

Expert Report to the Infected Blood Inquiry: Public Health and Administration

August 2022





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Preamble

This report has been prepared by the convenors of a group of experts in public health and administration appointed by Sir Brian Langstaff in 2021 on behalf of the Infected Blood Inquiry. The Report draws upon contributions made by and advice received from the members of the Group who are listed in the Authors section of this report. In the letter of instruction from the Inquiry we were asked to respond to a series of specific questions and the Report is organised around the responses to each question numbered as per the letter of instruction. With regard to terminology, we have used the term patient to indicate a person receiving healthcare of any kind, while conscious that other terms such as client or service-user may be more appropriate in some contexts. In some cases, we have cross-referenced between questions to indicate the relevance of material covered in more detail elsewhere in the report.

We have been invited to offer our opinion on the strength and weaknesses of current systems and practices, how these have developed and how they might be improved. We are conscious that there is no simple answer to the questions we were asked and that there are many different, strongly held views. We have sought to refer to these in the Report but, at the same time, to provide some consensus where that is possible. It is, of course, for the Inquiry to draw conclusions and make recommendations but we hope that this Report assists in that difficult process.

General principles concerning public administration

15. Please:

- a. identify and explain what ethical principles, norms, rules or frameworks arise within, or apply to, public administration and in particular government decision-making and actions (please note that there are more detailed questions about candour and transparency below);
- b. explain what is meant by the principle or convention of ministerial responsibility;
- c. identify any relevant guidance, publication, analysis or principles which may assist the Chair in considering where responsibility lies for effective decision-making that involves ministers, civil servants and experts such as clinicians and, in particular, when considering who is responsible for ensuring that advisory and decision-making structures are effective;
- d. identify and outline any other principles and/or conventions which you consider may be relevant to the assessment of government decision-making and actions.

The past twenty-five years have seen the establishment of regulatory mechanisms which have sought to clarify standards of conduct and behaviour which had previously been expected but not formally articulated. So, we have seen:

- the publication of a Ministerial Code which is effectively owned by the Prime Minister supported by an Independent Adviser on Ministerial Interests
- the Committee on Standards in Public Life and the Seven Principles of Public Life
- a statutory Civil Service Commission to regulate appointments and act as an appeal mechanism for civil servants who wish to raise concerns against the Civil Service Code.

We have reviewed each of these in the paragraphs below as well as explaining the long-held principle of ministerial responsibility.

Ministerial Responsibility

The principle of ministerial responsibility (or accountability) was developed during the 19th and 20th centuries as the separate roles of Ministers and Civil Servants were developed. It was therefore in place at the time of the events which are the subject of the Inquiry. The principle is not set out in law but is based on convention and precedent.

Put simply, the convention means that Ministers are accountable to Parliament for the actions of their Department and have a duty to take remedial action to right any wrong and to apologise for any failures. The convention is rooted in the fact that Ministers are democratically elected and selected from Parliament and should therefore be answerable to Parliament.

The convention means that a Secretary of State is responsible for the whole of their Department and its failure or errors. Similarly, Junior Ministers must answer for their particular area of responsibility. Ultimately it means that there is an expectation that they should resign if something has gone seriously wrong. Since 1997 the convention has also been set out in the Ministerial Code (see below) but the Prime Minister is the final arbiter of what should happen in the event of a breach of the Code.

In practice the convention of Ministerial Responsibility does not necessarily mean that Ministers have to resign if something has gone wrong. It is for Parliament to make that judgement and it will depend on what has gone wrong; how serious it was; what was known to civil servants and Ministers at the relevant time(s); what explanation the Minister offers and what action the Minister has taken to remedy the failures. Parliament cannot, therefore, force a Minister to resign although it can pass a vote of censure or no confidence.

If a Minister is, however, found to have misled the House then there is a stronger presumption that they should resign but once again Parliament cannot enforce that outcome if, for example, the Minister denies the accusation.

In the face of this convention, many commentators have argued that Ministers should not be accountable for everything that happens in their Department. In large, often devolved Departments, Ministers, it is argued, cannot know everything and it is also difficult, sometimes, to establish whether failures have occurred because of a ministerial decision, a lack of ministerial oversight or the actions of officials. As a result, resignations have not often been forthcoming.

Having said that, some Ministers have resigned even when the relevant actions were the responsibility of Civil Servants. The most famous such case became known as the Crichton Down Affair when a claim of unfair treatment of a landowner by the Ministry of Agriculture and the Crown Lands Commissioner led to a public inquiry. Although he had no knowledge of the actions of his official, the Minister did nonetheless resign saying that 'As Minister, I must accept full responsibility to Parliament for any mistakes and inefficiency of officials in my Department just as, when my officials bring off any successes on my behalf, I take full credit for them' (House of Lords, 2012).

More recently it has seemed that often officials have been held responsible for failures rather than Ministers. So, for example, in 2020 the Chief Executive of Ofqual and the Permanent Secretary of the Department for Education both resigned after a series of problems concerning A level results. Unusually, Parliament did not receive an account of what had happened and the Secretary of State, Gavin Williamson remained in post.

The doctrine of Ministerial Accountability cannot therefore now be regarded as absolute and whether a Minister does resign following failures in their Department will depend on a wide range of considerations.

Ministerial Code

The rules and principles which define the standards of conduct for Government Ministers are now set out in the Ministerial Code (Cabinet Office, 2022). There are separate codes for Ministers in the UK government as well as the governments of Scotland, Wales and Northern

Ireland. The Codes all include the overarching duty of ministers to comply with the law and the Seven Principles of Public Life (see below). The Northern Ireland Code also sets out rules and procedures specified in the Belfast Agreement, the Northern Ireland Act 1998, the St. Andrews Agreement and the Northern Ireland (St. Andrews Agreement) Act 2006 (Northern Ireland Office, 1998; 2006).

There are some significant differences between the various codes. The Scottish and Northern Ireland Codes both set out specific rules around how issues are brought to collective discussion whereas the UK Code sets out principles but leaves more flexibility to the Prime Minister (Cabinet Office, 2022; Northern Ireland Office, 2006; Scottish Government, 2018). The Northern Ireland Code includes a pledge to ensure the effective running of the power sharing agreement, promoting the interests of the whole community and challenging paramilitary activity. The Welsh code, alone, includes a specific reference to the well-being of Ministers.

A form of the Code(s) has existed since the Second World War but was only made public when it was published as 'Questions of Procedure for Ministers' by the then Prime Minister John Major (Cabinet Office, 1992). It was renamed the Ministerial Code under Tony Blair in 1997 and was last updated in 2022 (Cabinet Office, 2022). The Code mirrors the rules about conventions set out in the Cabinet Manual and the Civil Service Code (see below) but it has no statutory backing and is not therefore legally binding. There is, however, now said to be an expectation that breaking the code will lead to dismissal although that is by no means always the case. That was illustrated recently when the Home Secretary was found to have broken the code by bullying officials but remained in post with the support of the Prime Minister. As a result, however, the Prime Minister's adviser on standards, Sir Alex Allan, himself chose to resign. The Prime Minister subsequently appointed Lord Geidt as his new independent adviser but the terms of reference for him again made clear that it is for the Prime Minister to decide whether any investigation into potential breaches should take place. Also, the adviser cannot publish the findings of his investigations but can 'require' that they are published 'in a timely manner' by the Government. In the event Lord Geidt himself decided to resign having, it seems, been asked to advise on a proposed policy which would have breached the Code. As a result, the terms of the Code itself are being reviewed.

The Welsh and Scottish codes have a similar status to the Westminster original but the Northern Ireland Code does have statutory backing. The Welsh, Scottish and UK codes all make it clear that it is not for officials to enforce the Code whereas the Northern Ireland Code sets out the process for investigations.

As for content, all of the Codes cover how government functions, the impartiality of the Civil Service, accountability to Parliament, the use of government resources, propriety and ethics, and the separation of public and private interests.

New versions of the Code are most often published at the start of an administration.

The Nolan Principles

Following the 'cash for questions' scandal in the early 1990s the then Prime Minister, John Major, asked Lord Nolan to examine the arrangements that govern standards of propriety in public life. Lord Nolan reported in 1995 and set out the seven principles of Public Life (Nolan, 1995), namely:

- (i) *Selflessness*: acting solely in the terms of the public interest.
- (ii) *Integrity*: avoiding inappropriate influence and not seeking personal gain.

- (iii) *Objectivity*: taking decisions impartially, fairly and on merit.
- (iv) *Accountability*: accepting public accountability for decisions.
- (v) *Openness*: acting transparently and not withholding information.
- (vi) *Honesty*: being truthful.
- (vii) *Leadership*: behaving in accordance with these principles.

Although Lord Nolan's report was the first time these principles had been formally established they had long underpinned the spirit of public service in this country.

As the current Chair of the Committee on Standards in Public Life - Lord Evans of Weardale - observed in the Hugh Key lecture which he delivered in 2020:

'Since 1995 it has been increasingly accepted that anyone in public service should act in accordance with the Seven Principles. The Principles apply to Ministers, Civil Servants, local government officials, public bodies, the NHS agencies, as well as private companies and charities delivering services on behalf of the taxpayer. The Principles are not a rulebook but a guide to Institutional administration and personal conduct and are given hard edge when they inform law, policy, procedures and codes of conduct.' (Evans, 2020).

He went on to say:

'In their essence the Seven Principles are there to govern the legitimate use of entrusted power in public life. All of us in public life, whether through democratic election or public appointment have some degree of power afforded to us on the public's behalf whether it is the power to make decisions on benefits, spend money on schools, legislate to protect public health or influence debate. The power is lent to us to be used for the benefit of the public. Elections and institutions give us a constitutional framework but the Seven Principles define the character of our political system.' (Evans, 2020).

The Civil Service Code

The Civil Service Code was first issued in 2010 by the Minister for the Civil Service (Constitutional Reform and Governance Act 2010). It outlines the core values of the Service and gives illustrations of the standards of behaviour expected. Departments must make civil servants aware of the Code and consider any concerns raised under it. Unresolved concerns can be referred to the Civil Service Commission.

As with the other codes referred to above, the Civil Service Code is the articulation of standards long recognised and sometimes referred to as the 'eternal verities'. In essence, Civil Servants are expected to act with:

- (i) *Integrity*: fulfilling their duties responsibly, complying with the law and not misusing their official position.
- (ii) *Honesty*: setting out facts truthfully, using resources only for the authorised public purpose and not misleading ministers.
- (iii) *Objectivity*: providing information and advice on the basis of evidence and not frustrating the implementation of policies.

(iv) *Impartiality*: acting solely according to the merits of the case and serving equally well governments of different political persuasions.

The Civil Service Code outlines the values and standards of behaviour but it is not a comprehensive manual telling civil servants what to do in different situations and does not cover Human Resources and management issues. The Civil Service Management Code deals with performance and conduct in more detail (Civil Service, 2016). The Code covers all existing civil servants but it does not cover people employed in the wider public sector, NHS staff or employees of local authorities.

The 2010 Constitutional Reform and Governance Act sets out the requirement for a civil service code in statute stating that ‘the code must require civil servants to carry out their duties for the assistance of the administration ... whatever its political complexion’ and must require civil servants to carry out their duties with integrity (Constitutional Reform and Governance Act 2010).

Summary

Although these various codes and manuals stand alone, the thrust of them all is perhaps best captured by the seven principles of public life first articulated by Nolan. These do define best what is expected of those working in public life and, in the words of Lord Evans, ‘define the character of our political system’ (Evans, 2020). It is increasingly clear however that the consequences of breaching any of the codes, conventions and principles depends upon the judgement of the Prime Minister and Parliament. Their importance, however, should not be underestimated because of that. They do still define the expectations and, as such, still exert real influence on the behaviour of elected representatives and civil servants.

General principles concerning public health

16. Please explain what the concept and/or discipline of “public health” encompasses today, in the United Kingdom.

In the UK, a widely accepted definition of public health is ‘the science and art of preventing disease, prolonging life and promoting health through the organised efforts of society’ (Acheson, 1988). Early definitions emphasised sanitary conditions, control of community infections, and education about personal hygiene. However, the 1988 Acheson report into the future of public health in England emphasised the need ‘to give as much weight to the importance of lifestyle as to environmental hygiene in the preservation and promotion of health.’ The current principles of health promotion give more weight to a positive health concept, the participation and involvement of key stakeholders and equity in health (Lillefjell and Maass, 2022).

The public health specialty in the UK, which was until 2003 a branch of medicine, has been formally widened to include workforce groups from different disciplinary backgrounds. The Faculty of Public Health (FPH), which determines training and curriculum competencies, describes six essential public health functions: health protection, health improvement, health services, public health intelligence, academic public health, and workforce development. The current focus of the National Institute of Health Research public health programme on changing lifestyle, health promotion and wider environmental influences reflects this.

In terms of service work, the public health profession, i.e. those on either the registers of the General Medical Council / General Dental Council or voluntary UK Public Health Register, is now split between medical doctors and the non-clinical workforce. The activities of medical doctors are mainly concerned with epidemiology, health services, and health protection work. In 2021, of the service medical workforce 172 FTE (42%) were located in the newly established UK Health Security Agency (UKHSA) and the Office of Health Improvement and Disparities (OHID) within the Department of Health and Social Care under political control, and 110 FTE (27%) in the NHS. Of non-clinical specialists, which include the majority of directors of public health and consultants, 422 FTE (90%) were in local authorities and largely concerned with health promotion (Edbrooke-Hyson, 2022).

- 17. Please explain, in broad terms, how public health expertise and institutional arrangements have been, and are, funded, structured, organised and utilised by the governments and the NHS in the United Kingdom. To the extent that you are able to, please:**
- a. identify any particularly significant historical developments; and**
 - b. address the development of the Public Health Laboratory Service and the Communicable Disease Surveillance Centre and their role in assessing risk.**

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 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 full account of these changes would require a substantial report in its own right and is beyond the scope of this group. We will however summarise the principal changes in public health services and the critical topic of disease surveillance with Appendices A and B of this report providing further details.

The 1974 reorganisation

The newly created NHS in 1948 instigated a tripartite split of public health between local authorities, regional hospital boards, and general practitioner services but retained the localism of public health developed since the 1870s. Until 1974 local authorities employed medical officers of health (MOHs) with their own departments. They were medically trained, had substantial expertise, received disease notifications, and exercised executive powers. They were abolished in 1974 when both local government and the NHS underwent significant simultaneous reorganisations, at a time when the government considered that the 'main infectious diseases which were once the major cause of death of people of working age have been virtually eliminated as health problems' (Department of Health and Social Security, 1970).

In 1974, most of the public health responsibilities of local authorities, which had included vaccination, immunisation, and prevention of illness, were transferred to newly-created regional and area health authorities in England and Wales, and to health boards in Scotland. Similar changes had been instituted in Northern Ireland the year before. Communicable disease control functions remained with local authorities, but with weakened capacity and complex working arrangements with the new health authorities. MOHs in local authorities moved to become community physicians in area health authorities (AHAs), with responsibilities that included health service and workforce planning, needs assessment, screening, child health, and vaccination programmes, and medical administration. Health visitors, district nurses and community midwifery also moved to the NHS from local authority control. Community physicians also performed a part-time role as medical advisers to local authorities and as their 'proper officers' for receipt of disease notifications. This meant that local authorities lost their own medical departments and now only had access to one part-time medical officer (Department of Health and Social Security, 1973).

The Acheson report, 1988

Following serious outbreaks of salmonella and legionnaires' disease in Wakefield and Stafford in 1984 and 1985, a Committee of Inquiry into the Future Development of the Public Health Function was set up, chaired by the then Chief Medical Officer, Sir Donald Acheson. The inquiry noted how 'the trauma of the 1974 and 1982 reorganisations', combined with a reduction in community medicine posts, had led to a worsening morale among community physicians. The committee recommended district health authorities (which were created when AHAs were abolished in 1982) should appoint a director of public health (DPH) to coordinate health protection, and should assign executive authority for communicable disease control to a medical doctor with epidemiological expertise, who would receive district and regional NHS support for contact tracing. Contrary to Acheson's recommendation the expansion did not take place, most communicable disease consultants were part-time, and performing many other functions (O'Brien et al., 1993).

The 1990s would see a shift in the practice of public health from clinical epidemiology, communicable disease control, and medical administration to a growing emphasis on lifestyle, health education, and health promotion across society as a whole. Acheson had regarded it as important that public health specialists had a medical education and clinical training, but there were longstanding concerns about the lack of career structure for the non-medical and technical public health workforce. After extensive discussions, in 1999 the government committed to develop a new non-medical role of specialist in public health. In 2003 the Faculty of Public Health Medicine opened up its membership and professional training to all disciplines and staff groups, changing its name to Faculty of Public Health.

Specialist training in public health as a branch of medicine now became a generalist training enabling other disciplines and non-medical staff groups to become consultants in public health or DPHs. The protected status of public health with the requirement of a medical degree and postgraduate medical training prior to entry was in effect abolished (Griffiths et al., 2007). The title of public health specialist is not protected like that of biomedical and clinical scientists and a range of other health professionals (Health and Care Professions Council, 2018).

A new central body for health protection

In January 2002, the then chief medical officer Sir Liam Donaldson, published a new strategy for combating infectious disease and enhancing health protection (Department of Health, 2002). The report led to the establishment of the Health Protection Authority as a special health authority on 1 April 2003, covering England and Wales. It was replaced the following year when the Health Protection Agency (HPA) Act 2004 established the HPA as a UK-wide non-departmental statutory public body. The health functions of the HPA in England and Wales were to protect the community against infectious disease and other dangers to health, and to prevent the spread of infectious disease. For the first time, controlling the spread of infectious disease within those countries became the statutory function of a centralised public body.

The HPA took on responsibility for providing or commissioning the functions that had since 1946 been the responsibility of the Public Health Laboratory Service (PHLS), including the Communicable Disease Surveillance Centre (CDSC), the Centre for Applied Microbiology and Research, emergency planning, and other protection support. Abolition of the PHLS led to the break-up of its extensive network of laboratories which were transferred mostly to NHS trusts and NHS foundation trusts with only eight laboratories and the Colindale campus passing to the HPA (discussed below). In 2009, the National Biological Standards Board,

which since 1976 had responsibility for setting the safety standards for biological substances, including Factor VIII and other blood products, was abolished and its functions, staff, and funding transferred to the HPA.

The NHS 'internal market' posed huge challenges for the HPA and its responsibility for providing a cohesive approach to infectious disease and other risks. Funding for those 38 PHLS laboratories transferred under the direct management of NHS providers (trusts) now passed to NHS commissioners (Primary Care Trusts (PCTs)) as part of their block allocation. In its first year, HPA had to negotiate over 300 agreements with PCTs and at least 140 agreements with hospitals regarding microbiological testing of patient samples (plus over 390 arrangements to test food, water and environmental samples on behalf of local authorities) (Health Protection Agency, 2004). Local PHLS capacity was neither a priority for the trusts nor the PCTs. Trusts which were struggling to make efficiency savings from contracts were only concerned to pay for the laboratory services they required for their own patients and those of local GPs (Duerden et al., 2020). NHS laboratories had no incentive to address public health challenges and laboratory services had to compete with clinical services for the allocation of scarce resources (House of Lords Select Committee on Science and Technology, 2003; Department of Health, 2006). These disruptive changes resulted in the loss of vital PHLS capacity and neglect of the specialty with serious staffing shortages and high vacancy rates in consultant medical microbiology posts throughout the 1990s and 2000s (Duerden, 2005). The consequence was that microbiology laboratories managed by the HPA and NHS trusts were unable to act in a coordinated manner to deliver effective surveillance and to provide surge capacity (Duerden et al., n.d.).

The 2012 NHS reorganisation and the present day

The Health and Social Care Act 2012 fundamentally reorganised the NHS in England and changed yet again the institutional arrangements for public health. The HPA was abolished. The Act cemented institutionally the distinction between health protection on the one hand, and health improvement and promotion on the other.

Public Health England (PHE) was established on 1 April 2013 as a non-statutory executive agency of the Department of Health to carry out the secretary of state's duty to protect the health of the public. Local authorities were given the duty to take such steps as they consider appropriate for improving the health of the people in their area. Most of PHE's expenditure went to local authorities for health improvement. The Act required each local authority to appoint a director of public health. These posts however had no health protection functions (other than in an emergency) and were vulnerable to cuts associated with local government austerity measures. There was little communication between DPHs and their clinical colleagues as most DPHs are not medically qualified or familiar with clinical medicine.

In August 2020, the UK government announced that from spring 2021, a new executive agency, the National Institute of Health Protection, would be established, bringing together PHE, NHS Test and Trace, and the Joint Biosecurity Centre. In the event PHE's health protection tasks were transferred to a new executive agency, the UK Health Security Agency (UKHSA). The UKHSA is now responsible for protecting every member of every community from the impact of infectious diseases, chemical, biological, radiological and nuclear incidents and other health threats, working in collaboration with Public Health Scotland, Public Health Wales and Northern Ireland's Public Health Agency. The UKHSA describes itself as providing intellectual, scientific and operational leadership at national and local level, as well as on the global stage, to make the nation's health secure.

The distribution of the public health workforce today reflects the legislative and organisational shifts described above. In 1988, Acheson recommended a 16% expansion from 649 to 750 public health physician consultants over ten years to 1998, from 11.4 to 15.8 per million population (Acheson, 1988). However, by 2021 the number of public health consultants had fallen to 405, equal to 7.2 public health physicians in service per million population in England. Surveys of public health specialists and their registration show that between 2014 and 2021, the number of public health physicians decreased by 17% (from 1,476 to 1,219) whereas non-clinical public health specialists increased by 39% (from 540 to 748) (Centre for Workforce Intelligence, 2014; Milsom et al., 2019; Edbrooke-Hyson, 2022). Separately, the public health grant allocations to local authorities in England were cut by 24% in real terms per capita between 2015-16 and 2021-22, with some local authorities using public health funds for other purposes (Iacobucci, 2014; Finch et al., 2021).

The development of the Public Health Laboratory Service and the Communicable Disease Surveillance Centre and their role in assessing risk

The Public Health Laboratory Service (PHLS) was established under section 17 of the NHS Act 1946, and from 1960 was administered through an appointed board accountable to the minister of health (Howie, 1965). It ran a national (England and Wales) network of local and regional laboratories, as well as the Central Public Health Laboratory (CPHL) and later incorporated the Centre for Applied Microbiology and Research at Porton Down (Howie, 1965; Galbraith, 1981; Acheson, 1988). PHLS was linked with NHS hospital diagnostic laboratory services and provided advice and assistance to local public health officials, including a bacteriology and virology service (Howie, 1965; Galbraith, 1981).

Although laboratory services were highly effective, health protection services across England were inadequately coordinated (Galbraith, 1981). There was no central function for communicable disease control, other than disease notification, until the establishment of the Communicable Disease Surveillance Centre (CDSC) within the PHLS in 1977 following the 1973 smallpox outbreak in London (Galbraith, 1981). The CDSC brought together scientific specialism with policy and advice in the national surveillance of communicable disease and coordination of disease investigation and control (Acheson, 1988; Donaldson and Donaldson, 1993). It reported to, and liaised with, the DHSS' Med IMCD (International Health, Microbiology of Food and the Environment and Communicable Disease), the section responsible for communicable disease, who would also communicate concerns about blood and blood products.

The PHLS was highly regarded throughout its existence, the Acheson authors commenting that the evidence submitted to them 'demonstrates almost universal support for the PHLS and its epidemiological 'nerve-centre' the CDSC' (Acheson, 1988, at 4.19).

With a national overview and local involvement, the PHLS was able to build up a national picture of communicable disease, but had no executive powers to intervene. From a peak of 63 laboratories in 1969, it slowly declined to 52 laboratories in 1980, and 49 in 1996. In 2003, the number of laboratories was reduced to nine and 38 were transferred to NHS trusts (Kirchhelle, 2022). National coordination was further set back by the ending of ring-fenced budgets in 2005, combined with efficiency savings and budgetary cuts, and a policy of increasing outsourcing to private laboratories (NHS Improvement, 2017; Satta and Edmonstone, 2018; Duerden et al., 2020). The PHLS was weakened and fragmented, its network of local, regional, and national laboratories reduced to eight regional hubs and the

Colindale campus (Kirchhelle and Dougan, 2020). The head of the US Centers for Disease Control and Prevention questioned the approach, suggesting that the UK was planning to break up what the US was trying to create (Bamford and Daniel, 2005).

In 2020, Lord Turnberg, who resigned in protest as chairman of the board of PHLS in 2004, in a letter to the Times urged a return to a fully funded and robust system of public health surveillance noting that:

‘...the government decimated the nationwide network of public health laboratories overseen by the Public Health Laboratory Service ... Further damage was done when public health surveillance was handed over to local authorities in 2012 that were then slowly but surely starved of funds.’ (Turnberg, 2020)

The role of PHLS and CDSC in surveillance and assessing risk

Surveillance is the key to the detection and control of all diseases and monitoring risk of disease. It may be defined as ‘the continuing scrutiny of all aspects of the occurrence and spread of a disease through the systematic collection, collation and analysis of data and the prompt dissemination of the resulting information’ and ‘to monitor disease trends, identify epidemics or outbreaks and evaluate prevention and control programmes’ (Donaldson and Donaldson, 1993, p388; Hawker et al., 2006, p271).

