants who work in NHS hospitals treating NHS patients. Its objectives are to preserve, protect and relieve persons suffering from haemophilia and other inherited bleeding disorders; to advance the education of the medical profession, the nursing profession, professions allied to medicine and the general public in the knowledge of haemophilia and other inherited bleeding disorders and their treatment; and to promote or assist in the promotion of audit and research into the causes, prevention, alleviation and management of haemophilia and other inherited bleeding disorders and to disseminate the useful results of such research.[226]

Currently the NHD is funded, through the UKHCDO, by a mixture of NHS, charitable and pharmaceutical money. There is a need for additional funding if it is to become a better tool for patient-centred care, and to be enabled to encourage equity of access by generating comparative reports. Additional funding would also support additional expert statistical input (for instance, enabling a mutually beneficial collaboration with universities), and enable a review of the database structure and its migration to more up-to-date technology.

UKHCDO and the Scottish Territorial Health Boards propose that further resource should be provided to enable these steps to be taken.[227]

If more public money is to be spent in enabling these improvements to the NHD, it might be thought that the NHD should be brought within the NHS, rather than remaining technically independent of it though entirely dependent on clinicians employed in the NHS and patients treated by it agreeing to provide it with the data on which its operation entirely depends.

I consider that there would be little advantage in this: it would expose the NHS to greater expense (at the moment, it contributes about half the cost of running the NHD: if the NHD were incorporated fully within the NHS the cost would all then fall upon its shoulders). If the NHD were formally made a part of the NHS itself it would inevitably be subject to the natural fluctuations of the health budget, and the uncertainties that come with that.

I have been persuaded that, at least for the foreseeable future (though matters should be kept under review) the NHD should continue to be run by the UKHCDO, funded as is currently the case, but that additional resource as indicated above should be made from public funds.

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226 United Kingdom Haemophilia Centre Doctors' Organisation *Constitution* November 2013 p1 WITN4031004

227 Submissions on Recommendations on behalf of UKHCDO 16 December 2022 para 290 SUBS0000050, Submissions on Recommendations on behalf of NHS Scotland Territorial Health Boards 14 June 2022 para 14 SUBS0000006

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I therefore recommend:

(f) that the National Haemophilia Database, run by the UKHCDO, merits the support of additional central funding.

10. Giving patients a voice

One of the most striking aspects of the evidence has been a failure adequately to listen to patients and to hear what they wanted, rather than assume the "listener" already knew.

There is no easy way of ensuring that medical authorities, and government, become less defensive when patients tell them that their care could have been better, or has failed in certain respects. The recommendations made already in this Report should go some way towards meeting that challenge. However, without enabling the patient voice to be heard better those improvements will be incomplete.

Accordingly, I recommend that steps be taken to help the patient voice to be both heard and taken into account in developing clinical policies, and healthcare policies in future.

There are a number of steps which it is desirable to take to achieve this. Some may seem minor, but they are, taken together, part of a composite picture of how patients can be enabled to play a full part in what is best seen as a patient-doctor partnership in care.

The first follows on from my recommendation that multidisciplinary regional network meetings to discuss policy and practice in future haemophilia care and treatment be facilitated. It is important that they involve patients, as they already do in the Scottish regional network system. That recommendation looks to give a stronger voice to people with bleeding disorders. It therefore does not apply in the same way to the far greater number of people who were infected with Hepatitis C as a consequence of transfusion when treated for conditions other than haemophilia.

Elisabeth Buggins has the perspective of a parent of children infected at children's hospitals, as well as experience of management within the NHS. Her view is that in more recent years the policy of the NHS internal market, intended to promote healthcare competition for patients' benefit, has led to a focus on performance management concentrating on NHS institutions rather than on the clinical benefits of decisions to individuals and to the health and happiness of communities. A cultural shift from focus on the institution to the individual needs, in her view, to be systemically supported by the way in which healthcare is organised. She argues that as part of this patient-reported outcomes and experiences should be measured in the process of clinical audit: too little of (otherwise very useful) clinical audit which is currently performed in hospitals routinely includes patient-reported outcomes or experience measures. She says that:

> "*The picture cannot be complete without it. Instead, the system relies on patients feeling strongly enough to write in with thanks or complaints and much useful insight is lost. Where patients are not routinely seen, such as those with milder*

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> *conditions, the incentive to write diminishes rapidly and should problems occur some distance from treatment, the treating hospital is unlikely to be informed about it."*[228]

A number of submissions have recognised the importance to patients of organisations or bodies which can speak for them, or lobby for them. Organisations can give people voice: the evidence of campaigners speaking for various different interest groups in the Inquiry has demonstrated that. Some organisations have charitable status, often now of some pedigree.

The Hepatitis C Trust operates on a truly UK-national basis. It has earned plaudits for the information it has been able to supply, the support it has been able to give, and the signposts by which it has directed individuals to find the support that they have needed. It has been able to speak for people infected with Hepatitis C in an undemonstrative but effective manner. Its ability to help people to understand that they are not alone, to help them access support and treatment and to understand it, and to speak for them has drawn almost unanimous unstinting praise across, and for the duration of, the Inquiry.

For people with haemophilia, the Haemophilia Society has been long established. The chapter about it describes some of its past history.[229] For the future, it can continue (as it has in recent years) to realise its potential as a fully effective voice ensuring that the patient view is made known not only at national but also, because of its organisation, at regional levels. In Scotland, there is a separate charity – Haemophilia Scotland. In Scotland there is also the Infected Blood Forum ("SIBF"), focused on giving patients a voice; in Wales, Haemophilia Wales; in Northern Ireland, Haemophilia Northern Ireland. In Northern Ireland, there is an allied organisation, Families and Friends of Haemophilia Northern Ireland, which is not itself a registered charity.