In the 1970s local community physicians and the CDSC carried out surveillance using information collated by the laboratory and hospital reporting systems and death certification along with the Office of Population Censuses and Surveys’ (OPSC) notifiable disease information and seroprevalence studies (Berrie, 1977; Hawker et al., 2006). GPs treated the majority of people with communicable diseases. In 1967 the Royal College of General Practitioners (RCGP) established a network of sentinel practices which sent returns on communicable disease to the RCGP’s research unit in Birmingham, which had, however, limited analytic capacity (Birmingham Research Unit, 1971). The RCGP continues to sponsor surveillance through its Research and Surveillance centre.

A key mechanism for advising on planning and operation of services for notifiable diseases and food poisoning was the Joint Consultative Committees established between local authorities and health authorities, on which PHLS sat (Department of Health and Social Security, 1973). We were unable to find evidence of whether PHLS played an active role on these committees giving advice on screening and contact tracing of recipients of infected blood and their contacts. In any case, proactive screening of asymptomatic families and contacts of recipients of infected blood would have presented ethical and practical difficulties in the absence of a treatment or effective intervention, which by 1968 was a key principle of WHO Wilson and Jungner screening criteria for tests (Wilson and Jungner, 1968). It might however have been possible to provide lifestyle advice or guidance on how to avoid infecting others.

Surveillance as ‘applied research’ in blood transfusion appears to have been limited to blood samples for prevalence and other epidemiological studies. The main research efforts were directed at screening and vaccine research, with little to provide a logical basis for broader policy decisions (Stanton, 1995).

The disease notification system

Disease notification is the main form of communicable disease surveillance that is legally required. The system dates back to the 19th century, requiring doctors to notify authorities of cholera and other communicable diseases. In the 1970s doctors notified the 'proper officer' of local authorities, usually a public health doctor and the community physician in the health authority. They were then obliged to inform OPSC which, from 1982 onwards, informed the CDSC, which collated and analysed the information, and circulated a weekly update (Donaldson and Donaldson, 1993, p388; Bartlett, 2003; Hawker et al., 2006, p272). The local authority's medical officer of environmental health was also to inform the chief medical officer of any serious outbreak of disease, including food poisoning.

The Health and Social Care Act 2008 removed the definition of 'notifiable diseases' from primary legislation in England and Wales. Ministers were given a new power to make regulations to prevent, protect against, control or provide a public health response to the incidence or spread of infection or contamination. This power was used to make the Health Protection (Notification) Regulations 2010 for England which provided a list of 31 notifiable diseases. Failure to notify is no longer a criminal offence. Currently the UKHSA requires notification of 33 diseases, including food poisoning, and a range of notifiable organisms such as the various hepatitis viruses (see Appendix B). Arrangements differ slightly in Scotland and Northern Ireland, but the essential principles are the same.

Detection of Acquired Immune Deficiency Syndrome (AIDS)

Since AIDS was not a notifiable disease (and neither AIDS nor the agent HIV has ever been notifiable in the UK, in sharp contrast to many other countries), there was initially no obligation for clinicians to notify or report cases. The CDSC had to develop other mechanisms for surveillance. The first case of AIDS was reported in the UK in December 1981. A national surveillance system was set up by the CDSC in 1982 comprising death registrations from the OPCS, laboratory reports of opportunistic infections from microbiologists, and confidential clinical reports from venereologists and dermatologists (Galbraith, 1989). In 1985, when laboratory tests became available, surveillance was extended to include reports of positive tests. This informal system provided most of the UK's collated data on clinical AIDS.

Although AIDS and HIV were not notifiable, certain control powers were applied to AIDS under the Public Health (Infectious Diseases) Regulations 1985, such as compulsory medical examination and detention. From 1987, the NHS was required to make periodic reports to the government (AIDS Control Act 1987); from July 1988 these included the 'number of positive results known to the [NHS] to have been obtained in the reporting period from blood samples taken for the purposes of HIV antibody tests by facilities or services provided by the [NHS]'.

18. Please explain the meaning, origins and development of the “precautionary principle” as it applies to public health and healthcare decisions in the United Kingdom.

Definition

The precautionary principle was originally developed in the 1970s to address risks to the environment but was subsequently expanded to also encompass risk to public health. The principle requires that ‘proactive action be taken to prevent or minimise threats to human health or the environment, notwithstanding the absence of full scientific certainty about the nature and scope of such threats.’ (Farrell, 2012).

Key elements informing whether the precautionary principle should be adopted in relation to managing public health risks include the following:

- the taking of preventive action in the face of scientific uncertainty;
- the shifting of the burden of proof to the proponents of a particular activity to show that it is not harmful;
- the exploration of a wide range of alternatives to possibly harmful actions;
- the need to increase public participation in decision-making about the use of precautionary strategies (Kriebel and Tickner, 2001; Farrell, 2012, p168).

The precautionary principle should be considered within a structured approach to the analysis of risk which comprises three elements, namely risk assessment, risk communication and risk management. The application of the principle has been seen as particularly important in relation to decision-making regarding the third and final element, as this dealt with risk acceptability which was recognised as being ultimately a political decision (Farrell, 2012, p170).

In some jurisdictions, the precautionary principle has the force of law, whereas in others it is a matter of policy only. It is therefore difficult to make any universal claims regarding how it should be defined, interpreted and enforced. In the final analysis, however, its application is likely to be determined by political imperatives with respect to managing a given risk to public health. It is also important to note that some interpretations of the principle suggest that cost-benefit analysis should be undertaken in determining whether or not precautionary measures should be adopted in relation to risks posed to public health, whereas others do not.

The use of the precautionary principle has been embedded in public health policy and regulatory processes for many years at the European Union (EU) level, along the lines set out above (Commission of the European Communities, 2000). However, it is unclear what the political and/or legal status of the principle will be in a post-Brexit climate in the UK (Read and O’Riordan, 2017). The COVID-19 pandemic has shown that the UK government and the devolved administrations were prepared to take a range of precautionary measures to protect the public from risks posed by the disease (Taleb and Bar-Yam, 2020). However, it remains unclear how the UK government (or indeed the devolved governments) will employ the use of the precautionary principle in managing future risks to public health.

The precautionary principle and blood safety

In considering whether to apply the principle in relation to emerging risks to the blood supply, different approaches have been proposed. In a strict interpretation, it has been argued that preventive action should be taken where there is evidence that a potential disease-causing agent is or may be blood-borne, even where there is no evidence that recipients have yet been affected. If there is potential for harm to occur, then it should be assumed it will occur and measures taken accordingly (Krever, 1997).

A broader interpretation of the principle has also been suggested, which is that precautions should be taken in situations of scientific uncertainty where there is simply a possibility of risk, even in the absence of definitive information of either risk or harm. When this occurs, measures should be taken to deal with potentially serious risks (Alter and Klein, 2008, p2620). Other commentators have suggested a more structured approach to its application in the context of managing blood safety, which is based on assessing risk as being high, intermediate or low (Wilson, 2011). In all cases, it is accepted that an in-depth risk assessment based on available medico-scientific evidence is highly desirable (Farrell, 2012, p176).

The manner in which the principle is applied may ultimately turn on public perceptions or expectations about blood safety. Heightened concern is much more likely to be the case where there is a serious or catastrophic risk, such as the one previously posed by HIV. In the wake of the political fallout from HIV blood contamination scandals across a range of countries, blood safety became a highly politically sensitive area of public health policy. Against this background, the precautionary principle acquired an increased significance (Wilson, 2011). However, the assessment of risk and the need for precautionary action has at times involved a less than robust application of established scientific risk assessment techniques, with insufficient cost effectiveness and proportionality criteria in assessing risks to the blood supply (Farrell, 2012, pp167, 174).

19. Please identify any other particular principles that underlie the current understanding and practice of public health and how these principles have changed over time (if at all).

Public health medicine requires locally based disease surveillance, an understanding of the aetiology of disease and disease in patients, and local epidemiological and clinical expertise closely integrated with local public health laboratory capacity. The national role of public health and associated laboratory services is to coordinate, support, and advise local outbreak responses, undertake workforce planning and development, training, advice, standard setting, and surge capacity where locally requested. These principles should ensure the generation of timely and reliable information and data, and require mechanisms to ensure effective and coordinated service responses close to local communities. Public accountability, good communication, multidisciplinary collaboration, and transparency are no less important.

Those practising public health today have to apply these principles in the face of the difficulties we have explained in response to Question 17.

In 2003, the widening of entry requirements for public health from being a branch of medicine to a generalist training track open to all changed the practice of public health. It was extended to include health promotion, health education, health intelligence/information and other activities some of which were specialties in their own right and organised in separate departments. These principles are described in response to Question 16.

In reality the legislative and organisational changes have led to a disciplinary and organisational split between the medical and non-medical workforce. The majority of the medical workforce are located in the centre, under political control, and undertake health protection activities. There has been an extraordinary loss of expertise in clinical public health and especially within local health services and local authorities. In contrast, the majority of the non-medical specialist public health workforce are mainly located within local authorities where much of the focus is on health promotion activities.

20. Please consider and explain the role of public health and epidemiological expertise in response to an emerging health risk; how such expertise should best be used; and where responsibility lies for ensuring that such expertise is utilised.

Public health expertise in the context of emerging health risks, in particular from communicable diseases, is derived from clinical, microbiological, and epidemiological expertise. The early detection of an emerging health risk depends on rapid access to data and information drawn from a variety of sources, including case reports, case series, disease notifications via clinicians, death certification, morbidity data from community and hospital systems, prevalence surveys, pathology and laboratory reports, yellow cards, and environmental health reports. The identification and interpretation of relevant data are complex and require specialist training and skills.

Responsibility for ensuring this expertise in England is utilised lies with the secretary of state via his or her public health functions, with power to arrange for local authorities (and NHS England, the new Integrated Care Boards to be established under the Health and Care Act 2022, and any other prescribed body) to exercise those functions. To date this responsibility has generally been retained centrally, first within PHE, and now within the UKHSA, which relies heavily on management consultants and privatised services (Harries, 2022). This expertise would be best used if based, primarily, in properly funded and statutorily empowered local authorities, supplemented and supported by coordination, workforce planning and development, training, advice, and emergency assistance where locally requested, from national and regional bodies which would have default intervention powers. As the above sections have shown however, public health expertise and workforce have been considerably eroded over the years, and are largely absent from local authorities and local health services. Responding to future and emerging risk requires a fully funded system of surveillance and anticipation based on local epidemiological and clinical expertise, closely integrated with local laboratory provision and nationally coordinated and supported.

Government decision making and implementation in respect of health policy in the United Kingdom

21. Please explain, in broad terms, the way in which health policy is made and implemented in the United Kingdom and identify any relevant systems, structures, processes and principles, taking into account the conflicts inherent in central policy making and local delivery, and the prevailing ethos for many years of the NHS.

The fundamentals of health policy making are broadly the same as in other areas of government, with general direction and oversight coming from ministers and officials working in central departments and implementation happening locally. But there is significantly more delegation of decision-making and responsibility to other bodies and parts of the health system than is true of most other policy areas – not least given the political and administrative devolution of healthcare, the history of which is covered in the next section of the report. In England alone, implementation of policy that has been arrived at by ‘the centre’ is unusually complex, involving a plethora of bodies including local authorities, Clinical Commissioning Groups, which will be closed with the introduction of Integrated care boards, NHS trusts, the new Integrated Care Systems (ICSs), GP practices and more. Each of the devolved administrations takes its own, separate approach.

Although its role with respect to managing the NHS has decreased since the creation of NHS England in 2012, the Department of Health and Social Care (DHSC) still sits at the heart of health policy making in England. The Department, on behalf of the Secretary of State for Health, is the only body with oversight of the whole English health and social care landscape and acts as a ‘system steward’, working to ensure its disparate parts function effectively to meet citizens’ needs (Department of Health and Social Care, 2013). It sets national priorities – although NHS England also now produces planning documents such as the ‘NHS Long Term Plan’ (National Health Service England, 2019a) – and creates and updates the policy and legislative frameworks within which the health system operates. A similar role is played by the health departments (or in Scotland’s case, the Health and Social Care Directorates) of each of the devolved nations, but with government more heavily involved in the management of the health services: there is more direct ministerial oversight, and the Director-Generals of the Welsh Health Department and relevant Scottish Directorates are also the Chief Executives of their respective health systems.

As with other areas of government, the priorities and policies that guide the system are arrived at through collaboration between ministers and officials, with input from relevant bodies, businesses, and (sometimes) members of the public. The process of policy development itself is typically imagined as a six-point ‘ROAMEF’ cycle, set out in HM Treasury’s ‘Green Book’ (HM Treasury, 2022). The acronym incorporates six stages: outlining the *Rationale* behind the policy, defining the *Objectives*, conducting an *Appraisal* of policy options, *Monitoring* and then *Evaluating* the impact and capturing that as *Feedback* to inform future policies. In reality, the process is rarely, if ever, this neat, but officials aim to cover each stage of the cycle at some point (Rutter and Hallsworth, 2011).

Major decisions about which policies to pursue and when, or any that have novel spending implications, are usually made by ministers. Others might be delegated to senior civil servants, with executive agencies also delegated authority to act in certain policy areas (e.g. MHRA on approving new medical technologies). The question of whether and when to refer an issue to a minister is left to the judgement of civil servants, although ministers can also request submissions and briefings on areas of interest. Ministers' Private Offices decide which submissions to draw their attention to. Straightforward questions are dealt with in written responses drafted by the Ministerial Correspondence Unit or civil servants working on the policy area in question, with Ministers checking and amending the drafts before they are sent and printed in Hansard. More complex matters are likely to be discussed and debated in meetings with relevant officials and advisors. Really significant or contentious decisions, especially with wider cross-government implications, should be debated and agreed by a Cabinet Committee or Cabinet itself.

Throughout the policy making process, officials and ministers draw on a range of expertise. Some of this is internal: the Chief Medical Officer plays a central role with respect to health policy, especially in supporting Ministerial decision making, and is in turn supported by deputies and a team of civil servants. But in the case of England, much of it comes from outside the core department. Where previously (e.g. in the 1980s) the Department for Health employed a cadre of medical advisors that functioned in a parallel hierarchy to more 'administrative' officials, medical experts are now largely employed by the 15 arm's-length bodies that support DHSC's work, including the Care Quality Commission (CQC), the National Institute for Health and Care Excellence (NICE), and the Medicines and Healthcare products Regulatory Agency (MHRA) (Department of Health and Social Care, 2022). Advisory committees are also used to bring greater specialist expertise to particular areas, often feeding back to the Chief Medical Officer.

As this expertise has been farmed out over recent decades, DHSC has gone from being the clear 'leader' on health policy and delivery to taking on more of an oversight role, with many decisions taken by these other bodies – and especially NHS England, when it comes to the management of the NHS, although this still happens in collaboration with DHSC (as noted above, the devolved governments maintain more direct control of their respective health systems). But there has also been a significant devolution of decision making from the centre to more local levels, including to local authorities, NHS Trusts, and now (in the wake of the Health and Care Act 2022) 'Integrated Care Systems'. This devolution reflects the sheer complexity of the health system, which is seen as limiting the effectiveness of a centralised approach to managing and improving healthcare (Ham, 2022). While the centre still has a role to play, in many areas local leaders, with a better understanding of their specific contexts and implementation challenges, are in theory better positioned to make decisions.

22. Please consider, and include any observations that you have about, the respective roles and responsibilities of

- a. government ministers;
- b. the Chief Medical Officers and Deputy Chief Medical Officers;
- c. the civil service;
- d. NHS executives and administrators; and
- e. external/independent expert advice/advisors;

in decision-making regarding emerging health risks and in particular in terms of ensuring that the response to an emerging health risk is timely and effective.

Depending on the perceived severity of the risk, or the nature of the action being taken, responsibility for a decision regarding an emerging health risk might sit with any one of the first four groups considered here (scientific advisors very rarely have the authority to make these decisions themselves). Similarly, each of the groups, albeit much less frequently in the case of government ministers, is likely to be responsible for giving advice that feeds into a decision made by someone else from their group or one of the other groups, at some point.

Government ministers

Ministers are accountable for any decisions that are made within their policy area; Secretaries of State are likewise accountable to Parliament for anything that happens under their junior ministers. But as outlined above, only issues that are considered particularly significant are likely to be referred to ministers for a decision in practice, with the role of the Private Office in deciding what to show any given minister also important. The source of the referral and the nature of the advice provided will also significantly shape the decision taken and subsequent response. For instance, it would be very unusual for ministers to ignore the advice provided by the CMO on primarily medical matters. They might ask questions to challenge that advice, but even this can be difficult given limited expertise – especially when ministers are new to the role.

This is not to give ministers a ‘free pass’ when it comes to decision making around emerging health risks. It is simply to acknowledge their dependence on the effective functioning of other parts of the health system to understand the significance of any risk, and the different responses that might be available. Ministers still play a crucial role in weighing up evidence from different parts of the system and government more broadly, relating not only to medical concerns, but also those around funding and the wider social, economic and political implications of any course of action.

Chief Medical Officers and Deputy Chief Medical Officers

The Chief Medical Officers (CMOs) of England, Scotland, Wales and Northern Ireland are responsible both for advising their respective governments on epidemics and disease prevention, and keeping abreast of emerging issues across the clinical landscape. They act as an interface between the government and medical or clinical professionals (clinicians can always raise concerns by writing to their respective CMO, for instance), and they often chair relevant expert committees. They have more power arguably than any other official – with the exception, perhaps, of a Permanent Secretary, who is at the same level of seniority – to draw

ministerial attention to an issue, through requesting an urgent meeting or otherwise, and take significant responsibility for whether and in what manner information is provided to clinicians, health bodies, patients and the general public about any given risk.

As with ministers, the breadth of a CMO's remit means they are often reliant on expert advice – from their Deputies (DCMOs), who lead on certain policy areas (mirroring the relationship between Secretaries of State and more junior ministers), and from specialist doctors in certain areas – and are supported by a team of civil servants. The CMOs also work together, sharing information and discussing concerns, and occasionally issuing joint statements or guidance.

The Civil Service

Civil servants play a range of roles in decision making around emerging health risks. Perhaps most prominently, they might be involved in developing advice to be passed to a minister about any risks and the different policy options available to them. They can also serve as a channel for picking up on emerging issues, with information coming from contacts in specialist bodies, attendance at meetings and conferences, and so on.

Much of the work that civil servants do to support decision making around emerging risks happens in public bodies rather than central departments, however. This is where the bulk of the expertise that would feed into subsequent advice sits, and where staff are most likely to be sufficiently 'plugged in' to pick up on emerging issues quickly. Some public bodies, such as the new UK Health Security Agency (UKHSA), are also granted a degree of operational autonomy around emerging health risks, exercising specific functions for anticipating, assessing and responding to threats as they arise on behalf of the Secretary of State (although the Secretary of State remains accountable for their actions).

NHS Executives and Administrators

NHS executives and administrators, or 'managers', work to ensure that clinicians have what they need to care for patients effectively. As part of managing staff, facilities and reporting systems, they work to ensure that NHS organisations are prepared to handle major incidents and emergencies while maintaining services (National Health Service England, 2019b). Depending on their level, they might be responsible for monitoring different aspects of service provision and identifying or anticipating issues and concerns. These may be addressed locally or, if they have possible system-wide implications (for instance, if they indicated an emerging national health risk), reported 'up' to relevant national bodies and regulators. NHS managers must also foster an open culture in which safety concerns can be raised without fear of criticism or censure.

External/independent expert advice/advisors

Advice from external experts is central to lots of health policy making, and often proves a vital supplement, with respect to emerging health risks, to advice coming from various parts of government. This advice is generally sought or commissioned by ministers or parts of government where they feel they are lacking sufficient insight, for instance through the appointment of an expert group. However, it is important that it is seen only as one input among many, particularly when the decisions it is feeding into could have wide-ranging effects.

External advice also underpins the decisions made and oversight provided by various parts of the health system beyond ministers' immediate purview. For example, the work of MHRA's Commission on Human Medicines, which has delegated authority to make decisions on the use or discontinuation of human medicinal products under the authority of the Secretary of

State (taking on the roles of the Medicines Commission and the Committee on the Safety of Medicines, which were active at the time of the infected blood scandal), is conducted by Expert Advisory Groups that specialise in different areas.

23. What (if any) weaknesses does the Group identify in the way in which decisions about health policy and in particular decisions about the response to emerging health risks are made? Please include consideration of the impact of structural reorganisations, and frequent movement of both Ministers and civil servants, on the ability of governments to identify and address relevant issues such as infected blood. How could those weaknesses be addressed?

The current system has a number of weaknesses both generally and in respect of public health and emerging health risks. The answer to this question focuses on the general weaknesses, and the answer to Question 24 focuses on public health and the response to emerging health risks. We also emphasise that the response to Question 17 is of particular relevance to this section (Questions 23-27) in that the long-term fragmentation of a previously integrated public health surveillance system has greatly reduced the ability to detect health risks and the ability to respond and manage crises when they arise.

Complexity and fragmentation of the NHS

The necessary delegation of healthcare responsibilities to local government and various other bodies, trusts and organisations, while with its benefits, has resulted in different parts of the system operating increasingly independently. Effective collaboration and information sharing (as seen to some extent during the COVID-19 pandemic) is the exception rather than the norm – partly because structures to facilitate it are underdeveloped, and partly because those working in the system are culturally adapted to working within their bubbles and may not know who they should be communicating with, what they should be sharing, or when.

Continual reorganisation of the NHS

The situation is worsened by frequent reorganisations of the health system, which undermine the ability of those working within it to understand its complexity or effectively develop structures and processes that cut across silos. Arguably, efforts to join up work across the English health system following the enormous overhauls of 2012 only began to build up steam during the pandemic, but 2022 has brought yet another set of changes, disrupting this progress.

Lack of communication across government, and between the devolved nations

This disjointedness is also evident in government at large: the independence of departments and separation of different forms of advice results in parts of government developing different, not always complementary policies and approaches, as we have seen at points during the COVID-19 pandemic. Communication between the UK Government and the devolved administrations is also often lacklustre – we address this in more detail in our response to Question 30.

Turnover of senior staff

High turnover at the centre – DHSC has an annual turnover rate of approximately 15% – means that those nominally ‘stewarding’ the system have little time to get to grips with its complexity, while relationships that are built across silos are quickly lost (Sasse and Norris, 2019). Senior ministers typically stay in post for no longer than two years, with every new minister bringing new priorities and ways of working, requiring further adaptation. NHS senior management exhibits a similarly high rate of turnover: more than half of executive directors were appointed in the last three years, undermining efforts to build relationships and work across organisations towards more integrated models of care (Anandaciva et al., 2018).

Inadequate monitoring and reporting systems

The recent Independent Medicines and Medical Devices Safety Review (IMMDS Review) concluded that the health system ‘cannot be relied upon to identify promptly significant adverse outcomes arising from a medication or device because it lacks the means to do so’ (Cumberlege, 2020). It does not typically know how many people (and who) have received a particular treatment, on the NHS or otherwise, let alone what the consequences of that treatment have been. In some cases, MHRA may not know what devices and medications are even in use in the UK until there is a problem with them.

Lack of attention to the patient voice

In healthcare, patients often know something is wrong before any official would, making mechanisms for public reporting and complaints processes all the more significant. As we explain in responses to Questions 31 and 32, patients who observe safety issues face many challenges in bringing these issues to the attention of NHS staff and organisations. This is exacerbated by a culture of defensiveness in some parts of the medical community, with women who do raise complaints to clinicians, in particular, often having their concerns dismissed rather than taken seriously.

Limited scope for challenge and testing of policy decisions

Not only is policy often made in bubbles on account of silos, but it can be difficult to make even the people who are in the room feel free to ‘speak their minds’ in difficult decision-making conversations. Structures do not help in some cases: the CMO, for example, is an independent expert, but also needs to maintain their relationship as a trusted advisor to political leaders, with these roles sometimes coming into tension (Haddon et al., 2020). Meanwhile, ministers’ lack of scientific or medical knowledge (due to lack of prior expertise and, often, being new to the job) undermines their ability to be good policy “customers” who can interrogate advice effectively and challenge more confident, knowledgeable advisors.

Reluctance to act on a precautionary basis

During the COVID-19 pandemic, the UK Government, especially, has appeared reluctant to make decisions on a precautionary basis, setting a much higher bar for evidence – in some cases waiting for it to be ‘overwhelming’ – than many other countries (Haddon et al., 2020). This has proven costly, with countries that locked down faster, for example, suffering proportionately fewer fatalities. This can be a difficult balance to strike, especially when acting entails major social, political or economic upheaval. But even when the government’s own assessment of risk has tipped in a new direction, it has been slow to translate this into changed policies, and has often struggled to communicate any changes effectively to the public.

Lack of expertise in evidence and risk assessment

Ministers are not trained in how to be a minister, on how to assess evidence and evaluate risk, on how to deal with pressures from the media, or on lessons learned from previous responses to emerging health risks. This is exacerbated by the high turnover noted above – while they may pick much of this up over time, usually they leave their role before having the chance to benefit fully from the knowledge they have developed.

Poor corporate memory

Decision-making is weakened by poor corporate memory, with lessons learned from previous responses to emerging health risks not recorded and passed on in any consistent way; similarly, plans and policies developed under previous governments are not shared with incoming governments (although they might be repurposed by officials for new ministers).

Lack of long-term planning and preparedness

Mechanisms for identifying future risks have improved in recent decades: in 2008, the UK pioneered the use of national risk assessments, and there are a growing number of more dedicated horizon-scanning services that the health system, for example, can draw on. But government still expends relatively little energy and resource on integrating these risks into strategies and operational plans. The COVID-19 pandemic is a case in point: it was predictable, but ‘even the relatively low likelihood attached to a novel respiratory virus was not adequately carried into operational plans’ (Haddon et al., 2020).

Resource constraints

It is a truism to say that decisions about health policy have been driven by cost containment and harsh expenditure controls. The NHS had inherited and struggled to maintain a vast and crumbling infrastructure from its inception. However, the IMF crisis in 1976 saw funding for the NHS frozen - much needed capital to rebuild community and primary care services, hospitals, and laboratories was halted – while revenue was under extraordinary pressure. The epidemics of communicable disease were largely viewed as being a thing of the past thanks to improvements in living standards, the implementation of mass vaccination, and rapid development of antimicrobials. All this enabled a shift of care into the community and closure of TB and infectious disease hospitals. Lifestyles rather than living standards were increasingly implicated in the new epidemics of non-communicable disease such as heart disease and obesity, and with it a drive in policy emphasis to health education, health promotion, and personal responsibility, and away from health protection.

Tackling the weaknesses

We have been asked specifically to suggest how the weaknesses identified above should be addressed and we have set out some suggestions below:

Continuity of ministers and civil servants

Government needs to place a higher priority on outcomes so that competent ministers are kept in post longer because that is more likely to deliver results. At the moment, priority is given to career enhancement - for civil servants as well as ministers - and to patronage rather than the delivery of outcomes. Prime ministers need to exercise willpower in the way appointments are made and patronage is exercised. They need to ask themselves when considering ministerial

changes whether they will increase the chances of a key project or policy being delivered. At the moment that rarely seems to be the dominant consideration. Long-term projects especially require stable consistent leadership if they are to be successfully delivered.

Funding

Central Government should move towards longer-term funding settlements, especially for long-term projects or programmes (House of Lords Select Committee on COVID-19, 2022).

Data sharing and coordination

There are long-standing problems with sharing data which make it difficult for departments, or even different parts of the same department, to collaborate. The Government and the DHSC need to work with the Information Commissioner to develop clearer guidance on when and how to share data. Hitherto, the emphasis has been largely on how to protect data which remains important in the context of health. We do need, however, to accept that the responsible sharing of data is essential if government is to work in a more joined-up way and if patients/clients are to receive the most effective care. It needs to be addressed if the new Integrated Care Boards are to succeed.

Corporate Memory

Ministers need to put more political weight on learning the lessons from previous responses to health risks and the management of long-term projects and policies. Whitehall and Westminster need to spend more time on evaluation and learning than is currently the case.

Decreased reliance on major reorganisations

As we say in the answer to Question 27, Ministers need to avoid major reorganisations if at all possible. These not only cause great disruption, but they make collaboration more difficult during the transition. There are very few structural reorganisations that have delivered the hoped-for improvements in customer service. Health and public health have suffered more than most from the seemingly endless desire to restructure, as we make clear elsewhere (Murray, 2019).

Patients' Voice

There needs to be a more profound acceptance of the importance of the patient's voice and the need to make use of lived experience. As we say elsewhere in reference to patient involvement, this means that policies should be developed and services designed jointly with patients and users. They need to be involved from the outset rather than when things have gone wrong. Codesign is very different from involvement or consultation.

Encouraging challenge and critique

All parts of Government, not least Health, need to facilitate the greater external challenge of policy and decision-making. Independent teams with access to internal data and analysis should be encouraged to interrogate advice and decision-making, as began to happen during the COVID-19 pandemic (Haddon, 2020).

24. Please set out (i) any shortcomings that the Group may identify and (ii) any recommendations that the Group may have in relation to the following:

- a. Ensuring that there are effective structures, systems and cultures in place to enable an accurate, balanced and comprehensive assessment of health risks (in particular risks arising from NHS treatment itself).
- b. Ensuring that there are effective structures, systems and cultures in place to enable a timely and effective response to emerging health risks. Including the extent to which, if at all, the lack of continuity of officials and Ministers may contribute to those risks.
- c. Ensuring that ministers and other relevant decision makers are provided with accurate, timely and balanced information and advice about emerging risks to public health, particularly where those risks arise from the administration of medical treatment or products, and how best to respond to them.
- d. Ensuring that ministers and other relevant decision makers are able, where appropriate, to challenge the advice with which they are provided on risks to public health or the response to such risks.

The questions posed above are extremely wide-ranging and could form the basis of an entire independent report. The answers will vary according to the nature of the health risks in question, so it is difficult to provide a definitive response in respect of all potential risks. To provide some forward direction, we use blood products as an exemplar health risk. We first summarise some of the known short-comings of the system, many of which are described in more detail elsewhere in this report. We then set out some broad proposals for the Inquiry to consider which would strengthen the detection, monitoring and management of future public health risks.

First, we note that a statutory basis for establishing a national blood service was not included in the legislation establishing the NHS. This may have contributed to shortcomings in national planning which were, for example, noted in the BMJ in 1974 (BMJ editorial, 1974). A clause which would have provided this basis in England and Wales – namely, conferring a ministerial power to make arrangements for obtaining a supply of blood, for making it available for carrying out blood transfusions, and for preparing and supplying blood products for therapeutic purposes – was initially proposed in the draft NHS bill presented to the Cabinet on 1 March 1946. This clause however was omitted from the Bill as presented to Parliament, and replaced with a more limited provision which was eventually enacted.

The complexity of modern blood transfusion medicine, and the current size and nature of an increasing and globalised blood products market, present formidable risk assessment challenges. There are numerous opportunities for errors in the transfusion chains (Stainsby et al., 2005). As described in our response to Question 17, a variety of changes to public health from 1974 onwards have weakened the capacity for surveillance of known diseases and new threats to health. The lack of investment in the necessary expertise, coupled with

underfunding and repeated reorganisations, and structural changes severely undermined the capacity for risk surveillance and control of outbreaks and epidemics, including for infected blood products. The consequence of the lack of investment is that microbiology laboratories and public health surveillance, managed by the HPA and then Public Health England (PHE) and by NHS and local authority bodies, are unable to act in a coordinated manner to deliver effective risk surveillance and to provide surge capacity.

The current system of regulation of blood products is a part of the system for licensing other medicinal products. Since Brexit, this task is performed UK-wide by the Medicines and Healthcare products Regulatory Agency (MHRA) on behalf of the Secretary of State (though we are unclear on the precise position in Northern Ireland). Risks, harms, benefits, safety, and efficacy are integral concepts in the development and promotion of products, and their regulation. As the number of blood products continues to increase, so does the importance of addressing long recognised shortcomings, which extend beyond the UK, in the rigour, demasitransparency and effectiveness of the regulatory systems, most recently investigated by the British Medical Journal (Demasi, 2022). The MHRA provides important functions and valuable safeguards but operates under some constraints. For instance, most research and development is carried out by industry and most MHRA funding comes from industry sources, making it difficult for MHRA to be truly independent. Critically, there is a distinct lack of long-term pharmacovigilance and haemovigilance studies which are the most reliable means of detecting problems. The existing 'Yellow Card' system for reporting suspected adverse reactions, while a useful supplementary method, suffers from 'gross under-reporting', due in part to its complexity and lack of awareness (Cumberlege, 2020). In addition independent inquiry and scrutiny of iatrogenic and clinical risks by external researchers is restricted by prohibitively expensive NHS charges for patient data.

The recent Independent Medicines and Medical Devices Safety Review concluded that the health system 'cannot be relied upon to identify promptly significant adverse outcomes arising from a medication or device because it lacks the means to do so' (Cumberlege, 2020). In many cases it is difficult, or even impossible, to ascertain how many people (and who) have received a particular treatment, on the NHS or otherwise, let alone what the consequences of that treatment have been.

What therefore can be done to reverse past decline and establish more robust systems for monitoring and managing risks to public health? As we state in response to Question 20, rebuilding local infrastructure and expertise for infectious disease control that is centrally coordinated and supported, and reversing marketisation, outsourcing, and privatisation, are essential. The Winton Centre on risk is an important development as is the Oxford Centre for Evidence-Based Medicine and, for the NHS, NICE guidelines and the UK National Screening Committee. The relevant expertise exists. The difficulties lie more in translating this expertise into routine surveillance and effective decision-making. We suggest broad directions which the Inquiry might consider and develop:

Designing a system of risk detection, monitoring and response

To say the government and NHS should design a system for the detection of future risks seems almost too obvious to need stating. However, although there are many sources of risk information and expertise, it does not appear to us that enough attention has been given to defining the system architecture of risk detection and the processes by which the system overall operates to detect and manage risks. The response to Question 17 makes clear that previous generations of public health physicians and civil servants did design and implement such a system of risk detection which had considerable success, although much of this has now been dismantled. The most important lesson we can learn at this point is that they did

not just hope that risks would be detected but actually designed a system for detection. They began with a complete vision of what was needed, specified the requirements for effective risk detection and designed and built what was needed.

Monitoring of outcomes

Regulators and national bodies should create databases and registers that enable the ongoing monitoring of outcomes for all medical procedures and devices. Mechanisms for spontaneous issue reporting should also be reformed in line with the recommendations of the IMMDS Review (Cumberlege, 2020).

Increasing expertise in evidence and risk assessment

The very first training programme for prospective Ministers was undertaken by the Institute for Government before the election in 2010. More needs to be done to improve training available for Ministers and, in the context of Health, that should enable them to engage more effectively with scientific advice, models and levels of risk and uncertainty (Haddon et al., 2020).

Defining responsibilities for risk detection

Central departments should develop new protocols detailing the roles and responsibilities of different healthcare organisations when responding to emerging health risks, to facilitate greater coordination – as the IMMDS Review recommended with respect to action in the wake of new safety decisions (Cumberlege, 2020).

Adopting the precautionary principle

Government should rethink its management of health risks, and consider adopting a more precautionary approach, especially when the worst-case scenario is particularly severe.

25. What are the common pitfalls in decision-making that lead to failures to respond to emerging health risks and to risks to patient safety? What recommendations do the Group have to address such pitfalls? What is the impact of a lack of a cross-cutting approach to policy-making across Departments, particularly in relation to infected blood?

Some of these problems have been identified in previous answers, notably to Questions 23 and 24. To these we would add:

Managerial challenge

Where those who make decisions in this regard – whether in central and local government, the NHS, regulators or other public bodies – are in managerial positions, and have little professional technical expertise, they will also tend to be unfamiliar with the complex and largely invisible technical infrastructure, and professional knowledge, that are the necessary bases for enabling the system to respond to risks. In the NHS, these include for example:

- planning services to meet assessed needs;

- data and information systems for supporting needs assessment and monitoring of access and outcomes and quality of care, as well as for finance, workforce planning and administration, where data dictionaries and quality standards for data reporting and analysis are meticulously developed by experts and then collected by trained data gatherers to ensure consistency, repeatability and reliability;
- pathological, haematological, microbiological, virological and immunological laboratory services for ensuring that the diagnostic tests required by clinicians who interpret the results for patients are of high quality and conform to reference standards;
- architectural, surveying and estates' expertise for hospital design including space standards.

These technical infrastructures and services were traditionally provided in-house, but over the last 30 years or so have been increasingly outsourced by the NHS to management consultants, private companies and others, leading to fragmentation and loss of institutional expertise, and the shifting of risk – though of course at the end of the day it is the NHS and the public purse which must bear the responsibility and costs.

Managers in those positions therefore need to have the insight, and indeed humility, to appreciate where their knowledge and understanding ends, where authority to take these decisions should best lie within their organisation, and how to ensure the availability of professional technical expertise. This, however, is no easy task in the NHS, as there has been a loss of such expertise, which cannot be replaced by widespread outsourcing.

Culture

Culture, personalities, and/or behaviour commonly play out in group dynamics and within any organisation; increasingly, NHS CEOs talk about 'culture change'. Defensiveness, particularly when fearing punishment, or financial liability, is natural. The Francis Report 2015 into whistleblowing within the NHS addressed cultures and climates of intimidation and discrimination that can follow when concerns about patient safety and quality of care are raised (Francis, 2015). At the same time, care must be taken not to attribute the lack of safeguards or failings in a fragmented system to organisational culture or individual behaviour. For example, the 2013 Francis Report of the public inquiry into Mid Staffs NHS Hospital Foundation Trust drew attention to chronic staff shortages, efficiency savings and performance targets that led to the trust board failing to respond to concerns (Francis, 2013).

26. What role in the formulation and/or implementation of healthcare policy do/should the following have?

- International declarations and conventions regarding healthcare.**
- The recommendations of international organisations such as the World Health Organisation.**

International declarations and conventions regarding healthcare underpin and support health policy, feeding into government priorities and informing policy development and implementation. They are particularly relevant for the work of UKHSA (formerly PHE) in supporting global health security (this involves not just helping the UK address global initiatives and meet commitments, but also influencing existing and future initiatives, in collaboration with officials in DHSC). Notably, as with many other international treaties,

declarations and conventions on healthcare are not typically enforceable, except through a form of ‘peer pressure’ from other signatories. At the very least they should be carefully considered, and clear reasoning offered for following, or not following, them.

Recommendations from international organisations are treated in a similar way: as an input to policy, to be considered by officials, included in briefings, and weighed up by ministers. The WHO is exceptional in the landscape of global health insofar as it has legal power through the International Health Regulations, which set out the rights and obligations of countries around public health events and emergencies, including committing the UK and others to developing and maintaining the capability to detect, assess, and report global health threats. The World Health Assembly also has power to adopt regulations concerning standards for the safety and other aspects of biological, pharmaceutical, and similar products moving in international commerce, but the power has never been exercised. This power clearly extends to the global plasma market.

The WHO has no powers of enforcement or even inspection. Although its first constitutional function is to act as the directing and co-ordinating authority on international health work, in practice it operates more as an advisory body, relying instead on normative power to drive compliance.

27. Among the themes that the Inquiry is considering is that of (i) the ability of government to plan and implement long-term projects on matters related to healthcare, such as the efforts made during the 1970s and 1980s to achieve self-sufficiency in blood products, and (ii) the responsibility of government to advance long-term research and development and other measures to mitigate health risks. In respect of these themes, please comment on the following matters:

- a. **The strengths and weaknesses, historically, of the structures of government in the United Kingdom in respect of such long-term projects or planning (drawing on any examples that you consider to be relevant).**
- b. **How the structures of government could be improved in respect of such long-term projects or planning.**

The UK Government struggles to think, plan and deliver projects in the long-term. This is arguably unsurprising given that political incentives and the consequent incentive structures which have developed within government often run counter to long-term considerations. Pressures on resources can make it difficult to look beyond the immediate priorities. Public opinion and pressure can shift, and thus make it difficult for government to sustain its commitment to a long-term project. The degree of commitment in government can also wane as initial targets are met and political attention shifts elsewhere. In addition, changes of personnel, whether Ministers or NHS leaders, can lead to new priorities. The time a Minister spends in one post is, on average, about fifteen months and that does not encourage them to take a long-term perspective. Beyond these political pressures, government exhibits a range of more practical weaknesses identified in a recent report from the Institute for Government. These include devoting too little time to assessing early options, failing to understand and

communicate fully the project risks, and failing to have contingency plans in place to address problems as they arise. Government, in addition, are too often slow to learn the lessons from past projects or, indeed, to fully evaluate how past projects have fared (Atkins et al., 2017).

Until devolution, the structures of government in Great Britain in this regard were essentially as they are now in England, with the addition of NHS England: the Department of Health (and Social Care), the Treasury, and local government. Their strengths historically lay in the remit imposed upon them by Parliament to provide the NHS as a national, universal, equitable public service available to all on the basis of need (including the PHLS and, later, the CDSC), and in the systematic planning of health services and the development and provision over many years of the complex technical infrastructure which this required. Their weaknesses lay in the Treasury's failure to provide sufficient funding (for example, in delivering health centres, and the 1960s New Hospitals Plan), and in the gradual undermining of these strengths by eroding local and central government capacity by increasing incrementally the outsourcing of health and care services (including the centralisation and outsourcing of infectious disease control, not least as seen in the COVID-19 pandemic). The failure of Parliament at the start of the NHS to provide a statutory basis for a national blood service, as originally presented to the Cabinet, may also be thought of as a structural weakness.

Improving the capacity of the structures to deliver long-term projects and planning requires legislation in England to reinstate the founding principles of the NHS, reinstate regional and local area planning bodies, restore communicable disease control systems locally, and rebuild in-house technical expertise and infrastructure. The public still overwhelmingly supports the founding principles, despite satisfaction with the NHS being at its lowest since 1997 (Wellings et al., 2022). However, this public support does not currently translate into the political mainstream, and the recent further major reorganisation under the Health and Care Act 2022 takes health services in England in the opposite direction.

There are other issues which Government could address. The continual structural reorganisations cause confusion, and each time managers need to adapt to very different working environments. Each reorganisation undermines the ability of those working in the system to understand how it functions and how they should best collaborate with each other. Government could also accept that 'top-down' projects are more likely to fail than those built 'bottom-up' (Maughan, 2010). Many have also noted how the culture of the civil service and government is much more inclined towards policy rather than delivery, so that delivery/project management skills are undervalued and therefore underdeveloped.

Finally, the recent report from the House of Lords Select Committee on COVID-19 recommended that finance ministries should move towards more long-term funding settlements with more flexible pots of funding being set aside to respond rapidly to issues as they emerge (House of Lords Select Committee on COVID-19, 2022).

Devolution within the United Kingdom

28. Please outline how administrative and political devolution of responsibility for healthcare within the United Kingdom has evolved over time.

This section will outline, in broad strokes, the history of devolution in healthcare within the United Kingdom, from the 1890s to the present day. Throughout, we aim to distinguish between:

- political devolution: the transfer of responsibility for healthcare to locally-elected politicians
- administrative devolution: the separate administration of healthcare, public health regimes and policy-making within the constituent parts of the United Kingdom, overseen by the same elected government in Westminster (Appendix C)
- delegation: centralised policy-making but with responsibility for delivery held locally

While political devolution is a relatively recent development in much of the UK, administrative devolution and/or delegation have been the norm since the end of the nineteenth century. This history underpins many of the differences in arrangements across the UK that can be seen today.

From the 1890s, although all four parts of the UK were governed by a single UK Government at Westminster, healthcare and public health were administered separately by three Local Government Boards: one for England and Wales, one for Scotland, and one for Ireland (then wholly part of the UK). In 1919 this began to change, with healthcare being brought more closely within the sphere of central government. England and Wales came under the control and direction of the Secretary of State for Health, with Scottish healthcare brought within the remit of the Secretary of State for Scotland, supported by the then Scottish Office, (Scotland thus retained its administrative devolution, separate from England and Wales, but with more central oversight). In 1921, responsibility for healthcare in Northern Ireland was devolved to the new Northern Ireland Parliament and Government, supported by a newly-created Northern Ireland Civil Service.

For the next few decades, arrangements remained broadly the same, with political devolution in Northern Ireland, administrative devolution in Scotland and no devolution in Wales. This was the position when the 'national' health service was created in 1948. Rather than being a single health service, it was in fact three separate health services - one for England and Wales, one for Scotland and one for Northern Ireland - all founded on similar principles but set up under separate legislation. Within each of the health services, there was a considerable amount of decentralisation: to hospital boards, teaching hospitals, local authorities running community and ambulance services, and thousands of general practices.

In 1969, responsibility for healthcare in Wales was transferred to the Secretary of State for Wales, supported by the then Welsh Office, mirroring the arrangements that had applied in Scotland since 1919 - although legislation, and therefore core policy, continued to be made on an 'England and Wales' basis. From 1969, there was therefore political devolution in Northern Ireland, administrative devolution in Scotland and delegation of executive responsibilities in Wales.

In 1972, when political devolution in Northern Ireland collapsed and Direct Rule was imposed from Westminster, healthcare and public health became the responsibility of the Secretary of State for Northern Ireland, supported by the Northern Ireland Department of Health, staffed by the separate Northern Ireland Civil Service (rather than the newly-created Northern Ireland Office).

The following year, a major reorganisation of health services throughout the UK reinforced their decentralisation. In England and Wales, 14 Regional, 90 Area and 205 District Health Authorities were established in a three-tier structure, with 'Family Practitioner Committees' managing primary care. The National Blood Transfusion Service for England and Wales was reorganised to work directly to the new Regional Health Authorities. In Scotland, 15 Health Boards were created, with new local health councils. And in Northern Ireland, four Health and Social Services Boards were charged with delivering integrated health and social care there.

For the next 25 years, the three health services remained administratively separate, albeit overseen by the same government. The Secretaries of State for Scotland, Wales and Northern Ireland were not answerable to the Secretary of State for Health for their decisions in relation to health matters and, while there were regular cross-departmental cabinet committees that covered health matters on which all four departments were represented, there remained a considerable degree of autonomy within both Scotland and Northern Ireland. Major policy reforms - such as the 1990 reforms to split the NHS into 'purchasers' and 'providers' - applied, with some variations, across the whole of the UK. Other reforms, such as those that de-layered the three-tier structure in England and Wales, applied only there.

In 1999, following referendums in all three places, new devolved institutions were established in Scotland, Wales and Northern Ireland. In Scotland and Northern Ireland, the devolution framework included the transfer of primary legislative powers. In Wales, devolution was, initially only of executive functions, with legislative powers following, on a rolling basis, from 2006 onwards. The Welsh devolution model was eventually amended in 2017 to bring its structure into line with the models applying in Scotland and Northern Ireland.

Healthcare is now politically devolved in all three countries in light of these changes, with locally-elected politicians responsible for policy-making and legislating on the overwhelming majority of health issues. Matters such as medicines and medical supplies and the standards for and testing of biological substances are not devolved in Scotland and Wales. In Northern Ireland, medicines and medical supplies are fully devolved, but legislation on matters relating to standards for, and testing of, biological substances requires the consent of the Secretary of State for Northern Ireland.

There has also been a growing push for political devolution to the English regions. Public health was carved out of the NHS and some services were transferred to local authorities in the Health and Social Care Act (2012). Some healthcare responsibilities have also been devolved to the Greater Manchester Combined Authority (which now controls the region's £6bn health and social care budget) and Cornwall as part of their 'devolution deals' with the UK Government (Nicholson and Shuttleworth, 2020). The option of devolving further healthcare functions to combined local authorities through negotiation with the UK Government is legislated for in the Cities and Local Government Devolution Act (2016).

29. What have been/are the advantages and disadvantages of devolved responsibilities for healthcare in terms of the response to emerging health risks/issues of patient safety?

Advantages of devolved responsibilities for healthcare

Tailored decision-making

Pre-devolution and under Direct Rule, it was common for a policy developed for England to be replicated across the UK, albeit sometimes with minor adaptations. With political devolution, locally-elected politicians are able to take decisions independently of Westminster in the interests of local populations. These decisions can also be based on more local measures of public health, which show up issues (potentially highlighting emerging risks) and needs that might previously have been hidden in UK-wide health indicators (for example, the challenges of managing healthcare in large, remote, sparsely-populated areas; or of delivering effective healthcare on islands with limited connectivity with the rest of the country; or of managing disease control over an open land border).

More focus on health issues at a political level

Having dedicated Ministers in each administration heading up their respective health departments – rather than the three territorial Secretaries of State or their junior ministers, responsible for the full range of social and economic policy areas (and, in the case of Northern Ireland, significant constitutional, political and security responsibilities) on top of their health brief – should mean there is significantly more focus on health issues at a political level than there was in the past.

Increased local accountability

Similarly, political devolution should lead to increased local accountability, with opposition and local media able to scrutinise the actions of and apply pressure to politicians more effectively. Effective opposition and media scrutiny should also make it easier to hear and respond to the patient voice, which is an important way of picking up on matters of patient safety.

Agile decision-making

Smaller, more locally-attuned organisations should also be able to make faster decisions and be more responsive to evolving local needs and concerns – although this may not always happen in practice. One example where this did happen successfully was the Scottish Ministers' decision to ban smoking in public places in 2005, a year ahead of the equivalent decision in England.

Scope for learning

Having each country pursue its own policies and approaches to healthcare should, in theory, act as a useful space for experimentation, with each able to learn from the successes and failures of the others and adapt its own approach accordingly. This sort of comparison is difficult, however, in part due to each country collecting and publishing data in different ways (Atkins and Dalton, 2021). Governments can also be reluctant to adopt alternative approaches at risk of granting political victories to other governments led by parties they see themselves as 'in opposition' to.