Organisations which are campaign or mutual interest groups, rather than charities, have also played a very valuable role, helping to give a collective voice to different strands of opinion amongst those who were infected, or affected. They have campaigned indefatigably; have enabled people to share a collective comfort in mutual support; have kept their members informed; and have developed close connections amongst their members that have not only preceded the Inquiry but seem likely to outlive it by quite a while. The end of a six year Inquiry following years of struggle to have their views heard and considered will bring personal and emotional challenges which the continuation of these groups would help to meet, particularly in the short term. The end of the Inquiry gives an opportunity for the Government to go some way to facilitate this. To do so would underscore the sincerity of the apology that I hope and expect will be forthcoming, and would show that the government is not dismissive of the prospect that these groups will have more to offer as a compensation scheme takes shape, and would enable the patient voice to continue to be heard on the issues reflected in this Report.

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228 Closing Submission of Elisabeth Buggins 16 December 2022 para 2, para 4, para 18 SUBS0000054

229 See the chapter on the *Haemophilia Society*.

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One of the weaknesses of the evidence before the Inquiry has come from the relatively low numbers of people with thalassaemia or sickle cell disease being prepared to speak to the Inquiry about their experiences. Proportionately, they must have suffered at least the same likelihood of blood-borne disease as others – indeed, given their need for regular transfusion, it is to be expected that people with thalassaemia or sickle cell disease will have a significantly higher proportion of blood-borne disease than do most people who have had a transfusion of only a few units.

The Thalassaemia Society ("UKTS") said in its final submissions:

> "*It was disappointing yet understandable for the* [current team at the UKTS] *that despite their best efforts of trying to encourage their membership and families affected to come forward and testify, many chose not to due to the trauma of the diagnosis, the rigorous and horrific treatment regimes, experiences, stigma and fatalities … In most communities in which thalassaemia is prevalent, there is an enormous amount of social stigma associated with living with an inherited condition affecting the production of red 'blood' cells. Within some communities, the idea of someone living with thalassaemia was inaccurately categorised as them having 'bad blood'. As a consequence of this, individuals would wrongly be considered as a 'burden', 'less than' and not 'marriage material' … Unfortunately, the stigma and belief is still present today … The feelings attributed to psychosocial burden due to thalassaemia were then further reinforced by the stigma associated with Hepatitis C.*"[230]

One of the recommendations which the UKTS urged upon me was public funding for the UKTS and other charities "*who supported and continue to support individuals who were infected or affected to provide advice, education and advocacy services. Public funding would help UKTS and other charities provide ongoing assistance and campaigning to ensure horrific events like these do not occur.*"[231]

It is in my view of particular importance that where it is known (as is beyond doubt here) that there is a voice to be heard, but that it is currently speaking in a very quiet whisper, steps must be taken, as best can be done, to enable those who should listen to it to hear it far more loudly.

Patient feedback

The MHRA makes an online Yellow Card system available through the gov.uk website, in order to notify it of any adverse reaction from drugs or medicines.[232] The existence of this online opportunity to provide feedback is not well known. It deserves greater publicity. It is part of listening to what patients have to say. One way of drawing attention to it would be for a yellow banner to be put across patient data information sheets which accompany

230 Closing Submissions of UKTS paras 6-8 SUBS0000067
231 Closing Submissions of UKTS para 11 SUBS0000067
232 yellowcard.mhra.gov.uk

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medicines advising people, to say that if they feel that they have an adverse reaction, even if (and perhaps especially if) the reaction is a delayed one, they should use the online portal to report it. The action required for this would simply be to mandate it – the product data sheet is paid for by manufacturers, and this would simply be additional but mandatory content.

This – or some similar way of drawing attention to the online Yellow Card scheme – applies only to those taking pharmaceutical medication. Where patients are told, or know, that they have had a transfusion of blood or a blood component, they should as a matter of practice be told that if they have any adverse reaction as a consequence they too can, and should, report it; and that although their principal point of contact to describe an adverse reaction is likely to be the treating clinician or body, they can in addition make a report of it through the Yellow Card online scheme if they wish to do so – and it is important that they take up this opportunity.[233]

Drawing these threads together, I recommend:

10. Giving patients a voice

(a) That the patient voice be enabled and empowered by the following measures:

(i) clinical audit should as a matter of routine include measures of patient satisfaction or concern, and these should be reported to the board of the body concerned.

Success in this will be measured by comparing the measure of satisfaction from one year to the next, such that the reports to the board concerned demonstrate a trend of improvement by comparing this year's outcomes with the similar outcomes from at least the two previous years.

(ii) that the following charities receive funding specifically for patient advocacy: the UK Haemophilia Society; the Hepatitis C Trust; Haemophilia Scotland; the Scottish Infected Blood Forum; Haemophilia Wales; Haemophilia Northern Ireland; and the UK Thalassaemia Society.

(iii) that favourable consideration be given to other charities and organisations supporting people infected and affected that were granted core participant status (as listed on the Inquiry website) to continue to provide support for at least the next 18 months. Further support should be reviewed at that stage with a view to it continuing as appropriate.