Disadvantages of devolved responsibilities for healthcare

Lack of funding

The current funding approach uses the Barnett formula although this was created before devolution. This allocates roughly equivalent per capita amounts to the devolved nations as is spent on 'England only' activity. This has significant limitations. The per capita approach fails to account for socio-economic, demographic or geographic variations across the UK. What constitutes 'England only' expenditure is pivotal but difficult to define and fundamentally affects the freedom of choice available to devolved administrations. And, whilst per capita funding works to an extent for service delivery functions (where fewer people are generally cheaper to serve) it does not work as well for things like policymaking and data analysis when it is no easier to make policy for a country of 5 million as it is for a country of 55 million.

Difficulties with coordination

Increased devolution has made coordination across the UK more challenging. With different political parties in power in each of the UK's four administrations, it is inevitable that their health policies will move in different directions. There may also be less willingness to share information to avoid giving advantage to political opponents. Regardless of political leanings, though, each administration is responsible for its own population and will have its own unique, corresponding set of interests and concerns, and finding ways of managing these differences is far from straightforward – even on matters such as disease control or public safety where cooperation is vital. More practically, cooperation is also complicated by the differences in the organisation of public health services in each nation, with this structural asymmetry making it harder to know who should be talking to whom (more on this below).

Variation in standards

Differences in approach can lead to variations in standards and outcomes. Overall health outcomes in the four nations, such as treatable mortality (deaths that can be avoided by healthcare interventions) and life expectancy, have changed in similar ways since devolution despite policy differences (Atkins and Dalton, 2021). But at times one country has seen marked improvements while others have lagged, raising questions around fairness for citizens subject to these differences – for example, NHS waiting times in England fell particularly quickly for a period in the early 2000s whereas there was slower (or no) progress in the other UK administrations. On the other hand, as noted above, this divergence should also enable comparison and improvement across the four nations.

30. What relationships and mechanisms help to ensure that patient safety is not negatively affected by parallel decision-making arising from devolved responsibilities for healthcare, and how have these varied over time?

Mitigating any potential negative effects of parallel decision making for patient safety requires effective structures for coordination and regular, productive interactions between individuals at various levels of each of the four health systems in what is an increasingly complex landscape. Here we consider the evolution and importance of:

- relations between the four governments of the UK at a political level

- interactions between the health departments of each of the four nations
- the role played by professional bodies, regulators, outside experts, and others working in health delivery and the public health bodies.

Intergovernmental political relations

Relations at the political level between the four governments of the UK are fundamental to facilitating effective cooperation on healthcare issues. Since 1999, official interactions between the governments have theoretically taken place through the Joint Ministerial Committee (JMC), which refers to a set of committees made up of ministers from the UK and devolved governments intended, among other things, to facilitate discussion and coordination of devolved matters such as healthcare and their respective treatment in different parts of the UK.

In practice, however, the JMC and its committees had little impact on intergovernmental communications with the JMC health committee having met only a handful of times in its first two years and not at all since 2002. The JMC was replaced in January 2022 by a new set of arrangements in line with the recommendations of the Review of Intergovernmental Relations. These new arrangements consist of Council of the Prime Minister and the Heads of Devolved Governments, an Interministerial Standing Committee meeting every two months and inter ministerial groups addressing specific areas of shared interest. Although some have welcomed these new arrangements it remains to be seen whether they will improve relations and right the longstanding power imbalance. It also remains to be seen whether health, which has traditionally been low on the priority list for intergovernmental relations, will continue to enjoy the attention it has received during the pandemic.

The extent to which these and other mechanisms can be used effectively, however, depends on the quality of the relations between the four governments. Unfortunately, these have worsened significantly over the last 15 years. This deterioration is not an inevitable consequence of devolution: in 1999, in the wake of establishing devolved institutions in each country, relations were largely cordial between the different governments, in large part because the administrations of England, Scotland and Wales were all led by the same political party (Labour, albeit in coalition with the Liberal Democrats in Edinburgh) and there was, separately, a widespread political commitment to supporting and sustaining the new devolved institutions in Northern Ireland in the wake of the Good Friday Agreement.

This changed with subsequent changes of Government and reorganisations within governments, both of which disrupted the established interpersonal relationships between ministers. Since 2007, there has been no commonality of political ideology across the administrations and parties have found themselves in government in one place but in opposition elsewhere. Tensions were further heightened by the 2014 referendum on Scottish independence and the 2016 Brexit referendum.

The sense of mutual respect and trust may have been eroded by fifteen years of political and interpersonal tensions, but the COVID-19 pandemic has illustrated, at least in the initial response, that it remains possible for the four UK administrations to work together to tackle a shared threat. Although the JMC was not used (no JMC (Health) meetings have taken place since 2002), representatives of the devolved administrations were invited to participate in meetings of the Civil Contingencies Committee (CCC) and related groups, facilitating the joint publication of a UK-wide action plan and broad coordination of policies and messaging around new restrictions in the early phase of the crisis (Select Committee on the Constitution, 2022; Paun et al., 2020). These arrangements were subsequently replaced by two Cabinet

committees that the devolved administrations were not invited to, however, and the quality and quantity of engagement has been variable since then. The four governments have increasingly taken their own approaches and politicised even minor differences in these (Kenny and Sheldon, 2022). The results have often been confusing for the public, re-emphasising, rather than avoiding, the risks of parallel decision making.

Interactions between health departments

As well as the high level political interactions, there is also a varying degree of coordination between the health departments of the four nations to help mitigate any negative effects of parallel decision-making. In addition to formal ministerial level communication as mentioned above, civil servants working on related policy areas across the UK often interact regularly, on a more informal basis, regardless. It is at this level where the most productive inter-governmental information sharing and collaboration can take place at the necessary level of detail to identify emerging health risks and threats to patient safety, and devise workable solutions. The extent to which these interactions have taken place in practice has varied with fluctuations in the relations between political leaders: with a spirit of collaboration at the political level, collaboration at official level flows naturally (with the inverse also true).

Good relations are also difficult to maintain in light of the power imbalance. As with the higher-level political meetings discussed above, representatives from the UK Government tend to take the lead in all discussions. This imbalance is compounded by the uneven distribution of resources: it is not - and was not in the past - unusual to find a large team of staff working on a particular issue for England, whereas their counterparts in Scotland, Wales and Northern Ireland might be a single junior official, working on this alongside other responsibilities. This puts officials from the devolved administrations at a marked disadvantage. A system where there was a genuinely shared analytical resource that all four administrations could draw on to inform their policy development and understanding of emerging health risks would provide a better basis for collaboration.

Other fora for coordination

Beyond the level of politicians and policy officials, there is a complex landscape of interactions between individuals and groups working across the health system. These include:

- Chief Medical Officers (CMOs): each of the four administrations has its own, and they share information and discuss concerns, occasionally issuing joint statements or guidance, with the degree of interaction depending on the political climate, their relationships with each other, and the significance of any cross-cutting issues (such as COVID-19).
- Expert groups: some scientific advisory groups made up of external experts are convened at a UK level, providing advice to the CMOs, health authorities, and the four governments directly (Paun et al., 2020). The groups and their membership change over time to reflect current concerns and new developments.
- Regulators: UK-wide regulators such as the Medicines and Healthcare products Regulatory Agency (MHRA) and the Human Fertilisation and Embryology Authority (HFEA) work to ensure standards in their respective areas are maintained across the four nations, cooperating closely with relevant agencies and bodies in each jurisdiction. Not all regulators, however, operate on a UK-wide basis and levels of collaboration between these are variable.

- UK Health Security Agency (UKHSA): created in April 2021, UKHSA now leads on planning for, preventing and responding to external health threats on behalf of the whole of the UK, including joining up activity between and informing relevant devolved bodies.
- Royal Colleges may operate on a UK-wide level or within individual countries within the United Kingdom. Royal Colleges are increasingly likely to have direct relationships with the devolved administrations' health departments and, while their responsibilities are similar, their approach may vary in different parts of the United Kingdom. The Colleges are based on professional specialisms rather than being integrated 'medical' or 'nursing' bodies, and therefore cooperation to focus on patient safety needs to involve all the relevant specialisms.
- Health boards and hospitals: ensuring appropriate information flows to and from managers is important in dealing with matters of patient safety. As well as interactions between organisations, managers can also report issues up to relevant national bodies and regulators, who can share information between themselves in turn. There are also inter-service collaborative bodies, such as the UK Blood Services' Forum, founded in 1999 to bring together the UK's four blood services.
- Public health agencies: there are national bodies in Scotland, Wales and Northern Ireland but no longer any national entity in England, where responsibility has been delegated to local authorities. The different infrastructures, as well as the variations in powers and priorities from one English local authority to another, creates an asymmetry that makes ensuring adequate coordination between the four nations more difficult. But it is still vital.

Of course the problems of institutional asymmetry extend beyond public health.

Building cooperation and trust

Effective co-operation to mitigate risks to patient safety relies on the right people being connected on a regular basis in relationships of trust and mutual respect and working in an environment that allows for a frank, open exchange of views. This is not easy, especially in a multi-disciplinary world that operates across multiple jurisdictions, with the increasing structural asymmetry that has developed post-devolution adding further complexity. It requires structures which are designed to take account of the challenges rather than to mirror the structures of one part of the UK.

Building relationships of trust has always been affected by the power imbalance between the component parts of the UK and the unequal distribution of human resources, too. While it is unrealistic to think that the UK Government could, in future, effectively and convincingly distinguish between its 'UK' and 'English' roles, greater willingness to cede control and participate as an equal partner in inter-governmental liaison might help improve collaboration and build trust more effectively than in the recent past.

Maintaining constructive relationships has become even more challenging since devolution as the administrations have diverged in political ideology and as we have seen increasing 'competitiveness' between the parties in power. Tension at this level, unfortunately, often filters down, affecting engagement between actors across the health system. No amount of effective structures can compensate for a lack of political willingness to collaborate – or allow officials to do so – in the wider public interest. Matters of public health and patient safety are, however, perhaps areas where party political rivalry could and should be put aside in the interests of the wider public interest.

The role of patients and patient representative organisations in healthcare policy

- 31. Please explain the current role played by patients and patient representative organisations in informing and shaping health policy, including in response to emerging health risks, in the United Kingdom. In particular:**
- a. Please explain the principles underpinning the role played by patients and patient representative organisations.
 - b. Please comment on any shortcomings or recommendations the Group identify in this area.
- 32. Please comment on how the practice and principles of patient involvement have developed, identifying any significant changes that have taken place in the time period of relevance to this Inquiry.**

Patients and families may play an active role in their own care, they may provide a contribution to the organisation of care or, as citizens, may offer views or be actively engaged in the improvement of services or in wider policy initiatives. In this section, we first outline and differentiate the principal ways in which patients and the public may be involved in patient safety, either as individuals or collectively. We then describe some of the barriers to patient and public involvement and, in a final section, propose some principles and directions to increase engagement. Informal carers of patients (i.e. friends or volunteers) may also be engaged in these activities. For simplicity we refer only to 'patients and families' and include within that term anyone with a close caring relationship to a patient.

Degrees and levels of patient and family engagement

Patients and their carers and families can be involved in the delivery of healthcare services in many different ways (Table 1). To distinguish these various roles and activities, we have adapted a framework from Carman et al. (2013) with examples of how involvement in healthcare safety might differ for patients and the public, dependent on the type of engagement and the level of the healthcare system in question. The table shows that patient and public engagement in the NHS varies according to both degree and level of engagement. Patients and families may simply be informed about care, they may be consulted and asked their views, or engaged more actively in discussion about their values, preferences and suggestions. Potentially they can also be partners in their own care or the design or improvement of services and policies. Whilst most of the efforts to engage patients and families can be viewed as 'instrumental' to improving the safety of care, public involvement in healthcare governance should be additionally understood as a mechanism for achieving greater public accountability, responsiveness and democratic public engagement (Florin and Dixon, 2004; Martin, 2008).

Table 1. Degrees and levels of patient and family engagement in healthcare

Continuum of engagement			
Levels of engagement	Consultation	Involvement	Partnership and Shared Leadership
Direct care	Patients receive information about a diagnosis	Patients are asked about their preferences in the treatment plan	Treatment decisions are shared on the basis of patient preferences, clinical information and clinical judgement
Improvement and innovation	NHS Organisation conducts focus groups and surveys to assess patient opinion	Patients are interviewed about their priorities during design of a new service	Patients participate as full members of committees and as partners in the design of services
Governance and patient safety	Organisation surveys patients about their experiences	Trust involves patients as advisers or members of an advisory council	Patients play an active role in Trust safety investigations and or national policy committees

Note. Adapted from A Multidimensional Framework For Patient And Family Engagement In Health And Health Care, Carman et al. (2013)

Patient and family involvement in their own direct care

Patients and families play a direct role in ensuring and enhancing the safety of their own care, whether that care is provided in the home, community or hospital. The role of patients and families in patient safety is important in its own right and arguably also a necessary foundation for involving patients in the design and improvement of healthcare as equal participants in improvement teams. Patients and families can provide information about problems in care delivery and safety incidents by ‘speaking up’ about care failures, which can sometimes have the effect of ameliorating the harm event, or preventing it from happening (Vincent and Coulter, 2002). However, patients and families often find it difficult to speak up about safety issues, especially when they feel they are challenging healthcare professionals. Campaigns to persuade patients to ask professionals about hand washing for instance have had mixed results (Alzyood et al., 2018).

There are a number of barriers for patients which may make them reluctant or unable to support the safety of their care or speak up when something has gone wrong. Some staff may not be receptive to patients’ views and feedback, the organisation may not respond to patients and families raising concerns, and members of the public may not trust in the ability of the NHS to learn from safety failures. Raising concerns is even more difficult for people from disadvantaged groups, who may not have the time or resources or experience of dealing with professionals that is needed to make one’s voice heard on safety issues. In addition, people who are very dependent on healthcare may be reluctant to raise concerns for fear that their actions might adversely affect their future treatment.

Patient and public involvement in the improvement and innovation of services.

Patients and the public have only been involved in the design and improvement of health services to a limited extent. Healthcare service improvement is often undertaken by individual trusts or services, and the involvement of patients at local level varies considerably (Sutton et al., 2015). Methods for the involvement of patients and families in health service design or improvement include focus groups, surveys, or working with individual patient representatives. A number of frameworks have been developed to guide and support the process of co-production with, and the involvement of, patients and families and are used in a variety of settings (Fylan et al., 2021; Point of Care Foundation, 2022). However, these tools have not been applied consistently or systematically within health service design or improvement (Fusco et al., 2020).

There are, however, some innovative and encouraging examples of co-production with patients and families. One recent example is the development of new national guidance on involving and engaging patients and families in the investigation of safety issues and adverse events in which a patient has been harmed. The NHS England and Improvement Team have, over the past two years, been working collaboratively with the Healthcare Safety Investigation Branch, and the Learn Together research programme (Learn Together, 2022) to integrate evidence into the new policy that supports NHS Trusts to engage and involve patients and families in incident investigations and other learning responses (National Health Service England, 2022). The new guidance will replace the current Being Open policy, and will sit alongside the wider policy – the Patient Safety Incident Response Framework, released in August 2022. The guidance is founded on a range of evidence from patients and families, staff and investigators, about how to undertake involvement in ways that meet the needs of these stakeholder groups, and reduce any ‘compounded harm’ that can arise from poorly undertaken incident investigations (Wailling et al., 2022). The co-creation of the new guidance through this collaborative approach is regarded as a first for patient safety policy, and represents an innovative development in embracing user perspectives in patient safety policy generation.

Patient and family involvement in governance and patient safety

Past public and other inquiries into major service failures in the NHS have repeatedly demonstrated that public involvement in issues of patient safety has generally left much to be desired (Francis, 2013; Sibley, 2022). Concerns raised by individual patients and families, and by groups or associations of patients and carers, have often been dismissed, marginalised, or blocked. In the Independent Medicines and Medical Devices Safety Review, Baroness Cumberlege noted:

‘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 defensive. It does not adequately recognise that patients are its *raison d’être*. It has failed to listen to their concerns.’ (Cumberlege, 2020).

Regulatory organisations have frequently been slow to understand the extent and degree of failure and slow to intervene when patients have been at risk. It is not unusual for inquiries to find a trail of concerns raised by patient and public voices over many years until some egregious event, media attention and/or changes in leadership eventually and belatedly trigger the necessary institutional response. Public voices – even of individuals or organised groups with considerable social capital, professional expertise, financial resources and motivation – have consistently struggled to be heard, to be respected and listened to, and

to have an impact (Francis, 2013; McQueen et al., 2022). Since 2015, patient and family involvement in investigations of patient safety incidents has been encouraged within serious incident investigations, with a statutory obligation to undertake the Duty of Candour when an incident reaches a certain threshold. However, evidence suggests that involvement is not routine practice (Care Quality Commission, 2016; Kok et al., 2018).

In response to these concerns, there has been a succession of reforms to patient and public involvement structures and mechanisms in the NHS in England, intended to strengthen and support involvement, most recently NHS England's announcement of the Patient Safety Incident Response Framework in August 2022. Previous inquiry reports and government responses have led to the introduction of a number of new processes to embed patient and public involvement more firmly in the monitoring, design and organisations of the NHS. Examples include the successive arrangements of Community Health Councils, Patient and Public Involvement Forums, Local Involvement Networks, and most recently national and local Healthwatch (Zoccatelli et al., 2020). All these organisations were designed to institutionalise patient and public involvement in the healthcare system, usually with some dedicated, though usually very modest, resources. Some were also given some very limited statutory powers, such as the power to 'enter and view' healthcare premises given to Healthwatch.

Many of these initiatives were sensibly intended to improve public involvement – extending its scope and influence. But it is not clear that these successive changes have yet made a significant material difference to the way that public involvement in the governance of patient safety actually works in practice, or that they have produced systems of care in which the public voice has real impact on the safety of care.

The challenges of patient and public involvement

There is considerable potential for patients and families to play an important role in the safety of their care directly, and indirectly through service and policy design, and wider healthcare governance. However, there are a number of important barriers which prevent the patient voice being heard clearly, particularly when sensitive topics such as hazards, risks and potential harm are at issue. Some of the main barriers are:

- The threshold for raising concerns is often dauntingly high for many reasons— we do know that many people who suffer an adverse healthcare experience do not report it or take any action.
- Many of those who suffer adverse healthcare experiences are from disadvantaged or marginalised groups in society who find it harder to raise concerns than the general population.
- Individuals and families may be quite unaware that other people have had similar problems or concerns, and it is often only when a problem secures media coverage that other people come forward to share their experiences and the scale and scope of a patient safety problem may be understood.
- The profound asymmetries of power and information which exist between patients and the public on the one hand and healthcare providers and professionals on the other, in which it is very difficult for lay people to question and interrogate effectively complex issues of clinical performance and judgement.
- The strong formal hierarchies of the healthcare professions and healthcare organisations, make it difficult for anyone, especially patients, to challenge unsafe practice or behaviours.

Proposals for effective patient and public involvement

Improving patient and public involvement in patient safety demands, first and foremost, that patients and the public are placed centrally in the policy discourse, and in the systems and processes for dealing with quality and safety of care. Many NHS organisations now have well-developed patient strategy documents, usually expressing patient engagement as a core value and guiding principle of the organisation, whether an individual Trust or national agency. However, the aims of engagement are not always clear, nor how these aims might be achieved in practice.

We have therefore set out some proposals to guide the actual practice of patient and public involvement.

- Organisations must not rely on either staff or patients and members of the public reporting concerns about safety. Reporting is important, and useful, and should be encouraged and supported but it is not sufficient.
- Organisations have a responsibility to proactively seek out, identify and deal with patient safety issues and to assure themselves and their communities that they are doing so.
- NHS organisations of all kinds need to develop capacity to actively seek out and explore the patient experience in depth. Talking to small numbers of patients in depth about their experience, concerns and both positive and negative experiences of care is likely to yield more than any number of superficial surveys.
- Patients and families need to be involved as active partners in programmes of improvement and innovation. The degree and nature of involvement will vary according to the project, but should always be considered. Specific co-production frameworks are available to support the engagement of patient and family experience of care and services, within the context of service design or improvement.
- Whilst we have argued for seeking out the perspectives and experiences of patients, families and the public, we also caution against policy makers and organisations undertaking 'knee jerk' policy change based solely on the experiences of patients. Policy (both national and local) should be based on a wider analysis of the issues and an ongoing enquiry of the effects and wider impacts of the policy change.
- The duty of candour is just a starting point and a basic requirement to be open and transparent about safety issues. Patients who have suffered harm and their families will need, in serious cases, long-term support to recover both mentally and physically and to retain trust in the healthcare system.

We should be very hesitant about reaching for further structural reforms to improve public involvement in matters of patient safety. We already have methods available to enhance patient and public engagement within NHS organisations. The primary need is to make existing systems work properly rather than reform them, which requires action within NHS organisations rather than new policies. Proportionate and effective patient and public engagement is the foundation of any healthcare system that aspires to be truly patient-centred.

The communication of risk in the provision of healthcare

33. Please explain the current principles underlying the way in which the risks of receiving certain medical treatments or products and/or information about emerging health risks should be explained to:

- a. particular groups of patients (especially those who might be at particular or enhanced risk); and
- b. the public as a whole.

In answering this question please consider whether there are ever circumstances (and if so what) in which reassurance should take priority over the provision of clear and candid information about that which is known, that which is thought to be probable and/or that which is believed to be possible.

There is now widespread acceptance that patients should be fully informed of risks and that this is both ethical and generally in the best interests of patients and families. However, this welcome development has to be tempered by an understanding of the complexities of risk estimation, risk communication and the realities of clinical practice. For instance, the challenges and information available for a patient facing urgent cardiac surgery are very different from those for a patient considering trying a new medication for osteoarthritis. We should also note that the quantity of research on risk estimation, understanding and communication and other issues relating to this question is absolutely huge (McMaken and Lundgren, 2018; Balog-Way et al., 2020). In this section we endeavour to outline some of the principal issues but this can only be the briefest summary of a major field of research and inquiry.

Informing patients

Prior to about 1960, it was unusual for a patient to be told that they had a cancer that would cause them to die. At that time, clinicians felt this information would be too distressing for the patient. In contrast, it is now widely accepted that patients should be fully informed about risks, whether it is a specific diagnosis or the hazards that might accompany a blood transfusion or taking a drug. Guidance from the General Medical Council and other professional organisations is clear and explicit: a doctor has to take reasonable care to ensure that the patient is able to assess the balance of benefits and risks of treatment options or indeed interventions of any kind.

Estimation of risk

Reasonably accurate risk estimates can be provided for some routine and standardised treatments. However, in most areas of medicine, it can be difficult to estimate precise risks and probabilities can vary considerably. Policymakers, clinicians and patients therefore all have to make decisions on the basis of risk estimates that are likely inaccurate in unknown ways. As risks can vary from study to study, patients might be given different figures from

different clinicians or, at best, a fairly wide range of possibilities. Considerable efforts have been made to improve risk estimation in surgery and other fields but, while accuracy is improving, doctors can still only give broad estimations of risk in most cases even for relatively straightforward clinical scenarios (Bilimoria et al., 2013).

In addition, both patients and clinicians have to contend with a huge amount of information on risks which may be vanishingly small. For example, amoxicillin is an antibiotic in everyday use. In the British National Formulary (BNF), 17 potential side effects are listed for the penicillin class in general and 8 more for amoxicillin specifically. This includes 'skin reactions' (common), dizziness and hepatic disorders (rare or very rare). However, none is expressed as serious, life threatening, mild, transient, or irreversible. To rehearse all these risks each time would be impossible in practice, reduce the time for the discussion of other clinical matters and cause unnecessary anxiety for some patients.

Communication of risk

Research into risk and its communication has firmly established that most people have considerable difficulty in understanding risks, particularly when expressed numerically, and also find it difficult to apply risk estimates to their own situation. A person's willingness to accept a risk is strongly dependent on how that risk is presented (Altay and Mercier, 2020). For example, informing patients that a treatment has an 80% chance of success elicits a different response than if told it has a 20% chance of failure. In addition, both clinicians and patients will make different decisions based on whether they are given the relative or absolute risk. If a treatment increases survival from 5% to 6%, the relative risk improvement is 1% out of 5%, or 20%, but the absolute risk improvement is only 1%. Proponents of a new drug for instance may champion the 20% (relative) improvement in outcome, but the absolute figure of 1% improvement is the truer reflection of the value of the drug to the patient.

There have been attempts to make risk statistics more intuitive. One approach, derived from absolute risk reduction, is to provide the Number Needed to Treat (NNT), that is the number of patients who need to be treated for one to benefit. For example, patients without prior heart disease who are offered statins to prevent its development in the future can be informed that, over 5 years, 100 patients need to be treated for one to benefit. There are also many graphical ways of presenting risk, each with their own strengths and limitations. The use of patient decision aids, such as booklets, videos and web-based information, leads to modestly improved decision-making in the sense that patients feel more confident that they have made the correct decision for their particular circumstances (Spiegelhalter, 2017; Stacey et al, 2017).