(iv) particular consideration be given, together with the UK Thalassaemia Society and the Sickle Cell Society, to how the needs of patients with thalassaemia or sickle cell disease can best holistically be addressed.

233 Dr Alison Cave is Chief Safety Officer at the MHRA and told the Inquiry that patients with adverse reactions to a transfusion could report through the Yellow Card scheme using the option "*Report something not on our list*" at yellowcard.mhra.gov.uk. Dr Alison Cave Transcript 16 November 2022 pp76-77 INQY1000263

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(v) steps be taken to give greater prominence to the online Yellow Card system to those receiving drugs or biological products, or who are being transfused with blood components.

11. Responding to calls for a public inquiry

Rationale

By 1986 the Government can have been under no illusion about the scale of what had happened to people with haemophilia – many had been infected with HIV, a virus with an exceptionally high mortality rate for which there was no known treatment. Sufferers of HIV experienced public hostility and stigma. In addition, over the five years which followed it became apparent beyond question that the non-A non-B Hepatitis with which most had also been infected was far more serious than some clinicians would have wished to believe in the early 1980s.

Calls were raised suggesting that the root cause of the problem was a failure to plan for, and achieve, self-sufficiency in the supply of blood products. The decision by the regulator not to ban imports of commercial concentrate from the United States, recognised as being in the throes of an AIDS epidemic, was controversial.

Yet more people – many more – were known to be suffering from hepatitis transmitted by blood transfusion, and some more again had been infected by AIDS as a result of blood transfusion.

The sources of blood products and blood were said to be rife with disease, that insufficient precautions had been taken, and that the risks had never been spelt out to patients receiving blood and blood products

Yet as the chapter in relation to a *Delay in Holding a Public Inquiry* records that:

> "*there is no documentary evidence to show that it occurred to anyone within Government before 1989*[234] *either that there might be an important public interest in investigating and understanding precisely how this had occurred* [ie the fact that so many people had gone into hospital for treatment and come out infected by HIV or Hepatitis B or C]*, or that those whose lives had been devastated in this way might deserve answers as to how and why it had happened. It ought to have been clear that there were lessons to be learned for the future if something similar were not to recur.*"

234 It should be noted that Lord Norman Fowler, who was in office as Secretary of State for Health and Social Services prior to June 1987, has urged that it took far too long for this Inquiry to be held, and has himself criticised the prevarication over it being held.

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Reasons for not holding a public inquiry, as recorded in that chapter, were generally defensive and uninformative. The chapter does not bear repetition here: but it is worth reflecting that there were lessons to be learned from what had happened.[235]

A number of participants have called for the adoption of a recognised process in deciding whether or not there should be a public inquiry into a matter which is potentially of public concern, or from which lessons might be learned, or both. Given the background in the present case, they are right to do so.

The question involves resolving the circumstances in which an inquiry should be held, and who should have power to determine that the criteria for holding one have been met. The Inquiries Act provides, appropriately (but with a very broad level of generality) that:

> "*A Minister may cause an inquiry to be held under this Act in relation to a case where it appears to him that–*
>
> *(a) particular events have caused, or are capable of causing, public concern, or*
>
> *(b) there is public concern that particular events may have occurred.*"[236]

This means that the minister has a discretion. It is sufficient if it "*appears to him*" that there is, has been, or might well be public concern, and that there should be an inquiry. Equally, if the opposite appears to her or him, there will be no inquiry. For matters of UK-wide concern this is in practice the Prime Minister's decision.

The facts considered by this Inquiry indicate two shortcomings in this. First, the minister most likely to understand whether there is public concern may very well be the minister for the department of state which is most concerned with the subject matter. Where the inquiry is into the performance of (for instance) a particular hospital trust, poisoning by a hostile state, or murder by a healthcare professional, the minister of the department concerned[237] may well be inclined to think that public concern merits an inquiry. By contrast, they may be less inclined to hold an inquiry if the public concern is directed more toward the way in which their department discharged its responsibilities. It would be only human for civil servants in that department to be defensive – indeed, they may already have been, when concerns were first raised; and it may be also be understandable if a minister is worried in some cases that they, the minister, might be thought unsupportive of their department if they asked for there to be an Inquiry into it, and this might make it more difficult to lead it.

In short, the first weakness of Section 1 of the 2005 Act is that it provides a discretion liable to be exercised by someone in whose interests and inclination it may be to be defensive of their own department, who may well be assured by their own department that all the facts are known and that no harm was done, such that there is nothing to be concerned about and thus nothing to be inquired into – or nothing that an inquiry might add – and thus reject calls for there to be one. Further, if an inquiry is called, sponsored by and therefore paid by or

235 See the chapter *Lessons to be Learned*.

236 s1 The Inquiries Act 2005 p1 RLIT0002405

237 In the examples chosen, the health minister, or the Home Office minister.

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through a departmental budget, there are inevitably concerns that the independence of the inquiry may be compromised. The examples in the context of this Inquiry of the way in which the report about *Self-Sufficiency in Blood Products in England and Wales: a Chronology from 1973 to 1991* was handled, or the Scottish Executive report was unsatisfactory,[238] show that there can be good reason for worrying about the ability of an internal investigation to reveal the truth.

A further problem with the wording of the power is that it arises where there is "*public concern*". This is a very flexible concept. It must, practically, be linked to some concept of sufficiency. Is there enough public concern to justify holding one? How is this to be judged? Is it truly of interest to a wider public than a group with a particular sectional interest? If the bar is set too low, then inquiries risk becoming more common at great expense. If they do, the force that their recommendations might otherwise have is lost. There may be evidence of significant numbers of people who appear to share a particular concern, without there being an objective evaluation of whether that concern might actually be justified.

These concerns suggest there might be a need to amend the Act, to set out further criteria. However, that is a process which might take some time, and the flexibility the Act provides may be valuable. In the alternative, I propose an interim measure to provide the public with reassurance that widespread calls for an inquiry, or particular focussed concerns which justify one, have been properly considered by a body independent of the government department(s) of state most centrally concerned.

My recommendation is that the same body as I recommend should review progress towards responding to, and if accepted, implementing the recommendations of this Inquiry – the Public Administration and Constitutional Affairs Committee ("PACAC") – should have the more general function of considering whether to recommend to an appropriate minister that there be an inquiry. It should exercise this when there is sufficient support in Parliament for such a course.

This mechanism allows for significant flexibility to be retained as to the precise circumstances in which there should be an inquiry – inquiries take many forms, from those which consider a one-off incident, to those which involve considering the effectiveness of systemic controls, to those which consider historic practices which have recently come to light (eg the Inquiry into organ retention), to those which consider practices at a single institution (Strangeways; Mid Staffordshire), and those which consider the appropriateness of, or lack of, provision for certain groups. Each inquiry is unique: the procedure in each will differ. There is no room for a "one size fits all" approach. The Act remains in force, and the minister continues to have discretion as to ordering one, and if so whether it should be statutory.

The mechanism I propose ensures proper respect for the democratic process – the power to call an Inquiry remains ultimately within the hands of a minister (not necessarily the minister whose department is most centrally concerned), and the process is open to all the scrutiny,

238 See the chapters on the *Self-Sufficiency Report* and *Scotland*.

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and transparency, of the select committee process. It gives more confidence that if calls for an Inquiry are rejected there are good reasons for this, capable of being examined by a cross-party body; but it also provides a safeguard against inquiries being held too readily, as might be the case if more prescriptive criteria were to be set.

An inquiry hub has now been established within the Cabinet Office. In my view it is appropriate that in any case in which the department concerned is potentially subject to criticism at the conclusion of the investigation, the inquiry should be sponsored and supported by the Cabinet Office[239] (unless the Cabinet Office is itself the subject of inquiry; and with the exception of those inquiries where it appears to the minister that the department concerned is likely neither to be a core participant itself nor potentially subject to criticism at the conclusion of the Inquiry).[240]

This leads me to recommend:

11. Responding to calls for a public inquiry

(a) that a minister should retain the power to call an inquiry as the minister sees fit, in accordance with the Inquiries Act 2005 – but where a minister does not choose to do so, then:

(b) if there is sufficient support from within Parliament for there to be an inquiry, the question whether there should be one should be referred to PACAC for it to consider the question.

(c) If it appears to PACAC that there is sufficient concern to justify a public inquiry, either because what happened and why has caused concern (as the committee sees it) or there are likely to be lessons learned which may prevent similar concerns arising in future, the committee may recommend to an appropriate minister that there be an inquiry.

(d) If the minister disagrees with the recommendation, they must set out in detail and publish reasons for this disagreement which are sufficient to satisfy PACAC that the matter has been carefully and properly considered.

239 The present Inquiry is a case in point. An initial proposal was that the Department of Health and Social Care should sponsor the Inquiry. Since many of those likely to be participants in the Inquiry considered the department to have played a significant part in the failings which led to their suffering, and the reaction of the government in response, they rightly objected to this. The sponsoring minister became the Chancellor of the Duchy of Lancaster. I have been grateful for the support given by the Cabinet Office to this Inquiry, and also that at no stage has anyone from that Department sought to interfere with the inquiry process.

240 If, for instance, the Inquiry is into the behaviour of a single medical professional, or the performance of a particular hospital trust or board, it is unlikely to be necessary for public confidence that the DHSC stand aside from sponsoring the inquiry.

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12. Giving effect to Recommendations of this Inquiry

Part of the history of the Inquiry has been (a) delay on the part of successive governments; (b) the failure to account for inaction; and in consequence (c) a consequent loss of trust in authority by those who have been infected, and those in turn affected by the harm that had happened to people who were important to them.

As a public inquiry, it is being held in the public interest. That interest is essentially in three respects:

- what happened to lead to treatment causing so many serious infections, and why;
- how authorities reacted to what had happened, and why they did so; and
- the lessons to be learned from that and recommendations to be made so that the future is better, and past mistakes are not repeated.

It is important in the public interest, therefore, that recommendations are fully and properly considered. If they are to be rejected, then that should be for good reason, and the public (in whose interest an Inquiry is conducted) should be told clearly what the reason or reasons are.

Accountability is one of the seven principles of public life which Lord Nolan recognised and articulated.[241] The first question, therefore, is how government should be held accountable for the way in which it deals with the recommendations made both here, and those that have already been made over a year ago, in the Second Interim Report of the Inquiry and have so far resulted in little tangible result for people infected and affected by this tragedy.

I propose two mechanisms. They run together.