Communication of risk is of course only one element of the clinical consultation and is of no value unless patients can use the information to make the best decision for their particular circumstances. Recent research has explored the whole process of shared decision-making and set out both the aspirations and requirements for fully informed decisions (Elwyn et al, 2012). For instance, an innovative approach for high-risk surgery helps both patient and surgeon explore 'best case' and 'worst case' scenarios, which provide a much more truthful reflection of the actual impact on a person's life than simply thinking about numerical probabilities (Taylor et al., 2017).

Patient values and preferences

Patients vary considerably in their preference for knowing risks, often for very good reasons. If, for instance, a person has a serious condition for which there are well-defined treatment indications and few other options, they may very reasonably not wish to know about the risks

attached, but simply place their trust in the doctors and nurses to do what is best. In some other diseases however, such as prostate cancer, there are a variety of treatment options with different benefits and adverse effects. Assessing the risks and benefits of each option and integrating these with patient values and preferences is absolutely critical if the patients are going to not only choose the best option for them but live with the outcome of their choice (Say and Thomson, 2003).

There are also occasions where it may not be in the patient's best interest to know all conceivable risks, particularly if the potential adverse outcomes are both distant and uncertain. Information about risk can end up as another burden for a patient, particularly when the information cannot lead to any meaningful action or choices. The purpose of disclosure should never be to 'cover the doctor' in the event of an adverse outcome, but always to compassionately and sensitively help the patient to reach an informed, realistic decision.

Clinical realities

Most doctors and other health professionals would accept that ideally patients should be sensitively informed of risks to the degree that the patient wants. In reality however, this may simply not be possible. Doctors have to balance time for risk communication with the competing demands of time for explanation, questions, or wider patient concerns. For a major surgical operation, a patient can reasonably expect to have a substantial discussion with the surgeon who will perform that operation and an opportunity to reflect and discuss with family before finally coming to a decision. For a routine procedure, informed consent and discussion of risks may be delegated to an overworked junior doctor with multiple competing demands on their time. A full discussion of benefits and risks, even if desired by the patient, will simply not be achievable without compromising other aspects of care.

Time is often even more limited in general practice where a doctor will have only 10-12 minutes with each patient, each of whom may want to discuss two or three different problems. Decisions are often made in real time and applied with the pragmatism necessary to function in the NHS. Patients can be encouraged to seek further information on risks and decisions outside the consultation, via the NHS website and other sources. Some patients, families and carers will be willing and able to do this, others will not.

Informing the public

Risk communication in public health has been the subject of extensive research and much has been learned about how risk can be communicated effectively. For instance, there is strong evidence that mass media campaigns conducted in the context of comprehensive tobacco control programmes can promote quitting and reduce adult smoking prevalence (Durkin et al., 2012). Interventions that can be effective in reducing the initiation of smoking include increasing the price of tobacco products, mass media anti-smoking advertising, smoke-free policies, smoking curricula in schools, restrictions on marketing opportunities for the tobacco industry as well as social norms that lead to restrictions on adolescents' ability to purchase cigarettes (Pierce et al., 2012). The communication of environmental risks has also been extensively researched. A number of environmental disasters during the second half of the last century (e.g. Three Mile Island, Bhopal, Chernobyl) produced public concern which government and regulators struggled to address. Citizens increasingly wish to know if they run a risk from proximity to a power station, from overhead electric cables, from fuel pollutants and so on. In practice, many of these environmental risks are very small but the public still expects that such information will be made available to those who seek it (Balog-Way et al., 2020).

Risk communication is also critical in the control of pandemics. Organisations responsible for disease control have gained considerable understanding and experience of risk communication strategies. For instance, the European Centre for Disease Prevention and Control (ECDC) initiated the development of a training curriculum and programme to address the need for both conceptual and practical capacity, building in risk communication as an integral component of disease prevention and control (Dickmann et al., 2016). The World Health Organisation has manuals, training modules and other forms of guidance related to emergency and risk communication which are based on lessons drawn from major environmental disasters or disease outbreaks, such as the emergence of AIDS in the 1980s, the Severe Acute Respiratory Syndrome (SARS) outbreak of 2003, and the H1N1 influenza pandemic of 2009 (World Health Organisation, 2017).

34. What are the respective roles and responsibilities, in terms of both public messaging about risks and ensuring that there is a robust system for the provision of appropriate information about risks to particular groups of patients, of:

- a. ministers;
- b. the Chief Medical Officers and Deputy Chief Medical Officers;
- c. civil servants;
- d. NHS executives and administrators;
- e. organisations representing those within the medical profession (e.g. for example, organisations charged with providing advice on particular specialities and sub-specialities)?

Information about risk of medical treatment is generated and communicated by many different organisations and agencies, often without formal coordination of messages. Responsibilities are not necessarily clearly defined either within or across the organisations concerned though, for major risks or threats to public health. Responsibility for communicating risk which affects large numbers of patients across the NHS would ultimately rest with ministers in conjunction with the Chief Medical Office and advisers. For risks emerging within a particular NHS organisation, responsibility would rest with the Chief Executive, Medical and Nursing directors and the board. In our response to this question, we first address the roles and responsibilities of those in government or serving government, then address the roles of those in the NHS or in organisations linked to the NHS.

The roles and responsibilities of ministers, civil servants and Chief Medical Officers

The Nolan Principles (set out in full in the answer to question 15) include the principle of openness which applies to Ministers, civil servants and anyone in public life. This provides that the holders of public office should act and take decisions in an open and transparent way. In particular, it requires that information should not be withheld from the public unless there are clear and lawful reasons for so doing.

The Nolan principles, which were published in 1995, were founded on longstanding and well-established conventions in public life (Nolan, 1995). They are, therefore, a reasonable statement of what should have been expected of ministers and civil servants in the 1970s and 1980s on the subject of messaging risk as well as a guide to the present day.

The principle of ‘openness’ set out in the Nolan Principles clearly implies that Ministers have a responsibility to make information about risk publicly available unless it was judged to be speculative or incomplete and not therefore in the public interest. This responsibility would sit with ministers primarily, advised, as ever, by their civil servants. Ministers must make judgements about the quality of information available as well as what is in the public interest. Civil servants are to ensure that robust systems do exist to enable ministers to make the best possible decisions for those potentially affected. A core part of the role of a civil servant is to ensure that Ministers have the best possible data to help them reach the optimal decision. This would extend to seeking out information on risks to particular groups of patients by engaging, if necessary, with front line personnel, academics and representative organisations.

Ministers themselves cannot escape all responsibility for the data at their disposal because they should ask themselves whether the information offered to them is comprehensive, and they should challenge if they feel that any information they require to make the best possible decisions is missing. They may ask, for instance, whether information does exist but has not been presented? Is it just not discoverable in the necessary timescale? Does this influence their conclusion as to whether they have enough facts to enable messages to be reliable and therefore in the public interest?

For most hazards, of whatever nature, there are usually many risk estimates available with caveats around each one. The messaging of risk does not depend on a single universally agreed figure. Chief Medical Officers and their advisers are likely to be aware of this imprecision but will often need to relay the ‘best estimate’ figure to ministers, civil servants and NHS management. The latter policymakers might not be aware of the uncertainty around the risk estimates they are given. Medical groups may be more aware but may choose figures that promote professional interests. Political and professional interests therefore have a part to play in determining what is appropriate messaging given the range of available metrics and formats. It should be considered good practice to state uncertainties in estimation. Honesty about the strengths and limitations of evidence should be encouraged.

Ministers may reasonably withhold information from the general public, or particular patient groups, if there is a ‘clear and lawful’ reason for withholding information. The Freedom of Information Act (2020) requires the disclosure of any information held by a public authority unless it is automatically exempt (e.g. information from the security services) or where the public interest served by withholding information outweighs the public interest in disclosing it. The Information Commissioner’s subsequent guidance on this suggests that factors that favour withholding information would certainly include the disclosure of speculative or incomplete information which could mislead the public and cause them to fail to act or to act against their own interests.

The roles and responsibilities of the NHS and related organisations

Healthcare staff, particularly doctors and pharmacists, have a professional responsibility to communicate both risks and benefits of interventions to patients and families. There are, as set out above, many challenges in achieving a form of risk communication that is compassionate, effective and appropriate for each patient. Senior leaders in NHS and related organisations have a responsibility to support staff in conveying such information to patients and to ensure that appropriate policies and procedures are in place to guide risk communication.

Many different organisations produce guidelines on treatment and associated risks, variously based on opinion, clinical experience and evidence of different degrees of strength. Formal reviews of evidence are carried out by groups of experts, such as the Cochrane Collaboration, who collate available studies and try and reach a balanced conclusion. For instance, a review of the use of antiviral drugs to treat HCV, for example, showed that available evidence came from short-term clinical trials but longer-term benefits (or harms) were unknown (Jakobsen et al., 2017). Organisations providing advice to doctors include National Institute for Health and Care Excellence (NICE), the British National Formulary (BNF), Royal Colleges and specialist societies. The Medicines and Health Products Regulatory Agency (MHRA) will send out alerts to registered professionals when new significant information is available about a risk. However, general practitioners may receive twenty or more documents in a week regarding policy changes, making it almost impossible to keep up with the latest guidance.

The plethora of guidelines and information poses considerable practical problems. A study of guidelines in the NHS examined the typical journey of an elderly patient admitted for emergency surgery on a fractured neck of femur; a total of 75 clinical guidelines and trust-wide policies covered the different stages of management. The same study found that a clinical director of anaesthetics who wishes to ensure that the department is compliant with all relevant guidelines, would need to coordinate the guidelines of 21 different organisations (Carthey et al., 2011). Guidelines for clinical practice are of course concerned with much more than risk information, but illustrate how risk information may emanate from multiple sources with no single organisation having the responsibility for integration.

35. Please comment on how the practice and principles of warning of risk have developed, identifying any significant changes that have taken place in the time period of relevance to this Inquiry.

Until about 50 years ago, key ideas about risk were based on clinical experience: if the clinician had seen so many particular ‘cases’ of the disease in question they would have an idea of the probability of success or failure. This knowledge was augmented by the collective clinical experience of others as gleaned from medical textbooks and medical education. This form of knowledge was subjective and could not be quantified in any meaningful way. The ‘risk message’ that a clinician might give a patient therefore consisted of imprecise descriptors: ‘this outcome is probable’ perhaps, or ‘this treatment is unlikely to work’. There could be no greater accuracy as there were no denominator numbers available. This began to change over the last few decades with the development of epidemiology and the scientific evaluation of drugs and other treatments.

For most of its history the science of epidemiology has been concerned with managing and plotting the course of epidemics, but in the second half of the 20th century, it turned to the distribution of non-infectious diseases in populations. This interest led to determining denominators for clinical events. Instead of a clinical event being ‘probable’ it could be expressed quantitatively, say, as 20 in 100 cases. These new risk statistics emerged during the 1960s and 1970s in epidemiology and then began, slowly, to find their way into clinical practice. Nowadays, many of the studies published in leading medical journals involve assessing populations and risk probabilities.

Expectations of patients and doctors were steadily changing in parallel with emerging knowledge and understanding of both benefits and risks of treatment. The General Medical Council took a decisive step in 1995 with the publication of Good Medical Practice (General

Medical Council, 1995). This guidance, while not discussing risk specifically, explicitly stated that any doctor had a responsibility to give patients the information they ask for or need about, their condition, its treatment and prognosis; give information to patients in a way they can understand; and respect the right of patients to be fully involved in decisions about their care. Legal standards and expectations also evolved considerably from the 1970s to the present day broadly moving from a paternalistic model in which all decisions were left to the 'reasonable doctor' to a patient-centred model in which patients could expect to be full participants in decisions about their care (Appendix D).

Over the last two decades, knowledge about risks has accumulated on an increasing scale. However, while associations between risk factors and disease abound, definitive causation can rarely be established beyond challenge. In the new risk environment, medicine has now endorsed multifactorial causality, that is, very few, if any, diseases have a single cause. The quantification of probability that began half a century ago has not led to more precision as it seemed to promise but, ironically, has served to raise the salience of uncertainty in clinical practice.

In summary, there have been profound changes in the way in which healthcare staff and organisations view risk communication. At the time of the events relating to the Inquiry, decisions about risk communication were largely made by doctors without consulting patients about what they wanted to know. However, it is important to understand that this did not necessarily mean that information was being withheld. In most cases doctors were still guided largely by their own clinical experience and simply did not have access to the depth of research and understanding that is now available. Doctors and other staff are now much more open and appreciate the need to share information and decisions about medical interventions and treatments. However, as has been shown in responses to this and previous questions, there are many challenges in both the estimation of risk and the communication of risk in a way that is humane, effective and appropriate for a particular patient or population of patients.

The duty of candour, transparency, accountability and redress when mistakes are made

36. Please explain the current principles underlying duties of candour relating both to medical accidents, errors or harm and to poor practice or failings in public administration more broadly. In particular, please comment on:

- a. The principles underlying a duty of candour in respect of the UK government and the devolved administrations.
- b. The principles underlying a duty of candour in respect of NHS bodies.
- c. The principles underlying a duty of candour in respect of individual doctors, civil servants, NHS executives/administrators, and ministers.
- d. Whether the duties of candour discussed include a duty to apologise.
- e. How the relevant duties of candour are monitored, judged and enforced.

37. Please comment on any shortcomings or recommendations the Group identifies in this area.

38. Please explain how the principles underlying the duty of candour (and any associated duty to apologise) have developed, identifying any significant changes that have taken place in the time period of relevance to this Inquiry.

‘Openness and honesty when things go wrong’ (General Medical Council and Nursing and Midwifery Council, 2022) - this is the simple principle under which the duty of candour should operate, although the issues that surround it in actuality are inevitably more complex. In order to address the three questions posed above, we begin by providing some historical context to the current situation in the United Kingdom (UK). The duties of candour under discussion relate to (i) the statutory organisational duty of candour; and (ii) the individual professional duty of candour. Both are fundamentally concerned with ensuring an open and honest response when adverse events have occurred in relation to the care of patients and services users. However, there are key differences in how the two duties of candour operate and the actions required. As such, they will be addressed separately in this section. The problems related to carrying out a duty of candour in practice will be discussed and future considerations are proposed.

Historical Background

Prior to 1980, there was little in the way of a recognised legal duty of candour, and in the decade that followed, references to a need for candour in healthcare featured only occasionally and fleetingly when clinical negligence cases were brought (Quick, 2022). In 1990, the death as a result of a failure to diagnose and treat Addison's disease in a child, Robbie Powell, and the subsequent post-death cover-up, revealed serious failures in this area (AvMA, n.d.). The court ruling related to this case made specific reference to the issues regarding the absence of a legal duty of candour at the time. It specified that, as the law stood, there was no duty for doctors to provide families with a truthful account of the circumstances surrounding a death due to negligence or even to refrain from deliberately falsifying records after the event (Powell v The United Kingdom, 2000).

It was not until 1995 that the General Medical Council (GMC), which is the independent statutory regulator for doctors in the UK, published its first edition of the Good Medical Practice ethical guidance. It outlined the standards of care patients should expect and doctors should work towards (General Medical Council, 1995). Although it did not specifically mention a duty of candour, or provide any guidance on apologies, it did place a strong emphasis on trust and honesty as guiding principles. Subsequent versions made increasingly more explicit references to what doctors should do when things go wrong in this respect, which are described in more detail below.

In 2013, the publication of The Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry (Francis Inquiry) uncovered a culture of fear and bullying, in which staff felt unable to report concerns and prevented from doing their jobs properly (Francis, 2013). It also referenced a culture of secrecy that was evident at a system level, in which the Trust board distanced itself from these situations in its hospital and ignored its patients (Francis, 2013).

The Francis Inquiry prompted significant developments in this area, with the introduction of statutory duties of candour and the strengthening of the individual duty of candour. Having previously been minimal or non-existent, the regulatory space in which the duty of candour now exists requires that different individual and organisational duties are navigated and met. This marks a shift in focus away from the need for *more* regulation and towards *improving* the delivery of existing regulation that ensures healthcare professionals are open and honest with their patients when standards of care have fallen short of what should be expected.

Statutory Duty of Candour

The statutory organisational duty of candour is a legal duty which sets out how NHS bodies should tell those affected when things go wrong with care and treatment, and the actions that should be taken. Under the current constitutional arrangements, health competence is devolved, meaning separate legislation applies in each of the four countries that make up the UK:

- *England*. Provisions for the duty of candour are outlined in The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, Regulation 20. It states that a 'notifiable safety event' meets the threshold for when this duty should be applied.
- *Scotland*. The Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 and The Duty of Candour Procedure (Scotland) Regulations 2018 stipulate that an 'unintended or unexpected incident' fills the necessary criteria for the application of a duty of candour by organisations.

- *Wales.* Duty of candour became law on 1st June 2020, as outlined in the Health and Social Care (Quality and Engagement) (Wales) Act 2020, and is due to come into effect in the Spring of 2023. The threshold for its application is any unexpected or unintended harm that is more than minimal.
- *Northern Ireland.* A statutory duty of candour was recommended by Justice O’Hara in his published report following the Inquiry into Hyponatraemia-Related Deaths (IHRD, January 2018), however there are no provisions currently in force for a duty of candour.

As shown, the legal position on the statutory duty of candour differs between each UK jurisdiction, as do the circumstances in which it should be applied. However, there are commonalities in the legislation enacted between the four nations. They each broadly require that certain steps are taken when the relevant provisions are triggered, such as notifying the relevant parties when something has gone wrong, offering an apology to those affected and incident reporting requirements.

Enforcement arrangements for this legislation also differ between each of the four countries. For example, the Care Quality Commission (CQC) is the body responsible for enforcing the statutory organisational duty of candour for NHS Trusts in England. The CQC can use their powers to issue warning and requirement notices, to impose conditions and to bring a criminal prosecution (Care Quality Commission, 2022). There are now a number of examples where action has been taken in England, although there was initially some concern that these provisions were not being adequately enforced. Legislation was introduced more recently in Scotland, and we are not aware of any enforcement action taken in this respect to date. As aforementioned, in Wales, the law on duty of candour is not due to be brought into force until 2023.

Individual Duty of Candour

The individual professional duty of candour applies to all UK registered doctors. Following the publication of the Francis Inquiry in 2013, professional regulators (including the GMC) published a joint statement encouraging their registrants to be candid (General Medical Council, 2014). It stated that every healthcare professional must be open and honest with patients when something has gone wrong with their treatment or care which causes, or has the potential to cause, harm or distress. More specifically, it specified that healthcare professionals must:

- (i) Tell the patient (or, where appropriate, the patient’s advocate, carer or family) when something has gone wrong, apologise and fully explain the short and long-term effects of what has happened, offering the appropriate remedy or support to put matters right, if possible.
- (ii) Be open and honest with colleagues, employers and relevant organisations, taking part in reviews and investigations when requested.
- (iii) Be open and honest with regulators, raising concerns where appropriate.
- (iv) Support and encourage each other to be open and honest and not stop someone from raising concerns.

These directives are also reflected in the individual duty of candour set out for doctors by the GMC in their current version of the Good Medical Practice ethical guidance (General Medical Council, 2013). A breach of this guidance could result in a concern being raised about an individual doctor’s conduct to their regulator (the GMC) and in fitness-to-practise proceedings

(General Medical Council, 2012). Anyone can raise a concern about a doctor's conduct to the GMC: members of the public, other doctors or colleagues, responsible officers; and doctors can even refer themselves (General Medical Council, 2012). The most serious sanction that may be issued by the Medical Practitioners Tribunal Service (MPTS), which adjudicates on such matters, is the removal of the doctor in question from the medical register to stop them practising (General Medical Council and Medical Practitioners Tribunal Service, 2018).

Problems in Practice

The Professional Standards Authority (PSA) published an influential report in 2019 on the progress regulators had made in embedding the duty of candour for individuals (Professional Standards Authority, 2019). It identified certain barriers to individual candour in practice, including:

- Toxic working environments where an organisation has a culture of blame or defensiveness.
- Fear of litigation, disciplinary action, or of public and media perceptions and the associated impact on their career.
- Heavy workloads which limit the time practitioners can spend with patients to have timely and meaningful discussions when problems have occurred.

Additionally, the thresholds for individual and statutory duties of candour are not the same. This means there may be some instances in which the professional has a duty of candour as an individual, covering all situations where mistakes have been made, but that falls short of the threshold for an organisation's legal duty, which applies only in response to notifiable safety incidents. There is also some concern among professionals that the statutory duty of candour has become a tick-box exercise, rather than a genuine interest from organisations in being candid with patients about poor practice (Gardiner et al., 2022).

The duty of candour is only a starting point for both individuals and organisations in their continuing duty of care to the patient. If an adverse event occurs, then much depends on how it is understood and the ongoing care and support for the patient and family. An organisation can, for instance, simply seek to blame a single individual rather than be candid about wider organisational failings which were the principal reason for the problem. Most importantly, NHS organisations must have procedures in place for providing ongoing support after disclosure of adverse events. The duty of candour needs to be a long-term commitment, not a single point of disclosure.

Future Considerations

The PSA provided some considerations on how candour may be encouraged in their 2019 report. They proposed that professionals are given education and training which covers the importance of candour and the communication skills needed to have difficult conversations with patients. They also suggested that a whole sector response is necessary to improve workplace environments, increase engagement with frontline staff in order to listen to concerns, and dedicate time for professionals to be able to reflect on, discuss and review experiences with their peers. The key message from a PSA co-hosted conference held in 2021 expressed that the delivery of candour and openness towards patients and families should not be thought of as a legal and professional obligation, but rather a cultural and behavioural change that is embraced at all levels of an organisation (Godfree and Sorbie, 2021).

We suggest that there are three broad areas for consideration in the recommendations of the Inquiry. First, a patient-centred approach is vital to ensure that the duty of candour, whether organisational or individual, does not become a matter of minimal compliance, or a ‘tick box’ exercise, but rather a meaningful process between organisations, professionals, patients and their families when things have gone wrong. Second, there is a need to focus not only on top-down regulation, but also the individual skills, behaviours, processes and cultures within healthcare that encourage candour at every level, and to remove barriers that impede this. Third, the complexity of this issue requires a multi-faceted solution as candour is undoubtedly a sector-wide challenge. As such, a sustained and collaborative approach between stakeholders over time would be beneficial, which includes the involvement of healthcare providers, patient groups, charities, regulators, indemnifiers and professional bodies, among others.

39. Please comment on the role and significance of reflective learning in achieving best practice in the provision of healthcare and decision-making regarding public health risks. Please consider how, if at all, such reflective learning applies to those within relevant government departments (i.e. ministers and civil servants) and to those working within the NHS.

Regulatory bodies have increasingly placed an emphasis on reflective learning in the healthcare profession, with the view to strengthen individual competence and improve patient care. The Health and Care Professions Council (HCPC) refer to reflective practice as the process by which healthcare professionals think analytically about their working practices, the insights developed and lessons learned, which may be applied to maintain good practice or to develop and improve (Health and Care Professions Council, 2021a). The aim of reflective learning is to strive for best practice by encouraging individuals to evaluate their own thoughts and actions, build on existing knowledge and skills, enhance clinical judgement and develop collaborative working (Miraglia and Asselin, 2015). Such learning needs to be embedded in a wider positive culture if it is to be effective. Senior leaders in both government and the NHS need to build a culture which seeks to learn and improve systems and practices, rather than simply seeking to cast blame for problems and failings.

In this section, we first describe what is meant by reflective learning in clinical practice and how this can contribute to achieving best practice. We then describe the role of reflective learning in healthcare organisations and government departments in a variety of contexts, settings and timescales. We suggest in a final section that reflective learning is an essential foundation of effective organisations.

Reflective learning in clinical practice

Donald Schön first used this term in the context of professional practice when he introduced the idea of *reflection-in-action* and *reflection-on-action* (Schön, 1983). Reflection-in-action refers to the concept of ‘thinking on your feet’, when a professional acknowledges the current situation, examines what is happening and reacts accordingly (Schön, 1983). Reflection-on-action takes place after the event, and is the process whereby the individual considers the situation in more depth, and their own part in it, in order to gain new knowledge and understanding (Schön, 1983).

In their professional guidance for doctors, the General Medical Council highlights the importance of reflective learning to their own personal and professional development, their patients and the wider system. All doctors have a professional responsibility to engage in reflective practice, share learning and facilitate change as part of their continual professional development. Reflective learning may take place in the context of personal reflection or group learning within teams (Health and Care Professions Council, 2021b). The Care Quality Commission suggest that clinical supervision be a way in which Trusts may support staff in reflective learning, by giving them the opportunity to discuss cases or experiences and identify possible changes for improvement (Care Quality Commission, 2013).

The practice of reflective learning and associated benefits has been observed across different healthcare professions and clinical practice settings. For example, strategies used to incorporate reflective practice in the nursing profession included structured debriefings after an event, facilitated group discussions, mentoring, reflective diaries and workshops (Miraglia and Asselin, 2015). These strategies led to positive outcomes such as increased confidence through the gaining of knowledge and skills, reduced work-related stress, better care delivery to patients and enhanced professional development (Miraglia and Asselin, 2015).