First, a number of the submissions made by core participants endorse a submission made on behalf of those core participants represented by Milners solicitors:

> "*In our submission, Parliament's intention in passing the Inquiries Act 2005 was to give the chair of a statutory inquiry the power to scrutinise the actions of Government in accordance with its terms of reference, and to do so in a flexible and more expansive way than is available to a court considering a judicial review challenge. Indeed, it could be argued that the primary purpose of the Act and of many inquiries, is to scrutinise the decisions and actions of the Executive.*"[242]

241 Lord Nolan *Standards in Public Life: First Report of the Committee on Standards in Public Life* May 1995 p18 RLIT0001795

242 Submissions on behalf of the core participants represented by Milners Solicitors August 2023 p3 SUBS0000070. In my view, this is critically dependent upon the terms of reference: many statutory inquiries may consider the actions of public bodies such as individual NHS trusts, the police services, local authority actions, and general disasters which require scrutiny across many fields: not every inquiry is of an Arms to Iraq nature.

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Section 14(1)(a) of the Act provides: "*For the purposes of this Act an inquiry comes to an end – on the date, after the delivery of the report of the inquiry, on which the chairman notifies the Minister that the inquiry has fulfilled its terms of reference*".[243]

Focussing on the wording of this, it is said to me that an inquiry does not end with the delivery of the report, but with the chair's notification to the Minister.

There is a precedent, to show that the report of the Inquiry is not necessarily the last word. Thus, when Sir Michael Bichard presented his report to the Home Secretary on 14 June 2004 into the deaths of two children in Soham he wrote in a covering letter "*I look forward to the Government's response to my findings and to the recommendations which I make. As you know, I aim to reconvene my Inquiry in six months' time to assess progress on those recommendations which the Government chooses to accept. I am confident, as I acknowledge in my report, of the spirit in which my recommendations will be received and taken forward.*"[244] Six months later he was sent a progress report, and provided an update himself on 15 March 2005, in which he said "*I am also clear that the fact that this public review was known to be taking place has concentrated minds* ".[245] In an accompanying press release it was said "*He asked for preparatory work on these schemes to be completed by Spring 2006 and suggested that the Home Secretary should commit to publishing reviews of progress in September this year and March 2006. Sir Michael also said he hoped such reviews of Inquiries would occur as a matter of course in the future.*"[246] Though his findings and recommendations were contained entirely within his June 2004 report, his actions after June 2004 were concerned solely with the implementation of the recommendations which he had made.

The Inquiry's terms of reference cover an unusually wide period: they began at the start of the NHS. There is no specific end date. That is because the Inquiry is charged, amongst other matters, with examining the nature, adequacy and timeliness of the response of government (in particular the Department of Health and Social Care), NHS bodies, other public bodies and officials, the medical profession, the UK Haemophilia Centre Doctors Organisation, the pharmaceutical industry and other organisations (including the Haemophilia Society) to the use of infected blood or infected blood products to treat NHS patients; and "*To consider the nature and the adequacy of the treatment, care and support (including financial assistance) provided to people who were infected and affected (including the bereaved)*".[247] Though this Report (together with the Second Report which says all I have to say as to compensation) is a full report and I do not anticipate that it should be necessary to add any more to it, the Inquiry has a function to consider the appropriateness, and timeliness, of the response to the recommendations it makes.

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243 s14(1)(a) Inquiries Act 2005 RLIT0002407

244 The Bichard Inquiry Report 22 June 2004 p4 RLIT0002389, The Bichard Inquiry Final Report 15 March 2005 p6 RLIT0002390

245 The Bichard Inquiry Final Report 15 March 2005 p6 RLIT0002390

246 Submissions on behalf of the core participants represented by Milners Solicitors August 2023 p4 SUBS0000070

247 Infected Blood Inquiry Terms of Reference para 5a, para 8 INQY0000458

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There has been some concern, as anyone who has followed the proceedings of the House of Lords Statutory Inquiries Committee will be aware, as to the follow up of progress towards considering and, if accepted, implementing the recommendations of public Inquiries. The penultimate chapter in this Report considers the response of government to the recommendations made to it by Sir Robert Francis, and the recommendations made to it by this Inquiry in its Second Interim Report which followed. It has shown that assurances have been given, and not kept. It has demonstrated that the reasons for this have not been revealed in full to the public. It has led to a real and understandable fear that without a clear process or timetable there may be a dragging of feet. As I have said repeatedly in public, delay not only causes frustration, but compounds the harm and suffering many of those infected and affected have endured. In the context of this Inquiry, perhaps beyond all other, it is unconscionable to allow a state of affairs to exist in which these fears are realised. I am satisfied that I must do what I properly can within my powers to try to ensure this does not happen.

As to the timetable, I anticipate that **within** the next 12 months the Government will have considered and either committed to implementing the recommendations which I make, or has given sufficient reason, in sufficient detail for others to understand, why it is not considered appropriate to implement any one or more of them. During that period, and **before** the end of this year, the Government should report back to Parliament as to the progress made on considering and implementing the recommendations. I anticipate that at that stage I should be able to tell the Minister that the Inquiry has fulfilled its terms of reference. But I shall do so only if I am satisfied that there is no further role I can usefully play in preventing delay.

I also recommend that the Public Administration and Constitutional Affairs Committee ("PACAC") should review both the progress towards responding to the recommendations, and, if they are accepted, towards implementing them. Though the recommendations are capable of covering the work of different select committees (health, home affairs to name but two) it is essential that the response be viewed as a whole. The rationale for there being a select committee which should have these tasks is:

- The reputation for independence which select committees have, especially in recent times with the live broadcast of many of their proceedings. They are part of the Parliamentary process. The Inquiry reports to a Minister; the Minister is answerable to Parliament; select committees have the ability to scrutinise the actions (or inaction) of the Minister.
- A 2017 Institute for Government report suggested that select committees could examine annual progress updates from government on the state of implementation of inquiry recommendations;[248]

248 Institute for Government *How public inquiries can lead to change* December 2017 p6 WITN7523003

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- INQUEST proposed that there should be a National Oversight Mechanism which is structurally and operationally independent;[249]
- Dame Diana Johnson MP (herself chair of a select committee) has argued that select committees are well equipped to carry out "*detailed scrutiny*" on the adequacy of the government's proposed response to inquiry recommendations, and feels that this approach should become the norm;[250]
- The House of Commons Health and Social Care Select Committee has set up a new independent expert panel, which appears to be the first committee linked arrangement, to evaluate "*progress the Government has made against its own commitments*".[251]
  - Advice to ministers from civil servants may well be tempered by knowing that a body likely to command respect will potentially examine the outcome, apparent logic and timeliness of that advice – and will do so in public.
  - Such a process is within the general scope of Parliamentary powers, and also generally open to press and media comment. The history set out in the chapters of this Report which record the Government response to what had happened show that on a number of occasions action appears to have been prompted by impending publicity.

The rationale for recommending that, of the select committees that might have been suggested, PACAC take on this function is that its role includes the scrutiny of government operation. The committee is experienced in high profile matters of public interest. Government generally provides responses to committee recommendations, and often there are further reports and responses. PACAC is appointed by the House of Commons to examine the reports of the Parliamentary and Health Service Ombudsman which are laid before the House, and matters in connection therewith; to consider matters relating to the quality and standards of the administration provided by Civil Service departments and other matters relating to the Civil Service; and to consider constitutional issues. The members of the committee are drawn from the three largest political parties, and the committee itself publishes its results through reports and making its recommendations known to the government.

PACAC also has some experience in providing post-inquiry scrutiny of government. Following controversy over the Iraq Inquiry PACAC launched a short inquiry into the conduct of public inquiries and the machinery of government. The committee's report recommended that the government must assess, as a matter of urgency, how the Iraq Inquiry could have been carried out more quickly, and must report its findings to Parliament. In that connection

249 Inquest *No More Deaths: Learning, action, and accountability: the case for a National Oversight Mechanism* June 2023 p4 RLIT0002401

250 Johnson *How to hold the government to account on public inquiries* The Guardian 30 May 2023 RLIT0002397

251 House of Commons Health and Social Care Committee *Expert Panel: Evaluation of the Government's progress on meeting patient safety recommendations* 19 March 2024 p5 RLIT0002393

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it wrote "*We remain concerned about the lack of mechanisms for meaningful Parliamentary oversight over the establishment of both statutory and non statutory inquiries.*"[252]

The state and capabilities of the Civil Service has been a long running concern for the Committee.[253] It has considered and reported on propriety of governance in the wake of the collapse of financial services firm Greensill Capital and revelations about its closeness to government and its lobbying activities.[254]

These considerations lead me to recommend:

12. Giving effect to Recommendations of this Inquiry

(a) Within the next 12 months, the Government should consider and either commit to implementing the recommendations which I make, or give sufficient reason, in sufficient detail for others to understand, why it is not considered appropriate to implement any one or more of them.

(b) During that period, and *before* the end of this year – the Government should report back to Parliament as to the progress made on considering and implementing the recommendations.

(c) This timetable should not interfere with earlier consideration and response to the Recommendations of the Second Interim Report of the Inquiry

(d) The Public Administration and Constitutional Affairs Committee ("PACAC") should review both the progress towards responding to the Inquiry's recommendations and, to the extent that they are accepted, implementing those recommendations

(e) PACAC should accept the role in respect of any future statutory inquiry of reviewing government's timetable for consideration of recommendations, and of its progress towards implementation of that inquiry's recommendations.

The Recommendations

1. Compensation

My principal recommendation remains that a compensation scheme should be set up now.

252 Public Administration and Constitutional Affairs Committee *Lessons still to be learned from the Chilcot Inquiry* 27 February 2017 p16 RLIT0002400

253 Public Administration and Constitutional Affairs Committee *Developing Civil Service Skills: a unified approach* 30 November 2015 RLIT0002395

254 Public Administration and Constitutional Affairs Committee *Propriety of Governance in Light of Greensill* 29 November 2022 RLIT0002402

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2. Recognising and remembering what happened to people

(a) A permanent memorial be established in the UK and consideration be given to memorials in each of Northern Ireland, Wales and Scotland. The nature of the memorial(s), their design and location should be determined by a memorial committee consisting of people infected and affected and representatives of the governments. It should be funded by the UK government.

(b) A memorial be established at public expense, dedicated specifically to the children infected at Treloar's school. The memorial should be such as is agreed with those who were pupils at Treloar's.

(c) There should be at least three events, approximately six months apart, drawing together those infected and affected, the nature and timing of which should be determined by a working party as described above, facilitated by some central funding.

3. Learning from the Inquiry

(a) The General Medical Council, and NHS Education for Scotland, Health Education and Improvement Wales, Northern Ireland Medical and Dental Training Agency and NHS England, should take steps to ensure that those "lessons to be learned" which relate to clinical practice should be incorporated in every doctor's training.

(b) They should look favourably upon putting together a package of training materials, with excerpts from oral and written testimony, to underpin what can happen in healthcare, and must be avoided in future.

(c) The Inquiry website is maintained online.

4. Preventing future harm to patients: achieving a safety culture

(a) Duty of candour

(i) A statutory duty of candour in healthcare should be introduced in Northern Ireland.