Reflective learning in organisations

Health system leaders have a responsibility to engage in reflective learning to ensure the welfare of their staff and patients, and to develop health system resilience. Failure to learn from incidents or share learning is a common issue for under-performing hospitals, whereas most well-performing hospitals and services display organisational learning, with a particular impact on quality improvement and system performance (Akhnif et al., 2017; Care Quality Commission, 2019).

In 2019, the CQC published a report on how eight hospitals in England sought to improve services by reflecting on current practices following a CQC inspection (Care Quality Commission, 2019). These hospitals implemented reflective learning using a variety of methods, including:

- *A questioning mindset:* What we are doing, why we are doing it and what we are hoping to achieve? Included examples of reflection-in-action (who are we worried about, what concerns do we have and where are the issues?), and reflection-on-action (what can we learn from this, what could we do to improve things and how can we make that happen?).
- *Public and patient engagement:* Patient groups, focus groups and forums as well as complaint handling.
- *Staff communication:* Staff forums and engagement surveys, and regular meetings within teams and with leadership covering the day's activities, in which patients are reviewed, incidents and concerns are discussed, and forward planning is made.
- *Information sharing:* Lessons arising from issues and experiences are shared across the hospital to achieve widespread learning. Dedicated weeks set up for staff to share learning around specific themes, such as patient safety and human factors in delivering care.

Whether in the NHS or government departments, it is essential that organisations establish an open and supportive culture where staff at any level feel able to speak up about incidents and concerns, so that learning may be achieved and progress is made. This is encapsulated in the term psychological safety, which refers to the shared belief that speaking up about ideas and concerns in the workplace, free from interpersonal risk, is vital to team learning and performance (Edmondson, 2018; Hunt et al., 2021).

An example of reflective learning at a cross-system level can be found in a report published this year by the NHS confederation on the current state of integrated care systems (ICSs) in the UK (Pett and Bliss, 2022). Using the views of system leaders, it reflected on where the ICSs have progressed, where improvements were needed and any barriers to successful implementation. Based on their findings, recommendations were made to NHS England and the government on ensuring the right support is provided to the ICSs going forward to ensure progress continues to be achieved.

Reflective learning in government settings

Current and previous governments have emphasised that policy-making must be a learning process and that the public service must become a learning organisation (Cabinet Office, 1999). In their literature review of organisational learning in government sector organisations, Gilson and colleagues (2009) identify the key sources that government may use to engage in learning, which include:

- Internal resources and experience, drawing on the experience and expertise of ministers, civil servants and other staff working in government.
- Research and feedback from citizens (e.g. citizen redress processes) as well as experimentation and piloting.
- Partners, rivals and comparators, including contractors and consultants, private sector agencies, and overseas examples.
- Critiques and advice from bodies such as select committees, stakeholders and think tanks as well as responding to media scrutiny.
- Testing interactions, crises and review through systematic learning from mistakes, departmental crisis management and response, as well as internal and external (e.g. Healthcare Commission) audits and reviews.

Reflective learning within government can be embedded both within and between organisations (King et al., 2021). For example, the Beacon Council Scheme, which ran from 1999-2010 in England, sought to engage all councils simultaneously in learning from their own experiences and from each other in order to facilitate continuous improvement, as part of the government's modernization agenda (Rashman and Hartley, 2002). Based in the principles of shared learning and the spreading of best practice, the government introduced the scheme into other public sectors, such as education and health.

Public inquiries represent a form of system-level reflective learning, in which participants reflect on problems that have occurred, consider their causes and make recommendations to improve the NHS or other organisations. For instance, the Patterson Inquiry revealed multiple weaknesses in systems for listening to patient concerns and for monitoring the standards and performance of doctors (Department of Health and Social Care, 2021). In their response, the government outlined the various ways in which it would act on the recommendations of the inquiry, including actions from the Department of Health and Social Care, the GMC, the CQC and NHS Resolution.

Reflective learning may occur over long timescales, but is also critical in fast-moving crises. In such situations, learning may take place in rapid cycles in frequent daily meetings and information exchange. In the recent COVID-19 pandemic, ministers, civil servants and healthcare workers faced unprecedented scenarios which often required an immediate and in-situ response to manage the constantly changing situation. Reflective practice

was imperative during this time and provided a timely and effective mechanism to enable healthcare professionals to respond and adapt effectively to evolving events in order to uphold good working practices and maintain patient safety (Walpola and Lucas, 2020). Adaptation was necessary at all levels as new data and information emerged from various sources on the development of the virus, meaning guidance to inform best practice was continuously updating.

Future Considerations

Government and healthcare organisations need to encourage reflective practice at all levels by creating an environment receptive to learning and setting aside time so that healthcare professionals as well as ministers or civil servants can build learning into working routines and practices. Many examples of effective reflective learning are available to draw on, together with descriptions of the practices that enable it to happen. The culture of the organisation is however all-important. Senior leaders need to demonstrate, both inside the organisation and externally, that the learning is not just a display of being seen to be doing something, but a sincere desire to learn and evolve (Common, 2004).

40. How effective have government and the NHS been in learning from past errors, failings and poor practice and why? Please comment on what improvements the Group feel could be made in this area, and provide recommendations on how such improvements could be achieved.

The Independent Medicines and Medical Devices Safety Review (Cumberlege Review) was published in 2020, which examined how the healthcare system in England responded to reports about harmful side effects from medicines and medical devices (Cumberlege, 2020). Drawing on three case studies of systemic patient safety failings, recommendations were made on how best to reform the current systems, procedures and practices to address safety concerns. The Cumberlege review, and the government response (Department of Health and Social Care, 2021), directly address the issues raised in this question. We have therefore drawn directly on the Cumberlege review to frame our response and to ensure consistency in recommendations from concurrent inquiries. In this section, we first summarise the Review's findings to provide context on why learning was necessary, and then move on to cover the recommendations made, and subsequent government response, and close with some broader suggestions and principles to guide future learning.

The Cumberlege Review

The Cumberlege Review found that the healthcare system had not adequately identified trends nor acted to learn from past errors (Cumberlege, 2020). A number of detailed findings were presented, with the following being of particular relevance to the present inquiry into infected blood:

- A healthcare system that did not listen, act or rectify mistakes when necessary, which led to patients being poorly informed and overlooked when it came to their care.
- The absence of vigilant and long-term monitoring of treatments and devices meant that the scale of the problem remained largely unknown. Crucial opportunities were missed to learn about what was and was not working or safe. Neither doctors nor patients understood the risks and patients were unable to give truly informed consent.

- Failures to acknowledge any wrongdoing by the system for fear of litigation, an institutional and professional resistance to changing practice even in the face of mounting safety concerns, and a culture of dismissive and arrogant attitudes towards patients; ‘mistakes were perpetuated through a culture of denial, a resistance to no-blame learning, and an absence of overall effective accountability’ (Cumberlege, 2020).
- A system that could not be relied upon to promptly identify significant adverse outcomes arising from a medication or device. This was considered due to overly complex and diffused reporting and complaints systems (e.g. the yellow card scheme) and low public awareness of the role of regulatory agencies such as MRHA, which led to gross underreporting and the hindering of early signal detection.
- Manufacturers whose motivations were preoccupied by sales, speed to market and returns to shareholders, and who contested liability towards patient groups. This meant patients had to resort to litigation to have wrongdoings acknowledged.
- Significant gaps in knowledge and evidence gathering on the safety and effectiveness of interventions through a lack of prioritisation and funding of necessary research; a view previously expressed by the National Institute of Health and Care Excellence (NICE), among others.
- Research funded by manufacturers that contained unfavourable findings was not made public. Conflicts of interest when positive results were reported via this funded research were also not always made transparent.

Specific Proposals and Government Response

Based on the findings, the Review made several recommendations related to the errors, failings and poor practice exposed by these case studies for the government to review. The government issued a response to the report (Department of Health and Social Care, 2021), outlining a programme of change. We consider that all the recommendations made by the Cumberlege Review have some relevance to the work of the Infected Blood Inquiry, but that the following are of particular note for the purposes of this report:

Recommendation 2: Appointment of a Patient Safety Commissioner who would champion the value of listening to patients and promoting users’ perspectives in seeking improvements to patient safety.

Response: A Patient Safety Commissioner is legislated for in the Medicines and Medical Devices Act 2021 which requires the Commissioner to consult on the principles and approach to the role.

Recommendation 6: MHRA needs reform in relation to adverse event reporting and medical device regulation as well as engagement with, and involvement of, patients in their work.

Response: The MHRA has initiated a substantial programme to develop a more responsive system both towards patients and the reporting of adverse events, and to strengthen the evidence-base behind decisions that protect patient safety.

Recommendation 7: A central patient-identifiable database of implanted medical devices should be created in order to monitor device safety and patient reported outcomes.

Response: The Medicines and Medical Devices Act 2021 provides legislative powers to establish a Medical Device Information System. Funding has been set aside to develop this system with healthcare partners and a 5-year programme of work has been prepared.

Recommendation 8: Increased transparency through the mandatory reporting of financial conflicts of interests from individual clinicians, pharmaceutical/medical device manufacturers, healthcare organisations and research institutions.

Response: Ensure that healthcare professionals are required to declare and make available their relevant interests. Options to expand and reinforce current schemes regarding industry reporting will also be explored.

The government response specified a number of deliverables based on recommendations made by the Review and stated that they aimed to publish an update on progress in implementation in 12 months' time. The government's response will be crucial to establish whether the government and NHS have been effective in implementing the recommendations and can demonstrate real learning from past errors, failings and poor practice.

Future Considerations

The Cumberlege Review showed that the NHS had been slow to learn from past errors. The review made a number of recommendations as to the way forward, some of which are being implemented by the government. Principles that were particularly emphasised, and which are relevant to improving safety in all healthcare settings are:

- Improve how the system listens to and responds to concerns raised by patients by putting patient voice at the centre of patient safety.
- Strengthen the evidence base on which decisions are made, including through making sure the right data is collected and used.
- Build an honest culture in which mistakes are learned from and barriers to disclosure are removed was considered overdue and essential.
- Regulatory systems should become learning systems themselves, with continuous monitoring and updating of its practices.

The Infected Blood Inquiry can draw on the Cumberlege review both in respect of the principles emphasised and specific recommendations, alongside the many other proposals and recommendations put forward in the present report and the wider Inquiry.

- 41. Please explain what if any mechanisms are currently in place to provide for (i) transparency and (ii) accountability, when mistakes are made in the provision or regulation of healthcare or the response to public health risks in the United Kingdom.**
- a. Please comment on how such mechanisms have developed, identifying any significant changes that have taken place in the time period of relevance to this Inquiry.**
 - b. Please identify any mechanisms or examples that the Group consider to have been particularly successful or unsuccessful in this area (including examples of good practice drawn from elsewhere in the world, if relevant).**
 - c. Please comment on any shortcomings or recommendations the Group identifies in this area.**

We have addressed the organisational and individual duties of candour in detail at Question 36 - Question 38, which we would identify as a key mechanism for facilitating transparency and accountability when mistakes are made in the provision of healthcare or response to public health risks. This brief history demonstrates that in the 1970s and 1980s there was little formal guidance on the appropriate response to mistakes with decisions being the responsibility of individual doctors. Guidance from the General Medical Council and other regulators, and legislation in three of the four countries of the UK, now places a clear duty of candour on clinicians and organisations respectively.

This issue was also directly considered in the context of the recent Cumberlege Review which refers to patients' experiences of a lack of openness, including clinicians who were '...reluctant to admit to any mistakes made during, or acknowledge any adverse outcomes from, an intervention' (Cumberlege, 2020, para. 2.46). The Review echoes the progress that has been made in this area, as we have previously highlighted, but also the need for more to be done in circumstances where '...a cultural shift away from blame is needed to create a healthcare system where people are open and honest' (Cumberlege, 2020, p. 33).

The concept of 'just culture'

The Cumberlege Review emphasises the need to move away from a 'blame culture', a theme which has emerged in other recent government and regulatory reviews in relation to addressing failures in the provision of healthcare in the NHS. This builds on extensive research and experience in healthcare and other industries, stressing that safety can only be achieved in an environment in which it is safe to speak up, both to prevent errors occurring and after mistakes have been made (Weaver et al., 2013; Braithwaite et al., 2017). The move away from a blame culture is often expressed in more nuanced and positive terms, such as building a just culture. The term 'just culture' also implies that, although a blame culture must be avoided at all costs, people can and should still be held accountable for their actions and behaviour in a proportionate manner (Vincent, 2010).

In respect of the legislative framework of healthcare, the recent Williams and Hamilton Reviews (Williams, 2018; Hamilton, 2019) suggest that the development of a just culture would involve 'systems, procedures and processes surrounding the ... law and regulation being applied', in circumstances where healthcare professionals would be able to learn 'without fear of retribution'. At the same time, healthcare professionals would be encouraged to admit to

errors in such cases, while necessary steps would be taken to ensure that they, their patients and their families, were dealt with in a ‘fair and compassionate manner’ (Williams, 2018; Hamilton, 2019). A just culture is of course equally important in any organisation working within the NHS and in government departments.

The challenge of building a just culture clearly has been the subject of extensive research and discussion in many papers and books. Despite the clear benefits of a positive organisational culture in healthcare, it has proved very difficult to achieve in practice and even more difficult to demonstrate. Recent systematic reviews investigating organisational cultural change on healthcare performance have shown that it is both difficult to achieve cultural change and difficult to sustain (Hunt et al, 2021; Parmelli et al, 2011).

Some organisations, in both healthcare and other industries, have however succeeded in fostering and sustaining a more open culture which allows risks to be openly discussed and errors acknowledged. These organisations exhibit some common themes (Hunt et al., 2021; Murray et al., 2022; Leape, 2021), including:

- policies and procedures that are designed to support a just culture
- an open and transparent leadership style in which leaders model just culture in their own behaviour
- policies which stipulate that support should be provided to patients and families after errors
- procedures and mechanisms for supporting staff after errors
- training in open disclosure methods
- formal assessment of just culture using one of the many instruments available

The recent authoritative history of patient safety by Professor Lucian Leape provides examples of healthcare systems, such as Virginia Mason in the United States, whose leadership has incrementally built and sustained a just culture over many years showing that, while difficult, it can be achieved.

Looking beyond just culture, both researchers and leaders are embracing the concept of psychological safety which promotes innovation and creativity as well as a just response to error and harm. Psychological safety is the shared belief that it is safe to engage in interpersonal risk-taking in the workplace and is vital to team learning and performance and facilitates willingness for workers to contribute towards a shared goal (Edmondson 1999; 2003). Ideally, staff are free from the fear of being rejected for speaking up with suggestions and will be treated fairly and compassionately when discussing concerns, errors, or identifying problems. Psychological safety has an additional resonance and importance empowering patients and families to voice their suggestions, concerns and anxieties, which is critical to the early identification of future risks (Hunt et al., 2021). Case studies of organisations of many different kinds suggest that psychological safety is a critical foundation for learning, innovation, improvement and organisation change (Edmondson, 2018). Further practical guidance on building a just culture and enhancing psychological safety can be found in Edmondson (2018) and Leape (2021).

- 42. Please comment on mechanisms that might be used to ensure that those (whether they are private or public bodies) who might be partially responsible for medical accidents, errors or harm and/or for poor practice/failings in public administration, would contribute to the costs of dealing with the consequences. In doing so, please consider:**
- a. Any mechanisms that are currently in place in the United Kingdom and, where the Group considers them to be of relevance, in other countries.**
 - b. Whether other mechanisms in other fields could usefully be implemented, or considered for implementation, in respect of healthcare in the United Kingdom.**

In the UK, the current route to recovering compensation when treatment has been negligent and caused harm is via individual legal action for clinical negligence in the courts. In order to bring a claim for clinical negligence, it is necessary for the claimant to prove on the balance of probabilities that there exists a duty of care, that there has been a breach of that duty of care, and that the breach has caused (in fact and in law), a compensable loss or harm.

There have long been concerns over the rising costs involved in clinical negligence litigation. The litigation system has been criticised on the basis of excessive costs, lack of accessibility, and a failure to improve patient safety at a systemic level. The costs of such litigation have a direct impact on care resources as ‘payments for negligence awards are resourced from the same funds used to provide care’, although this is also true of any industry that provides compensation for harm it has caused (Draycott et al., 2020). In addition, there are longstanding concerns about the adverse psychological impact on the parties involved in such litigation, although qualitative socio-legal research on parties’ experiences in this regard remain under-researched in the UK context (Dickson et al., 2016).

The clinical negligence litigation system remains the primary vehicle for obtaining compensation, although various other proposals have been put forward and some have been trialled. Following a recommendation from the then Chief Medical Officer in 2003, legislation was adopted in 2006 to establish NHS redress schemes in England and Wales for small value claims up to £25,000, where redress would involve the provision of explanations, apologies and lesson-learning (Farrell and Devaney, 2007). In the end, it was never implemented in England; however, it was subsequently adopted in Wales. The Welsh NHS redress scheme covers small value claims up to a maximum of £25,000, where a ‘qualifying liability’ is established. This eligibility criterion essentially mirrors tort-based liability and requires that where a patient has suffered harm as a result of a breach of a duty of care from an organisation or health care professional, then they must inform the complainant, provide copies of the records and any expert evidence and offer access to free legal advice. The scheme applies to Welsh NHS bodies, but not general practitioners or independent providers treating NHS patients (National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011).

No-fault compensation schemes

In 1974 New Zealand introduced a publicly funded accident compensation scheme with the goals of minimising the incidence and impact of injury. The scheme provides assistance with the cost of treatment and rehabilitation for all personal injuries, including medical injuries, regardless of fault. Consequently, in New Zealand doctors pay comparatively low medical indemnity fees. Doctors are held to account under separate processes including the Medical Council of New Zealand's competence and fitness to practise processes, an independent patient complaints system, and a separate disciplinary process.

Over the past decade, there have been academic and policy reviews of no-fault (and redress schemes) for patients arising from healthcare injury (for a recent overview, see Macleod and Hodges, 2017). A report commissioned by the No-Fault Compensation Review Group in Scotland provided a cross-jurisdictional review of such schemes in New Zealand, Sweden, Denmark, Norway, and Finland, and Virginia and Florida in the United States (Farrell et al., 2010).

Although the basis for such schemes varies, they often include the following common features:

- All have eligibility and threshold disability criteria which need to be satisfied before cover is accepted.
- There may be caps on certain categories of compensation and compensation for non-pecuniary losses, such as pain and suffering, may not be available.
- Levels of financial compensation/entitlements tend to be lower for comparative injuries in clinical negligence claims brought under tort-based systems.
- There is simpler and broader 'access to justice' in no-fault schemes, particularly in relation to the cost of initiating or submitting claims, as well as time to resolution.
- Access to the courts may be restricted.
- Clinical staff remain accountable for their actions through other regulatory systems (Wallis, 2017).

The Review identified the following advantages of no-fault compensation schemes, with particular reference to the schemes operating in New Zealand and Sweden:

- A principled social/community response to personal injury which includes a recognition of community responsibility; comprehensive entitlement; full rehabilitation; fair and adequate compensation; and administrative efficiency.
- More patients are eligible for compensation than under tort-based schemes.
- A clear and faster road map towards obtaining redress for patients who have suffered medical injury, than that available from litigation.
- Promotion of better, as well as less defensive, relationships between patients and health practitioners when medical injury has occurred.
- Greater efficiency in terms of both time and costs than would be the case in relation to the management of clinical negligence claims brought under delict/tort-based systems.
- Much reduced threat of litigation for clinicians and reduced insurance premiums.

The positive features of no-fault compensation are considerable and such schemes are well established in a number of countries. However, it is important to recognise that they are not a panacea and cannot meet all the needs of injured patients and their families. Clinicians and healthcare organisations still need to explain, apologise where needed and proactively support patients and their families, as outlined further below. It is also important to remember that no-fault schemes still require that causation be established (thresholds may vary). This is often the most difficult aspect to establish in clinical negligence claims brought under tort-based systems.

The effect of widening access to compensation inevitably tends to have the effect of lowering the level of compensation available to individuals as compared with levels awarded during litigation. In addition, although eligibility criteria may be considered more expansive under no-fault schemes allowing for a greater number of injured patients to obtain cover, existing schemes have a significant rate of rejection (40%-60%) due to a failure to satisfy eligibility criteria.

It is also vital that appropriate medico-legal expert advice is available to claimants to assess eligibility and causation issues under no-fault schemes. Medico-legal experts need to be remunerated appropriately for advice in relation to what can often be complex issues arising from substandard care and causation of harm in healthcare settings. Low fixed fees proposed by the UK government will necessarily impact on the preparedness of such experts to provide such advice, which in turn will impact the quality of justice provided to claimants (Department of Health and Social Care, 2022).

There is also the potential for significant cost of no-fault compensation given the numbers of patients injured by healthcare, which far exceeds the numbers who take legal action. Schemes worked best in conjunction with well-established and well-funded national social security systems and independent patient complaints processes (Farrell et al., 2010). In the United Kingdom, with low levels of social security provision, higher levels of compensation would be required to adequately support injured patients.

Proposals for no-fault compensation in the United Kingdom

In 2021, a UK parliamentary report was published, titled '*The Safety of Maternity Services in England*'. The report called for, inter alia, clinical negligence reform, which would involve a shift away from 'adversarial court-based dispute resolution to administrative compensation schemes,' resulting in lower costs. A recommendation was also made that a Swedish-style no-fault compensation scheme be established in relation to avoidable harm arising in maternity cases (House of Commons Health and Social Care Committee, 2021). At the time of writing, the Committee also launched a new inquiry to consider in more detail the reform of clinical negligence litigation in England, with a view to addressing rising costs, learning from error and improving patient safety (House of Commons Health and Social Care Committee, 2022).

The report of the Cumberlege Review (Cumberlege, 2020) recommended that an independent redress agency be established that would focus on 'a no-blame, systems-based approach to delivering redress as a substitute for litigation' (Cumberlege, 2020, para. 2.51). The advantages of the proposed redress agency were identified as offering easier access and 'one fixed point of contact; it would be flexible to adapt and respond to situations as they arise.' The Cumberlege Review also suggested that the redress agency would 'operate in line with the ombudsman model. It will listen to both sides, investigate impartially and reach a decision' (Cumberlege, 2020, appendix 3, para. 16).

The current UK government has indicated that it is committed to a programme of reform in relation to clinical negligence litigation (England only), with one of the potential options being the possible implementation of a no-fault compensation scheme for healthcare injury. The UK government has not accepted the recommendation to establish a redress agency as outlined in the Review. No details of the reform programme have been published to date (Dorries, 2021).

The Cumberledge review also recommended that separate redress schemes should be provided for the specific problems addressed in the review. They pointed out that such schemes had been established in the past for other iatrogenic injuries, both in the UK and in other countries. Most of these schemes are government funded, but some are part-funded by industry when they also bear some responsibility for the problems that have arisen. Such schemes may provide valuable exemplars and a potential model for the present Inquiry.

Future Considerations: The potential of no-fault compensation

There is no doubt that no-fault compensation has some significant advantages over tort-based schemes, as outlined above. No-fault schemes have the potential to compensate more injured patients and provide compensation more quickly, with less stress to all concerned. Patients will still however have to be assessed, and causation of injuries established. Compensation levels may be lower and much depends on how the eligibility criteria are specified. A narrowly focussed, inadequately funded no-fault system would not necessarily be beneficial to injured patients (Farrell and Frowde, 2021).

We should however not assume that the establishment of no-fault schemes will necessarily enhance safety learning or have a major impact on the blame culture, although it will certainly remove one obstacle to a more just culture. Detailed reflection is needed as to whether a no-fault scheme would represent a just response to the (avoidable) harms suffered by claimants in healthcare settings not only in terms of aspiration, but also in terms of practice. Much depends on how no-fault is implemented. A thoughtfully implemented, reasonably generous scheme could be of a great benefit to both patients and staff, but a narrowly focussed, ill-considered scheme could well be detrimental to patients and families.

43. Please outline what avenues of redress or support (outside of individual legal action) are available for those affected by medical accidents, errors or harm or by poor practice and failings in public administration. Please comment on any shortcomings or recommendations the Group identifies in this area.

Both clinicians and NHS organisations have a responsibility to care for injured patients and their families both in terms of a continuing duty of care and a moral obligation to help those they have injured. Industry too may also need to play a role where injury has been due to defective products. Patients and families should not, ideally, have to complain, litigate or take other action in order to receive the help they need. In practice of course, patients may find it necessary to take action themselves to seek explanations or redress. As noted above, there is currently heavy reliance placed on the pursuit of individual claims for clinical negligence in the courts. However, it is important to keep in mind that there are other avenues of redress and support for those affected by healthcare errors, as well as (avoidable) healthcare harms.

These include the following:

Patient advocacy organisations

Action against Medical Accidents (AvMA) is the UK's leading organisation campaigning to improve patient safety and justice. They assist patients who have been harmed in the course of receiving healthcare by providing specialist advice, explaining the options available to them, and helping them access the support and information they need (AvMA, 2022).