(ii) The operation of the duties of candour in healthcare in Scotland and in Wales should be reviewed, as it is being in England, to assess how effective its operation has been in practice. Since the duty was introduced in 2023 in Wales, the review there need not be immediate, but should be no later than the end of 2026.

(iii) The review of the duty of candour currently under way in England should be completed as soon as practicable.

(iv) The statutory duties of candour in England, Scotland, Wales (and Northern Ireland, when introduced) should be extended to cover those individuals in

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leadership positions in the National Health Service, in particular in executive positions and board members.

(v) Individuals in leadership positions should be required by the terms of their appointment and by secondary legislation to record, consider and respond to any concern about the healthcare being provided, or the way it is being provided, where there reasonably appears to be a risk that a patient might suffer harm, or has done so. Any person in authority to whom such a report is made should be personally accountable for a failure to consider it adequately.

Success in implementation will be measured by the extent to which there is an increase in the number of reports made of near miss incidents to the designated data collector; and a decline in the number of widespread or significant healthcare failures.

(b) Cultural change

(i) That a culture of defensiveness, lack of openness, failure to be forthcoming, and being dismissive of concerns about patient safety be addressed both by taking the steps set out in (a) above, and also by making leaders accountable for how the culture operates in their part of the system, and for the way in which it involves patients.

(c) Regulation

(i) That external regulation of safety in healthcare be simplified. As a first step towards this, there should be a UK wide review by the four health departments of the systems of external regulation, with the aim of addressing all the points made earlier in this Report and in other reports since 2000.

(ii) That the national healthcare administrations in England, Northern Ireland, Scotland and Wales explore, and if appropriate, support the development and implementation of safety management systems ("SMS"s) through SMS coordination groups (as recommended by the HSSIB), and do so as a matter of priority.

Success in implementation will be measured by the percentage of patients who know to whom they can express any concerns they may have about safety, who will take up their cause, and what they can expect from them. At the same time, it will be measured by the extent to which those who are busy working within the system, especially those in leadership roles, have clarity as to what, precisely, is expected of them, from whom. It should also be measured by a reduction in avoidable harm from both errors and systemic issues.

(d) Patient records

(i) Before the end of 2027 there should be a formal audit, publicly reported, of the extent of success of digitisation of patient records in each of the four health jurisdictions of the UK, measuring at least the levels of patient access to their

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personal records, their ability to identify and correct apparent errors in them, their interoperability, and the confidence of health professionals in the detail, accuracy and timeliness of any record they enter, and that little material which should be recorded has been omitted. Next steps should be identified.

(e) Consideration should be given by the national healthcare administrations in England, Scotland, Wales and Northern Ireland, to further coordination of their approaches particularly to ensure that patterns of harm, or trends, are identified and any response which for the sake of patient safety would be better coordinated than left to each individual administration can collaboratively be agreed and implemented.

5. Ending a defensive culture in the Civil Service and government

(a) The Government should reconsider whether, in the light of the facts revealed by this Inquiry, it is sufficient to continue to rely on the current non-statutory duties in the Civil Service and Ministerial Codes, coupled with those legal duties which occur on the occasions when civil servants and ministers interact with courts, inquests and inquiries, as securing candour.

(b) If, on review, the Government considers that it is sufficient to rely on the current non-statutory duties in the Civil Service Code, it should nonetheless introduce a statutory duty of accountability on senior civil servants for the candour and completeness of advice given to Permanent Secretaries and Ministers, and the candour and completeness of their response to concerns raised by members of the public and staff.

(c) The Government should consider the extent to which Ministers should be subject to a duty beyond their current duty to Parliament under the Ministerial Code.

6. Monitoring liver damage for people who were infected with Hepatitis C.

(a) All patients who have contracted hepatitis via a blood transfusion or blood products should receive the following care:

(i) those who have been diagnosed with cirrhosis at any point should receive lifetime monitoring by way of six-monthly fibroscans and annual clinical review, either nurse-led, consultant-led or, where appropriate, by a GP with a specialist interest in hepatitis

(ii) those who have fibrosis should receive the same care

(iii) where there is any uncertainty about whether a patient has fibrosis they should receive the same care

(iv) fibroscan technology should be used for liver imaging, rather than alternatives

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(v) those who have had Hepatitis C which is attributable to infected blood or blood products should be seen by a consultant hepatologist, rather than a more junior member of staff, wherever practicable

(vi) those bodies responsible for commissioning hepatology services in each of the home nations should publish the steps they have taken to satisfy themselves that the services they are commissioning meet the particular needs of the group of people harmed by NHS treatment

7. Patient Safety: Blood transfusions

(a) Tranexamic acid

(i) In England Hospital Transfusion Committees and transfusion practitioners take steps to ensure that consideration of tranexamic acid be on every hospital surgical checklist; that hospital medical directors be required to report to their boards and the chief executive of their Trust as to the extent of its use; and that the board report annually to NHS England as to the percentage of eligible operations which have involved its use. If the percentage is below 80% or has dropped since the previous year, this report should be accompanied with an explanation for the failure to use more tranexamic acid and thereby reduce the risk to patient safety that comes with using a transfusion of blood or red blood cells.

(ii) In Scotland, Wales and Northern Ireland offering the use of tranexamic acid should be considered a treatment of preference in respect of all eligible surgery.

(iii) Consideration be given to standardising and benchmarking transfusion performance between hospitals in order to deliver better patient blood management.

(b) Progress in implementation of the *Transfusion 2024* recommendations be reviewed, and next steps be determined and promulgated; and that in Scotland the 5 year plan is reviewed in or before 2027 with a view to determining next steps.

The responsibility for this in England is that of the NHS, shared with NBTC, the Royal Colleges (as appropriate), and NHSBT.

(c) Transfusion laboratories should be staffed (and resourced) adequately to meet the requirements of their functions.

(d) That those bodies concerned with undergraduate and postgraduate training across the UK of those people who are, or intend to be, working in the NHS ensure that they are adequately trained in transfusion, that the standards by which sufficiency of training is measured are defined, and accountability for training in transfusion be defined.

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(e) That all NHS organisations across the UK have a mechanism in place for implementing recommendations of SHOT reports, which should be professionally mandated, and for monitoring such implementation.

(f) Establishing the outcome of every transfusion

(i) That a framework be established for recording outcomes for recipients of blood components. That those records be used by NHS bodies to improve transfusion practice (including by providing such information to haemovigilance bodies).

Success in achieving this will be measured by the extent to which the SHOT reports for the previous three years show a progressive reduction in incidents of incorrect blood component transfusions measured as a proportion of the number of transfusions given.

(ii) To the extent that the funding for digital transformation does not already cover the setting up and operation of this framework, bespoke funding should be provided.

(iii) That funding for the provision of enhanced electronic clinical systems in relation to blood transfusion be regarded as a priority across the UK.

8. Finding the undiagnosed

(a) When doctors become aware that a patient has had a blood transfusion prior to 1996, that patient should be offered a blood test for Hepatitis C.

(b) As a matter of routine, new patients registering at a practice should be asked if they have had such a transfusion.

9. Protecting the safety of haemophilia care

(a) That peer review of haemophilia care should continue to occur as presently practised, with any necessary support being provided by NHS Trusts and Health Boards; and

(b) That NHS Trusts and Health Boards should be required to deliberate on peer review findings and give favourable consideration to implementing the changes identified with a view to ensuring comprehensive, safe, care.

(c) A peer review of each centre should take place not less than once every five years.

(d) The necessary administrative and clinical resources should be provided by hospital trusts and boards, integrated care boards, and service commissioners to facilitate multi-disciplinary regional networks to discuss policy and practice in haemophilia and other inherited bleeding disorders care, provided they involve patients in their discussions.

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(e) recombinant coagulation factor products should be offered in place of plasma-derived ones where clinically appropriate. Service commissioners should ensure that such treatment decisions are funded accordingly.

(f) that the National Haemophilia Database, run by the UKHCDO, merits the support of additional central funding.

10. Giving patients a voice

(a) That the patient voice be enabled and empowered by the following measures:

(i) clinical audit should as a matter of routine include measures of patient satisfaction or concern, and these should be reported to the board of the body concerned.

Success in this will be measured by comparing the measure of satisfaction from one year to the next, such that the reports to the board concerned demonstrate a trend of improvement by comparing this year's outcomes with the similar outcomes from at least the two previous years.

(ii) that the following charities receive funding specifically for patient advocacy: the UK Haemophilia Society; the Hepatitis C Trust; Haemophilia Scotland; the Scottish Infected Blood Forum; Haemophilia Wales, Haemophilia Northern Ireland, and the UK Thalassaemia Society.

(iii) that favourable consideration be given to other charities and organisations supporting people infected and affected that were granted core participant status (as listed on the Inquiry website) to continue to provide support for at least the next 18 months. Further support should be reviewed at that stage with a view to it continuing as appropriate.

(iv) particular consideration be given, together with the UK Thalassaemia Society and the Sickle Cell Society, to how the needs of patients with thalassaemia or sickle cell disease can best holistically be addressed.

(v) steps be taken to give greater prominence to the online Yellow Card system to those receiving drugs or biological products, or who are being transfused with blood components.

11. Responding to calls for a public inquiry

(a) that a minister should retain the power to call an inquiry as the minister sees fit, in accordance with the Inquiries Act 2005 – but where a minister does not choose to do so, then:

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(b) if there is sufficient support from within Parliament for there to be an inquiry, the question whether there should be one should be referred to PACAC for it to consider the question.

(c) If it appears to PACAC that there is sufficient concern to justify a public inquiry, either because what happened and why has caused concern (as the committee sees it) or there are likely to be lessons learned which may prevent similar concerns arising in future, the committee may recommend to an appropriate minister that there be an inquiry.

(d) If the minister disagrees with the recommendation, they must set out in detail and publish reasons for this disagreement which are sufficient to satisfy PACAC that the matter has been carefully and properly considered.

12. Giving effect to Recommendations of this Inquiry

(a) Within the next 12 months, the Government should consider and either commit to implementing the recommendations which I make, or give sufficient reason, in sufficient detail for others to understand, why it is not considered appropriate to implement any one or more of them.

(b) During that period, and *before* the end of this year – the Government should report back to Parliament as to the progress made on considering and implementing the recommendations.

(c) This timetable should not interfere with earlier consideration and response to the Recommendations of the Second Interim Report of the Inquiry

(d) The Public Administration and Constitutional Affairs Committee ("PACAC") should review both the progress towards responding to the Inquiry's recommendations and, to the extent that they are accepted, implementing those recommendations

(e) PACAC should accept the role in respect of any future statutory inquiry of reviewing government's timetable for consideration of recommendations, and of its progress towards implementation of that inquiry's recommendations.

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