Patient Advice and Liaison Service (PALS)

Patients can also contact the Patient Advice and Liaison Service at local NHS hospital Trusts. PALS teams fulfil their core responsibilities by acting as a point of contact for patients, providing information and resolving concerns. PALS staff also act as navigators of services, mediators between families and staff and, occasionally, patient advocates in supporting them to raise concerns. PALS has the potential to reduce complaints, increase patient satisfaction and provide rapid organisational feedback (Shepard et al., 2021).

Making an NHS patient complaint

If patients are unhappy with the treatment they received from the NHS in England, they are entitled under the NHS Constitution (England) (Department of Health and Social Care, 2021) to an investigation and response by the NHS body that provided the treatment. By following the formal NHS complaints procedure, 'patients can receive: an explanation for what happened; an apology or other statement of regret; and steps can be taken to review procedures so as to avoid such incidents in the future'. Typically, the NHS complaints procedure will not offer financial compensation, however, there may be some circumstances where the NHS will agree to a small ex gratia payment, which is a payment made without any liability or legal obligation. However, the procedure will not address issues of staff discipline, such as dismissing employees or having them struck off professional registers. Many reviews have found that patients are often dissatisfied with both the processes and outcome of complaints. Nevertheless, a recent review found that if healthcare settings were better supported to report, analyse and use complaints data in a standardised manner, complaints could impact on care quality in important ways, which would be an important outcome for those making complaints (Van Dael et al., 2020).

Making a complaint to the relevant Ombudsman

If an issue is not resolved after an informal complaint, and/or a formal complaint under local resolution, patients can pursue an independent review by the relevant healthcare parliamentary Ombudsman for their section of the United Kingdom (2022a). It must be noted, however, that the Ombudsman will not accept all cases for review and is more likely to accept those where there was a potentially avoidable death where serious service failures may have affected survival, wider public interest issues raised by the complaint, or a serious service failure. If the Ombudsman investigates the complaint and finds it to be justified, they can seek an apology or other remedy for the patient, which may involve calling for changes to prevent similar incidents from happening or reviewing procedures (Parliamentary and Health Service Ombudsman, 2022b).

Making a complaint to the statutory regulator of the relevant healthcare professional(s)

Patients also have the option of making a complaint to the statutory regulator of the relevant healthcare professional(s) who were involved in their treatment which relates to the complaint in question. For doctors, this would be the General Medical Council (GMC). Issues which may require involvement by the GMC include but are not limited to serious professional misconduct, criminal offences, repeated poor performance calling into question the professional's competence, and health problems such as addictions or mental illness. Outcomes of fitness to practise investigations may include restrictions on a healthcare professional's practice, and in most serious cases, removal from the register (General Medical Council, 2022).

Inquests

Medical inquests can take place when a patient has died following medical treatment. The inquest will investigate how, when, and where the patient died as a result of the treatment received. However, the Coroner who conducts the inquest is not permitted to make any findings in relation to liability or negligence. A recent review has shown that aggregation and continued analysis of these reports could offer more informed patient safety, workforce development and organisational policy. Improved data quality would allow for possible automation of analysis and faster feedback into practice (Leary et al., 2021).

While there are indeed several avenues open to patients and families who wish to raise safety concerns or complain about services, we should not underestimate the difficulty of accessing these services or obtaining an effective response. There are certainly examples of individuals and organisations who seek out the patient voice and are responsive to concerns about services. However, many patients and families continue to have great difficulty in raising concerns and safety issues because of the professional, organisational and cultural barriers described in this section and elsewhere in this report.

Record keeping

44. What principles do and/or should govern the approach to record keeping and archiving by:
- Government departments;
 - NHS bodies; and
 - regulatory or other bodies concerned with healthcare?
45. Please comment on how those principles have developed, identifying any significant changes and/or omissions that have occurred in the time period of relevance to this Inquiry.
46. What principles and practices govern the access that individuals have or should have to their own medical records (including medical information relating to them held by non-NHS organisations)? Please comment on how those principles and practices have developed, identifying any significant changes that have taken place in the time period of relevance to this Inquiry.
47. What principles and practices govern the ability that individuals have or should have to seek the amendment or correction of their own medical records (including medical information relating to them held by non-NHS organisations)? Please comment on how those principles and practices have developed, identifying any significant changes that have taken place in the time period of relevance to this Inquiry.

All modern organisations produce considerable quantities of written material that is used for administrative, fiscal, legal, and operating purposes. Healthcare organisations have in addition to consider the preservation or archiving of clinical records and the sensitive information they contain. Over time many of these records of activity, decision-making and policy lose their importance, often superseded by new documents, and are discarded. Yet while these discarded records may have lost their primary purpose, they still may have secondary value. They may contain information that, in retrospect, may be important and

they provide evidence of – and potential accountability for – the organisation’s functioning. The key question organisations have to face is which records are to be preserved and which destroyed (Cook, 1997).

The principles and practices governing record keeping, preservation and archiving have evolved considerably in the last half century. We first consider the records of government departments and then those of NHS organisations, covering both individual patient records and those of healthcare organisations. In the last part of this response, we report on the principles and practice that govern the ability individuals have to access and amend their own medical records, and how this has developed over time.

Record keeping in government departments

A new Public Records Act, passed in 1958, gave primary responsibility for selection of records worthy of preservation to the government department concerned based on departmental need and/or historical significance. What legislation could not specify, however, was which documents to preserve and which to destroy. Records officers could weed out documents that had no further primary use while making a guess at whether they should instead be preserved for historical or public interest. There was further culling before transfer to the Public Records Office given the limited available physical space.

Documents from the apex of government, such as Cabinet papers, would clearly be preserved, as would records of statutory bodies, but the paperwork emanating from the wider government/administrative machinery would seem more ephemeral and less likely to be preserved. In the end, it was determined by contemporary views on likely future value. Even this apparently coherent approach was subject to the vagaries of accidental destruction and record loss. For example, the frequent changes in ministry boundaries, such as when the Department of Health became the Department of Health and Social Security, established orphan records for which no-one was responsible nor knew what significance they held.

The digitalisation of administrative records over the last two decades has helped solve the constraints of physical storage. But besides the challenge of choosing digital formats that are unlikely to be superseded, digitisation has also added potential new domains of written communication, such as emails and texts. Which of these apparent ephemera might prove to be of future importance? And the sheer volume of records that can now potentially be stored makes it even harder to identify those that were key for any decision or policy (The National Archives, 2012).

Records concerning blood and blood products

Records concerning the supply of blood and blood products during the final three decades of the 20th century are unlikely to have survived. Responsibility for the supply of blood lay with regional centres, managed by Regional Health Authorities. Regional Health Authorities have long since gone and their successor organisations – Area Health Authorities, Family Health Service Authorities, etc – have also disappeared. Systematic preservation of administrative records from this level of decision-making seems unlikely. Some records from the Ministry of Health (later the Department of Health and then the Department of Health and Social Security) have survived but as most decisions were taken at a ‘local’ level, reflecting the decentralised origins of the NHS, most records were probably destroyed. The NHS consumes vast quantities of goods and services and there was no reason to assume that blood was special in any way.

In summary, it is improbable that any records of routine blood procurement decisions still exist, at least in a systematic format. At the time the destruction of these and other records was not regarded as controversial. What does exist, however, are contemporary reports in the media, particularly medical journals, of the struggle to supply sufficient safe blood products. These have been confirmed and amplified by personal recollections in the Wellcome Witness Seminar on the recent history of the management of haemophilia (Tansey and Christie, 1999) and from accounts provided by key protagonists directly to the Inquiry. These personal recollections may in fact be more valuable than contemporary records as there is now considerable evidence that minutes of meetings, for example, often do not accurately reflect discussions that occurred and even report 'decisions' that were not actually made (Booth and Glynn, 1979).

Record keeping in the NHS

When the NHS was formed in 1948 it integrated a complex system of local government funded hospitals and voluntary hospitals. Every hospital had a different clinical recording system and these differences persisted during the early years of the NHS. In 1956 the Public Records Act required clinical records to be preserved. Accordingly, each hospital arranged its own storage of patient records.

At the same time a national clinical record system was put in place across general practice. This was based on what was called the Lloyd George system which involved a record card – about A5 size – that fitted into an envelope on which was written the patient's name, address, NHS number, together with clinical information. At the outset of the NHS 90% of GPs were single-handed and most relied on close knowledge of patients and their families so it was unusual for much clinical information to be collected on these cards. On the patient's death, the Lloyd George record was sent to a central NHS repository where it was kept for up to eight years (later extended to ten years) before being destroyed.

The accumulation of clinical activity in the early years of the NHS put pressure on the available physical capacity for storing notes. In 1956 the Ministry of Health offered official guidance on the destruction of hospital records. Records from mental and mental deficiency hospitals were not to be destroyed nor were any clinical records of historical importance. Documents relating to legal actions or complaints had to be kept for at least six years. Otherwise, medical records, including blood transfusion records, were to be kept for six years after treatment and destroyed three years after the patient's death.

Records relating to donors in the Blood Transfusion Service could be destroyed one year after the resignation or death of the donor. When the Public Record Act of 1958 was passed it gave authority for local NHS staff to destroy records in accordance with an approved 'Retention and Disposal Schedule' (Nicol and Sheppard, 1985). In exceptional circumstances clinical records could be marked with 'Do not destroy' if they were believed to have historical interest, be of value in research or where it was believed litigation might be pending. But most clinical records were given a finite life after the patient's death – though in depending on local record management systems, this policy was not always efficiently implemented.

Record keeping in the 1960s and 1970s

In 1965 the Tunbridge Report addressed the chaotic and varied nature of hospital clinical record keeping and recommended some standardisation (Ministry of Health Central Health Services Council, 1965). The common format was to be an A4 folder. Even so, clinical records continued to be a jumble of different sections that struggled to encompass all the clinical care delivered to the patient whether in the form of different types of investigations,

attendance at multiple clinics and A&E, correspondence with GPs, and so on. Removing what was considered extraneous material happened on a haphazard basis. Further, patients attending several hospitals for a variety of illnesses would have different clinical records for each of those hospitals.

During the 1960s and 1970s there were frequent exhortations to keep better clinical records and it gradually became a standard of good practice to do so. By the 1980s, with the rapid growth of group practices, clinical records became a vital way for different GPs to communicate about a patient's medical history. The Lloyd George envelope therefore became an important record of the patient's illnesses and increasingly also contained other items such as the results of investigations sent from hospital laboratories, letters from hospital doctors etc.

Record keeping in the 1980s and 1990s

In 1985 fresh guidance stated that the minimum period for retention of records was extended to eight years after the conclusion of treatment or the death of the patient (with exceptions for mental health patients (20 years) and obstetric records (25 years)). In 1999, the Department of Health published 'For the record: managing records in NHS trusts and health authorities'. This document suggested minimum periods of retention for NHS records. In general, with exceptions for some groups of patients, clinical records were to be destroyed eight years after conclusion of treatment or death.

An Audit Commission review of 1995 was highly critical of clinical records (Audit Commission, 1995). It noted that culling was rarely carried out, that many hospitals continued to have multiple sets of notes, and that many specialities clung to their own versions. They observed that case notes tended to be too fat, many lacked a logical structure, many were illegible, and whilst professional bodies had set out their own 'standards', their members tended to ignore them. Hospitals were also notorious for losing patients' notes. A record required in one clinic could often not be found as it was being used by another consultant in another clinic or had simply been 'lost' in the system. Subsequent Inquiries into hospital failings have also commented on the quality and comprehensiveness of recording important events in the patient's journey through the NHS.

Current practice

With the rapid computerisation of general practice in the 1990s, the information on the Lloyd George record was transferred into a digital format. Electronic Health Records are now the standard for record-keeping in British general practice. The format contains many prompts and relies heavily on structured medical codes rather than free text. On the patient's death, it is recommended the electronic record is sent to Primary Care Support England for storage and kept for 10 years before being destroyed.

Hospitals started to develop electronic medical or health records (EHRs) in the new millennium, a decade or so later than general practice. The effort involved in digitising past records also meant that paper and electronic records co-existed for a considerable period of time. And given the unique systems developed by different hospitals, transfer of EHRs between hospitals ('interoperability') could be challenging.

Electronic records take no physical space and can potentially be stored indefinitely. Yet at the same time as the storage problem was solved, a new reason to destroy records emerged: personal data protection. The Data Protection Act of 1998 together with the earlier Caldecott Report on patient confidentiality emphasised the importance of destroying clinical records in a timely fashion. This meant records were to be retained for as long as they were required

but no longer. Records containing personal information were subject to Data Protection Legislation. The fifth principle of the GDPR, for example, stated that ‘personal data shall be kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed’.

In 2006 the NHS published a new code of practice on NHS records management that updated the 1999 guidance. This broadly followed earlier guidance but with renewed emphasis on data protection and potential litigation. As before, retention was ten years after death for GP records and eight years for hospital records. A new category involved patients who had had a transfusion: ‘As of November 2005 all records that contain information relating to blood transfusions will need to be retained for 30 years post transfusion. Information relating to transfusions carried out pre-November 2005 is not affected.’ Also, it was advised that CJD patients’ notes should be retained for 30 years. For the personal health records of patients who had been or were involved in litigation, records were not to be destroyed and kept permanently.

Access and ability to amend own medical records

Historically, clinical notes have provided a reminder to clinicians of the medical history of their patients. This information became more important during the 20th century as chronic illnesses began to be recognised and an accurate record enabled disease progression to be tracked. Even so, records were still a support for clinical decision-making and where memory did not have to be reinforced – as with many encounters in single-handed primary care where the GP was very acquainted with the patients and their problems – they were used in a perfunctory way. With the growth of group practice in primary care where patients might see different doctors and of the clinical team in hospitals where many individuals were involved in a patient’s care, the medical record became a more important part of clinical communication and care provision. But if the medical record then contained a detailed account of the patient’s illness, why should it be restricted to clinicians?

Despite several experiments by clinicians in enabling patients to see their records, the main driver for giving access was legislative. A series of reforms from the mid-1980s promoted Data Protection as well as Freedom of Information. The data about individuals held by any organisation, including the health service, needed to be accurate, fit for purpose and retained for no longer than necessary. The only way personal medical data could meet these criteria was by giving patients access to their records. But first, a number of hurdles had to be overcome.

Medical records had been used to remind the clinician of the patient’s illnesses, investigations and treatments. As such they contained comments that patients might have felt offensive or rude. They might also have contained clinical details which had not been disclosed to the patient. For example, until the 1970s it was unusual for a cancer diagnosis to be revealed to the patient in case they might become ‘alarmed’. A decade or so later this practice had begun to change but clinical notes still contained some diagnoses that the clinician had not had opportunity to discuss and explain to the patient. Also, some psychiatric diagnoses were viewed as particularly sensitive, especially given the stigma that might accompany them. Finally, clinical records often contained details about third parties. A GP, for instance, might record that a patient’s spouse was depressed or that a near relative had had termination of a pregnancy, especially for those GPs who tried to practise ‘family medicine’.

The first response to the legislation that gradually gave patients the right to see their records was to start writing more ‘sanitised’ notes. The second was to edit and censor older records, which was a time-consuming business. There were also more immediate practical problems

to be overcome. If the notes were in a physical format, a private space needed to be provided where they could be read (Fisher et al., 2007). With the spread of digitisation and internet access in the new millennium, the challenge became one of enabling secure remote access.

There have now been a number of studies that have shown that giving patients access to their medical records can benefit both the patient and their clinicians (de Lusignan et al., 2014; Mold et al., 2015). Communication and satisfaction are improved and the patient's involvement in their own care, particularly in terms of shared decision-making and adherence to treatments, gives them a greater sense of control.

Connecting for health: the ambition for access

The ambitious NHS digital strategy of 'Connecting for Health' envisaged everyone being able to access a summary of the clinical record including medications and allergies with the possibility for the patient to add information. The initiative, however, introduced in 2007, did not prove popular as patients found it difficult to use and unhelpful (Greenhalgh et al., 2010). Clinical records still existed primarily for managing clinical care and much of the information they contained was inaccessible without further support and clarification. In many ways, providing such assistance duplicated the full explanations that a good clinician should be giving their patients anyway.

The solution, as outlined in the 2010 Department of Health's vision of an information revolution incorporating internet access, was to recognise that the access that patients needed would depend on their circumstances and the nature of the record and its contents: 'A "one size fits all" approach to control is unlikely to develop the high degree of engagement in shared decision-making, supported self-care and self-management that we are hoping to encourage' (Department of Health, 2010). Digitisation and web provision enabled records-related access to be implemented particularly in primary care where services include booking and cancelling of appointments, ordering of repeat prescriptions and viewing a summary of records covering coded information about allergies, immunisations, diagnoses, medication and test results. Permission could be withheld if it was felt that access might cause serious harm to the physical health, mental health, or condition of the patient or any other person, or if the record contained information related to or be provided by a third person who had not consented to the disclosure.

The system of record access that has emerged might be described as a patchwork. Patients have legal right to access their records, though they need to know which ones. There always had been, and likely always will be, multiple records reflecting the different components of the NHS (ignoring records in private practice). GPs and hospitals still have different records and recording systems; different hospital specialities and specialties also have had different approaches. Nevertheless, compared with the situation a few decades ago the system has become increasingly more open as the medical record has begun to change its function. In effect, the medical record is taking on a new role. Instead of providing a rather paternalistic account of clinical care that was useful for clinicians, the ideas of shared decision-making, patient involvement and informed choice aimed to make the document potentially of value to both parties.

Priority treatment for those injured as a result of NHS treatment

48. An issue that has been raised for consideration by the Inquiry is whether an individual who is injured as a result of NHS treatment should thereafter be offered priority treatment, or priority access to specialists, by the NHS. Please consider the circumstances in which it might be appropriate for patients harmed by NHS treatment to be treated differently from other NHS patients (e.g. in respect of priority for remedial treatment, or access to psychological support and/or tailored treatment for the particular needs of a group of patients harmed).

The fundamental ethical principles that underlie access to medical treatment within the NHS are egalitarian (treating equally, not based on ability to pay), with prioritisation based on clinical need and urgency (Mossialos et al., 2018). Prioritisation can also be determined by other factors which include waiting time, the patient's personal circumstances and responsibilities and, sometimes, the circumstances of the injury.

The principle of treatment according to need remains fundamental to clinical practice in the NHS, though there are some circumstances in which the likelihood of benefit from treatment may be a stronger guiding principle. In routine clinical practice, prioritisation within the NHS is inevitably influenced by more than an assessment of clinical need, with an accompanying implicit acceptance of other values and principles in play. For example, patients who have been waiting a long time for an operation, and suffering unnecessarily during that time, may be prioritised over those whose need might be great but who have been waiting a shorter time. Long waits are in effect prioritised over clinical need. In addition, those dealing with waiting lists may also consider the patient's personal circumstances, such as whether their condition is affecting their ability to work or to be a carer for someone else. A knee injury, for instance, could have a major impact on a person doing manual work or caring for others, but only a modest impact on a person working from home without caring responsibilities (Hutchings and Mitchell, 2021).

Clinicians may also, in some circumstances, prioritise patients according to the benefit they might derive from the treatment, rather than strictly on need. For instance, in the recent COVID-19 pandemic, intensive care resources were limited, and it was reasonable to prioritise those patients who were most likely to benefit from intensive care. Clinicians reasonably, although with much internal struggle, prioritised patients who were most likely to benefit from the limited resources available rather than strictly on the basis of clinical need. Similar examples can be found in any settings where resources available outstrip clinical need (Wilkinson, 2020a).

The NHS does not have any formal policies to accord priority treatment to those injured by healthcare. However, there have been some examples of a degree of prioritisation of patients who suffered unsafe treatment. For example, in the late 2000s it was discovered

that some 47,000 British women had received breast implants which had been fraudulently manufactured with an unapproved silicone gel that were more likely to rupture or leak than other implants (National Health Service, 2019). The vast majority of these implants were cosmetic procedures undertaken in the private sector and most, though not all, of the private medical groups involved agreed to provide remedial treatment without charge. A limited number had been implanted by the NHS as breast reconstruction following cancer surgery. The NHS's response was to monitor recipients, removing and replacing those fitted by the NHS, while agreeing to also replace implants when medically necessary if a private provider refused to do so or had gone out of business. The NHS did therefore respond and give particular attention to women affected by unsafe breast implants, although the numbers were small and would have had little impact on wider services.

There are also precedents within the NHS for providing additional priority to some groups of patients. For example, veterans are in some circumstances able to receive priority treatment. The Armed Forces Covenant states:

‘Veterans receive their healthcare from the NHS and should receive priority treatment where it relates to a condition which results from their service in the armed forces, subject to clinical need. Those injured in service, whether physically or mentally, should be cared for in a way, which reflects the nation’s moral obligation to them, whilst respecting the individual’s wishes.’ (Ministry of Defence, 2011).

In practice, the prioritisation of service personnel may be inconsistently applied (McGill et al., 2019) and, in any case, prioritisation seems not to be guaranteed. NHS England advises veterans that ‘receiving priority treatment depends on your situation and the nature of the treatment required. This includes: if other people have a higher clinical need than you, the urgency of your treatment and the type of treatment you need’ (National Health Service, 2021). Prioritisation for veterans therefore appears to be limited and dependent on competing needs from other patients. However, underlying this is a clear acceptance that the State has a moral obligation to those injured during service of their country. In a similar vein, some have suggested that treatment for frontline healthcare staff infected by COVID-19 during their work should be prioritised, both out of a duty of reciprocity and because of the need for them to return to work to care for others as soon as possible (Emanuel et al., 2020; Wilkinson, 2020b).

The moral case for prioritisation

The ethical argument in favour of priority for treatment for those injured as a consequence of the NHS is that this would be a matter of fair compensatory justice (Mullen and Okimoto, 2015). Plausibly, if someone causes harm or damage to another, they have an ethical duty to help the other party to recover from that harm or damage. This is, for example, the basis for the expectation that someone (or their insurer) pay for damage in a car accident that they have caused. On this basis, both NHS staff and NHS organisations have a clear moral obligation to provide redress and further treatment. Importantly, this idea of compensation implies that it is over and above what would already be provided. For example, if a patient needs an operation (following a treatment injury), for the NHS to simply provide that surgery in the same way and in the same time frame as for other patients, would not amount to any meaningful compensation for the patient. This viewpoint was recently elaborated by Robert Francis in considering redress and compensation for patients harmed by infected blood (Francis, 2022). He considered that the State should actively intervene to provide redress and support on the grounds that:

- It is likely that in hindsight, the transmission of infection to these patients could have been avoided.

- The harm caused has been devastating and lifelong.
- Those who have been injured have lacked reliable information about the infection, treatment, or not given informed choices.
- They have endured a rollercoaster of raised and then dashed expectations with regard to support and recognition of their plight.
- Legal redress, even if obtainable, would be likely to be an inadequate response.
- The State has over a long period recognised that this group has been deserving of support not available generally and has gradually recognised the inadequacy of what has been offered previously.
- In a civilised and humane society, it is right for governments to recognise and offer a remedy for those who have suffered through no fault of their own from the actions of the State, or indeed natural disasters.
- In the circumstances of the infected, and at least some of the affected, a special case has been made out for compensation over and above the support offered to date.

Many of these points would also apply to other patients injured by healthcare, particularly those seriously affected. This implies a clear moral obligation to provide support and treatment, although Robert Francis did not explicitly address the issue of prioritisation. However, the case of injured service personnel suggests that a moral obligation might confer some priority in treatment.

Supporting patients injured by NHS care

The treatment required by patients injured by healthcare is not different in kind from those for any patient with similar injuries. The NHS needs to treat all injured patients, however those injuries were caused. We consider however, from the moral arguments set out above, that it would be reasonable to give some extra priority to those suffering harm due to medical treatment, though this would only be one factor in overall prioritisation of patients needing care.

Patients may seek or be offered compensation for injuries which would, in theory, allow them to purchase private healthcare for the injuries sustained. However, the great majority of patients will need treatment long before any outstanding litigation is resolved and there is no guarantee that any award would cover the necessary private treatment. According to the recent Infected Blood Compensation Study (Francis, 2022), negligence claims were brought against certain Trusts and Health Authorities for infection with HCV up to 1999. A total of £1.1 million was paid out, averaging £12,790 for each case. Sir Robert concluded: 'I infer that this low level of 'success' for claimants may be attributed to the difficulties in establishing legal liability' (Francis, 2022). Pay-outs at this level would fall well short of facilitating privileged access to private medical treatment.

Following the argument made by Sir Robert Francis, we suggest that there is a case for the relative prioritisation of NHS treatment for patients injured as a result of NHS treatment. Factors to be considered include (a) severity of injury due to failings in healthcare, whether physical or psychological (b) likelihood of deterioration without urgent treatment and (c) wider impact of injury on ability to work and to care for self and others. Severity and impact on life are of course relevant to any patient. Our argument is that some prioritisation should stem from the fact that the injury sustained was due to failings in healthcare, but we should give particular attention to those patients whose injuries are severe and have a major effect on their lives. These patients will not necessarily be treated first, or above others with pressing,

urgent needs. But, where possible, they may receive treatment earlier than they otherwise would. They could also, at no additional cost to the NHS, be given a wider choice of where they might be treated if, for instance, it might be distressing to return to the hospital where the original injury occurred.

We have argued that there is a case for prioritisation, but the practical details and impact of this would need to be explored carefully before being put into practice. Prioritisation of one group of patients inevitably risks disadvantaging other patients and the impact on other patients needs to be assessed. At the very least we would need to determine the criteria for prioritisation, the likely number of people concerned, the nature and degree of prioritisation and the potential impact on other patients.

Regardless of the specific argument about prioritisation, NHS staff and organisations have some clear and existing obligations in respect of patients who are injured by healthcare. These are covered in more depth in the earlier section on duty of candour but should be emphasised again in the context of prioritisation. These obligations include:

- Providing an apology where appropriate.
- Providing an explanation of what happened to patients and, where appropriate, their families and others affected.
- Provide treatment for any physical health problems arising as a consequence of healthcare, whether or not prioritised over other patients.
- Provide treatment and support for any mental health problems arising as a consequence of healthcare.

Irrespective of prioritisation, NHS organisations should fulfil their existing obligations to support patients they have harmed. There are some excellent examples of long-term support of injured patients by dedicated patient safety and risk management staff and much good practice that could be more widely shared, but support for injured patients appears to be extremely variable across settings and organisations (Gallagher et al., 2018; Cribb et al., 2022). Senior leaders of NHS organisations and NHS regulators should give much more attention to this issue and make it a badge of honour that they and their organisations are open about harm and support those they have harmed.

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Appendices

Appendix A

Summary of main NHS reorganisations in England, 1974-2021

Act	Comes into effect	Details
National Health Service Reorganisation Act 1973	1974	<p>Regional hospital boards abolished</p> <ul style="list-style-type: none"> environmental health functions and some health education remained with local authorities <p>14 regional health authorities (RHAs) established – to coordinate:</p> <p>90 area health authorities (AHAs)</p> <ul style="list-style-type: none"> coterminous with local authorities to facilitate cooperation especially around social services and public health single-district or multi-district hospital, family practitioner, and personal services transferred to AHAs public health responsibilities transferred from local authorities new post of district community physicians appointed by AHAs to district teams <p>Local authorities</p> <ul style="list-style-type: none"> medical officer of health abolished statutory powers for infectious disease control remain with local authority new lead for environmental health: chief environmental health officer to appoint a medical officer of environmental health (MOEH), usually a community physician employed by AHA – usually the proper officer
	1977	Communicable Disease Surveillance Centre (CDSC) established in the Public Health Laboratory Service (PHLS)
Health Services Act 1980	1982	<p>AHAs abolished</p> <ul style="list-style-type: none"> loss of geographical link with local authority <p>192 district health authorities (DHAs) established</p> <ul style="list-style-type: none"> based around district hospitals community physicians move to DHAs <p>RHAs remain</p>
	1987	<p>Health Education Council abolished</p> <p>Health Education Authority (HEA) established</p>

Act	Comes into effect	Details
Health Authorities Act 1995	1996	RHAs abolished 8 NHS Management Executive (NHSME) regional offices replace RHAs <ul style="list-style-type: none"> took some public health doctors out of NHS DHAs abolished 95 health authorities established
	2000	HEA abolished Health Development Agency (HDA) established <ul style="list-style-type: none"> health education and improvement
National Health Service Reform and Health Care Professions Act 2002	2002	Health authorities abolished Primary care trusts (PCTs) take on health authority roles 28 strategic health authorities (SHAs) <ul style="list-style-type: none"> de facto established in 2001 took performance management role from NHSME regional DPHs in the SHAs oversaw the implementation of health protection services working with PCTs, local authorities, etc
	2003	Creation of Health Protection Authority <ul style="list-style-type: none"> special health authority absorbed PHLS and CDSC; Centre for Applied Microbiological Research; National Focus for Chemical Incidents absorbed National Biological Standards Board, 2008
Health Protection Agency Act 2004	2004	Health Protection Agency set up as a statutory non-departmental public body <ul style="list-style-type: none"> absorbed National Radiological Protection Board
	2005	HDA abolished; functions moved to NICE
	2006	SHAs reduced to 10 PCTs cut from 303 to 152 <ul style="list-style-type: none"> 70% of PCTs coterminous with local authority
Health and Social Care Act 2012	2013	Health protection centralised in the Secretary of State, health improvement in local authorities HPA abolished creation of Public Health England (PHE) <ul style="list-style-type: none"> executive agency of Department of Health and Social Care took in 90 bodies including HPA, public health observatories, cancer registries, SHAs DPHs and some public health functions to local authorities Clinical commissioning groups (CCGs) replace PCTs

Act	Comes into effect	Details
	2021	PHE abolished Creation of UK Health Security Agency as a non-statutory executive agency <ul style="list-style-type: none"> • health protection Creation of Office for Health Disparities and Improvement <ul style="list-style-type: none"> • health promotion • Other PHE tasks to NHS England (eg, screening)
Health and Care Act 2022		CCGs abolished Creation of 42 integrated care boards

Appendix B

Summary of legal requirements for notifying notifiable diseases in England, Scotland, Wales, and Northern Ireland

Data type	Notifier	Notified	Timescale
England			
Suspected cases and deaths	Registered medical practitioner	Proper office of local authority, who then informs Public Health England	3 days (written) or, if urgent, orally as soon as reasonably practicable (for each body)
Confirmed cases and deaths	Operator of a diagnostic laboratory	Public Health England	7 days (written) or, if urgent, orally as soon as reasonably practicable
Scotland			
Suspected cases and deaths	Registered medical practitioner	Health board, which then informs the Common Services Agency and Public Health Scotland	Health board: 3 days (written) for health board or, if urgent, orally as soon as reasonably practicable PHS: no later than the end of the week in which the information is received or as soon as practicable afterwards
Confirmed cases and deaths	Director of a diagnostic laboratory	Health board in whose area the laboratory is situated, Common Services Agency, and Public Health Scotland	10 days (written), or, if urgent, orally as soon as reasonably practicable
Wales			
Suspected cases and deaths	Registered medical practitioner	Proper officer of local authority, who then informs Public Health Wales	3 days (written), or, if urgent, orally as soon as reasonably practicable (for each body)
Confirmed cases and deaths	Operator of a diagnostic laboratory	Proper officer of local authority, who then informs Public Health Wales	Local authority: 3 days (written) or, if urgent, orally as soon as reasonably practicable PHW: 3 days (written), or, if urgent, orally as soon as reasonably practicable
Northern Ireland			
Suspected and confirmed cases and deaths	Medical practitioner	Director of public health for Northern Ireland	As soon as suspected or confirmed

Appendix C

Healthcare and Public Health in the UK's Devolution Settlements

The table below shows the current devolution status of various health-and medicine-related matters in Northern Ireland, Scotland and Wales. The greater extent of devolution in Northern Ireland reflects in part the longer history of devolution there - the devolution framework in the Northern Ireland Act 1998 reflects very closely the framework of the previous 1973 and 1920 Acts (Northern Ireland Constitution Act 1973; Government of Ireland Act 1920) .

Devolution status of health – and medicine-related matters in Scotland, Wales and Northern Ireland

	NORTHERN IRELAND (Northern Ireland Act 1998)	SCOTLAND (Scotland Act 1998)	WALES (Government of Wales Act 2006)
All health- and medicine-related matters, other than those listed below	Devolved	Devolved	Devolved
Abortion			Reserved - meaning outwith the Parliament's legislative competence.
Medicines, medical supplies and poisons (including price regulation)		Reserved - meaning outwith the Parliament's legislative competence.	
Regulation of health professionals			
Embryology	Reserved - meaning within the Assembly's legislative competence but requires Secretary of State consent.		
Human fertilisation			
Human genetics			
Medical Research Council			
Standards for, and testing of, biological substances (including blood products)			
Surrogacy			
Vaccine Damage Payment Scheme			
Xenotransplantation			

Appendix D

Evolution of risk communication policy in law and in practice

Time period	Position Under English Law	Clinical Practice	
Late 1950s onwards	<i>Bolam v Friern Hospital Management Committee</i> [1957] 1 WLR 582	English law in line with informed consent in other common law jurisdictions. How much doctors told patients about the risks, benefits and alternatives of the proposed medical treatment was a matter to be decided by the 'reasonable doctor'.	Paternalistic
1985	<i>Sidaway v Bethlem Royal Hospital</i> [1985] AC 871 (HL)	A doctor who conformed to a reasonable body of professional opinion was not negligent.	Paternalistic
Late 1990s – mid 2000s	Case law examples: <i>Pearce v Anor v United Bristol Healthcare NHS Trust</i> [1998] EWCA Civ 865; <i>Chester v Afshar</i> [2004] UKHL 41	GMC guidance: advise patients of material risks in relation to medical treatment. (see GMC 'Consent: patients and doctors making decisions together' (June 2008; updated 9 November 2020)).	Shift from paternalistic to more patient-centred approach
2015	<i>Montgomery v Lanarkshire Health Board</i> [2015] UKSC 11	Affirms GMC guidance (2008). Doctor's duty involved taking 'reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments' (para 87). The doctor is also responsible for explaining to their patient why one treatment option may be medically preferable to others, having made the patient aware of the relative advantages and disadvantages of each option.	Patient-centred approach More formal consent consultations preoperatively, more senior doctors routinely involved, risk explicitly explained and recorded for interventions.

Appendix E

Question 23: Additional response

This additional response is provided by Professor Allyson Pollock and Dr Margaret McCartney.

23. *What (if any) weaknesses does the Group identify in the way in which decisions about health policy and in particular decisions about the response to emerging health risks are made? Please include consideration of the impact of structural reorganisations, and frequent movement of both Ministers and civil servants, on the ability of governments to identify and address relevant issues such as infected blood. How could those weaknesses be addressed?*

We wish in this Appendix to provide some more text which readers might find helpful, mainly in relation to Question 23, and to identify where we do not agree with the response.

Identifying, and compiling a list of, the system's general weaknesses only makes sense once the system, and the impact of funding cuts, structural reorganisations and marketization, are understood. The opening paragraph of the response to Question 23 does draw attention to the particular relevance of the response to Question 17, which addresses these issues, though these are only partially characterised in the opening. This might give the impression that the weaknesses listed in the response to Question 23 have been identified as a result of the analysis of the issues addressed in the response to Question 17.

If it had been, for example, the increasingly independent operation of 'the system' would not be placed at the door of delegation. There always was delegation in the NHS, right from the start, whereas local authorities were responsible for communicable disease control in their own right, not as delegates. The increasingly independent operation of the NHS in England, and disruption of information flows, began with the creation of Trusts and the internal market in 1990, and was furthered in 2003 by creation of NHS foundation trusts, in 2012 by the disestablishment of services from area bodies, abolition of the minister's duty to provide key services and introduction of virtually compulsory tendering, and has been taken yet further in 2022 by the creation of 42 integrated care systems (Roderick and Pollock, 2022).

The structures for effective collaboration and information sharing – between the local and the national, and between health authorities – were there, and have been eroded or dismantled, and replaced by marketized public bodies, or private companies pursuing their own strategies and interests. Public health departments in health authorities were able to access and exchange patient data from every other health authority without going through elaborate hoops, and there was never a data scandal; similarly for university researchers. The systemic problem with producing high quality data and information sharing is the increasing fragmentation and erosion of local systems for information sharing, and the commodification and sale of patient data.

Similarly, structures and mechanisms for and expertise in workforce and service planning and for ensuring public accountability of services to patients and the public have also been systematically dismantled. Specifically, lack of attention to the patient voice is due to the erosion and abolition of the different routes and mechanisms that were in place for patients and the public to highlight deficiencies in or additional needs for service provision. These included Community Health Councils, which although severely under-resourced were extremely effective in some areas, joint consultative committees with local authorities and boards of area health authorities with broad membership. The patient voice has been reduced to that of the consumer seeking redress through complex complaints processes.

Medical defensiveness towards patients also needs to be placed in context of general management reforms with loss of technical expertise and adverse changes in culture increasingly driven by league tables, performance targets, and Trust policies including reductions in staffing and lowering skill mix. There has been a politically driven downgrading of the value of expertise. These changes permeate clinical care and affect all patients and their interactions with clinical practitioners, not just women as stated.

Clinical autonomy - the power of consultant clinicians and staff to speak up for patients and for patient safety without risk - has been replaced by complex 'whistleblowing' protected disclosure policies as Trusts seek to protect and maximise income and reputation in the marketplace. Staff can no longer speak freely without fear of sanction.

Medicine is practiced in systems – a blame culture perpetuates blame, fear and defensiveness and does not lead to better care. A more critical analysis is needed.

The frequent reorganisations have indeed been extremely disruptive, but it is important to understand their purpose, and their additional effects on local accountability, abolition of PHLS, the centralisation of infectious disease control and the loss of capacity for local health protection in local authorities and carving out of public health from the NHS in 2012.

The suggestion of avoiding major reorganisations if at all possible is not insightful. The rebuilding of local public health and communicable disease control capacity and expertise, and reinstating the NHS in England as a publicly provided, funded and accountable system cannot be achieved without further legislation, as recommended in the responses to Questions 20 and 27, respectively.

Finally, we wish to comment on the following aspects of the response to Question 23 which touch on the COVID-19 pandemic.

Problems with information sharing across the NHS have already been well documented and should be addressed as part of wider initiatives. Contrary to the statement that '*Effective collaboration and information sharing (as seen to some extent during the COVID-19 pandemic)*', the inability to share information was part of the reason for the failures in the track and trace system to the extent that statutory requirements for disease notification were not followed, and/or data were not shared with public health departments in sufficient detail to undertake contact tracing (Roderick et al., 2020).

If the necessary systems, capacity and expertise had been in place the response to the pandemic would have been more coherent and far less costly to the public purse and society as a whole. Thus, we do not agree with two other statements in respect of the response to the pandemic. First, that '*During the COVID-19 pandemic, the UK Government, especially, has appeared reluctant to make decisions on a precautionary basis, setting a much higher bar for evidence – in some cases waiting for it to be 'overwhelming' – than many other countries. This has proven costly, with countries that locked down faster, for example, suffering proportionately fewer fatalities.*'

The pandemic is still ongoing and the evidence for the impact (harms and benefits) of early/late and prolonged lockdowns on the whole of society is still evolving. Ranking of country mortality rates from COVID-19 are continuously changing, due to different population demographics and exposure rates over time, while evidence of long term harms due to lockdowns is still emerging, for example in children and older people, on mental health, obesity, employment etc.

Nor do we agree with the statement that *'the government's own assessment of risk has tipped in a new direction....and has often struggled to communicate any changes effectively to the public'*. Government communications did not highlight uncertainties, absence of evidence (McCartney et al., 2021) nor did they adapt their communications when new evidence became apparent. As a result, risks were exaggerated for some groups and settings (particularly children, young people and schools) and failed to take account of other risks, including residents in long stay institutional settings, obesity and ethnicity.

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3. McCartney, M, Sullivan, F, Heneghan, C. (2021). Information and rational decision-making: explanations to patients and citizens about personal risk of COVID-19. *BMJ Evidence-Based Medicine*, 26:143-146.

Verifying Statements

Each contributing group member confirms that he or she understands his or her duty to provide independent evidence and has complied with that duty.

All contributing group members confirm that in respect of those parts of the report to which they have contributed:

- (i) They have made clear which facts and matters referred to in this report are within their knowledge and which are not.
- (ii) Those that are within their knowledge they confirm to be true.
- (iii) The opinions they have expressed represent their true and complete professional opinions on the matters to which they refer.

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Michael Bichard has had a career in local and central government and academia. He was Chief Executive of two local authorities - the London borough of Brent and Gloucestershire County Council - the Chief Executive of the Benefits Agency and then the Permanent Secretary of the Department for Education and Employment. He was Vice Chancellor of the University of the Arts and Chaired the Soham Inquiry before becoming the founding director of the Institute for Government. He has recently retired as Chair of the National Audit Office and has also chaired the Legal Services Commission, the Social Care Institute for Excellence, the Design Council and Shakespeare's Globe.

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Charles Vincent is Professor of Psychology, University of Oxford and Emeritus Professor Clinical Safety Research, Imperial College London. He trained as a Clinical Psychologist and worked in the British NHS for several years. Since 1985 he has carried out research on the causes and scale of harm to patients, the consequences for patients and staff and on methods of improving the safety of healthcare. He established the Clinical Risk Unit at University College in 1995 before moving to the Department of Surgery and Cancer at Imperial College in 2002. He is the editor of *Clinical Risk Management* (BMJ Publications, 2nd edition, 2001), author of *Patient Safety* (2nd edition 2010) and author of many papers on medical error, risk and patient safety. With Rene Amalberti he published 'Safer healthcare: strategies for the real world', Springer, Open Access (2016). He has advised on patient safety in many inquiries and committees including the Bristol Inquiry, Francis Inquiry and Berwick Review.

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Allyson Pollock qualified as a medical doctor in 1983 and is a public health physician and a clinical professor of public health with an honorary appointment at (what was) Public Health England. As well as working in hospital medicine, she previously worked as a public health physician in several health authorities in London, and also at the Kings Fund and the Health Education Council. She has held a number of university positions. She was director of the Public Health Policy Unit at University College London, as well as director of research and development at UCL Hospitals NHS Foundation Trust from 1998 to 2005. From 2005-2011 she was director of Edinburgh University's Centre of International Public Health Policy and honorary consultant in public health at Lothian Health Board. From 2011- 2016 she was director of the global public health policy unit at Queen Mary University of London. She is currently at Newcastle University where she was director of its Institute of Health and Society (2017-19) and its Centre of Excellence in Regulatory Science (2019-2021). She has expertise in health service reform and marketisation, and has for two decades, actively promoted universal public health care in the UK. Recently she has been a member of the Independent SAGE, advising on COVID-19 in the UK. She was a member of the BMA Council, is a founding member of Keep our NHS Public and is also currently president of the Socialist Health Association.

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Clare Salters is a former senior civil servant whose work over several decades focused primarily on devolution structures, constitutional frameworks, the Northern Ireland political process and human rights. In addition to her work at the Northern Ireland Office, she also worked briefly in the Department of Health, in the Northern Ireland Department for Health and Social Services, served as Deputy Secretary to the Iraq Inquiry and was Chief Executive of the Civil Service Commission.

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Nicholas Timmins is a senior fellow at the Institute for Government and the King's Fund. He is also a senior associate of the Nuffield Trust. He was previously public policy editor at the Financial Times. Nick is currently looking at the immediate impact of the legislative changes to the way the NHS operates, through the eyes of some of the chairs and chief executives of the new organisations.

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Kieran Walshe is professor of health policy and management at Manchester Business School. He was a healthcare manager before becoming an academic. His research focuses on reforms to health professions regulation, on the use of inspection and rating in the regulation of healthcare organisations and services, and on organisational capabilities and processes for improvement.

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Letter of Instruction

This report answers the following questions, extracted from the letter of instruction to the public health and administration expert group.

General principles concerning public administration

15. Please:

- a. identify and explain what ethical principles, norms, rules or frameworks arise within, or apply to, public administration and in particular government decision-making and actions (please note that there are more detailed questions about candour and transparency below);
- b. explain what is meant by the principle or convention of ministerial responsibility;
- c. identify any relevant guidance, publication, analysis or principles which may assist the Chair in considering where responsibility lies for effective decision-making that involves ministers, civil servants and experts such as clinicians and, in particular, when considering who is responsible for ensuring that advisory and decision-making structures are effective;
- d. identify and outline any other principles and/or conventions which you consider may be relevant to the assessment of government decision-making and actions.

General principles concerning public health

16. Please explain what the concept and/or discipline of “public health” encompasses today, in the United Kingdom.
17. Please explain, in broad terms, how public health expertise and institutional arrangements have been, and are, funded, structured, organised and utilised by the governments and the NHS in the United Kingdom. To the extent that you are able to, please:
 - a. identify any particularly significant historical developments; and
 - b. address the development of the Public Health Laboratory Service and the Communicable Disease Surveillance Centre and their role in assessing risk.
18. Please explain the meaning, origins and development of the “precautionary principle” as it applies to public health and healthcare decisions in the United Kingdom.
19. Please identify any other particular principles that underlie the current understanding and practice of public health and how these principles have changed over time (if at all).
20. Please consider and explain the role of public health and epidemiological expertise in response to an emerging health risk; how such expertise should best be used; and where responsibility lies for ensuring that such expertise is utilised.

Government decision making and implementation in respect of health policy in the United Kingdom

21. Please explain, in broad terms, the way in which health policy is made and implemented in the United Kingdom and identify any relevant systems, structures, processes and principles, taking into account the conflicts inherent in central policy making and local delivery, and the prevailing ethos for many years of the NHS.
22. Please consider, and include any observations that you have about, the respective roles and responsibilities of:
 - a. government ministers;
 - b. the Chief Medical Officers and Deputy Chief Medical Officers;
 - c. the civil service;
 - d. NHS executives and administrators; and
 - e. external/independent expert advice/advisors;

in decision-making regarding emerging health risks and in particular in terms of ensuring that the response to an emerging health risk is timely and effective.
23. What (if any) weaknesses does the Group identify in the way in which decisions about health policy and in particular decisions about the response to emerging health risks are made? Please include consideration of the impact of structural reorganisations, and frequent movement of both Ministers and civil servants, on the ability of governments to identify and address relevant issues such as infected blood. How could those weaknesses be addressed?
24. Please set out (i) any shortcomings that the Group may identify and (ii) any recommendations that the Group may have in relation to the following:
 - a. Ensuring that there are effective structures, systems and cultures in place to enable an accurate, balanced and comprehensive assessment of health risks (in particular risks arising from NHS treatment itself).
 - b. Ensuring that there are effective structures, systems and cultures in place to enable a timely and effective response to emerging health risks. Including the extent to which, if at all, the lack of continuity of officials and Ministers may contribute to those risks.
 - c. Ensuring that ministers and other relevant decision makers are provided with accurate, timely and balanced information and advice about emerging risks to public health, particularly where those risks arise from the administration of medical treatment or products, and how best to respond to them;
 - d. Ensuring that ministers and other relevant decision makers are able, where appropriate, to challenge the advice with which they are provided on risks to public health or the response to such risks.
25. What are the common pitfalls in decision-making that lead to failures to respond to emerging health risks and to risks to patient safety? What recommendations do the Group have to address such pitfalls? What is the impact of a lack of a cross-cutting approach to policy-making across Departments, particularly in relation to infected blood?

26. What role in the formulation and/or implementation of healthcare policy do/should the following have?
 - a. International declarations and conventions regarding healthcare.
 - b. The recommendations of international organisations such as the World Health Organisation.
27. Among the themes that the Inquiry is considering is that of (i) the ability of government to plan and implement long-term projects on matters related to healthcare, such as the efforts made during the 1970s and 1980s to achieve self-sufficiency in blood products, and (ii) the responsibility of government to advance long-term research and development and other measures to mitigate health risks. In respect of these themes, please comment on the following matters:
 - a. The strengths and weaknesses, historically, of the structures of government in the United Kingdom in respect of such long-term projects or planning (drawing on any examples that you consider to be relevant).
 - b. How the structures of government could be improved in respect of such long-term projects or planning.

Devolution within the United Kingdom

28. Please outline how administrative and political devolution of responsibility for healthcare within the United Kingdom has evolved over time.
29. What have been/are the advantages and disadvantages of devolved responsibilities for healthcare in terms of the response to emerging health risks/issues of patient safety?
30. What relationships and mechanisms help to ensure that patient safety is not negatively affected by parallel decision-making arising from devolved responsibilities for healthcare, and how have these varied over time?

The role of patients and patient representative organisations in healthcare policy

31. Please explain the current role played by patients and patient representative organisations in informing and shaping health policy, including in response to emerging health risks, in the United Kingdom. In particular:
 - a. Please explain the principles underpinning the role played by patients and patient representative organisations.
 - b. Please comment on any shortcomings or recommendations the Group identifies in this area.
32. Please comment on how the practice and principles of patient involvement have developed, identifying any significant changes that have taken place in the time period of relevance to this Inquiry.

The communication of risk in the provision of healthcare

33. Please explain the current principles underlying the way in which the risks of receiving certain medical treatments or products and/or information about emerging health risks should be explained to:

- a. particular groups of patients (especially those who might be at particular or enhanced risk); and
- b. the public as a whole.

In answering this question please consider whether there are ever circumstances (and if so what) in which reassurance should take priority over the provision of clear and candid information about that which is known, that which is thought to be probable and/or that which is believed to be possible.

34. What are the respective roles and responsibilities, in terms of both public messaging about risks and ensuring that there is a robust system for the provision of appropriate information about risks to particular groups of patients, of:
 - a. ministers;
 - b. the Chief Medical Officers and Deputy Chief Medical Officers;
 - c. civil servants;
 - d. NHS executives and administrators;
 - e. organisations representing those within the medical profession (e.g. for example, organisations charged with providing advice on particular specialities and sub-specialities)?

Please note that you are not being asked to explore in any detail the ethical and/or professional responsibilities of individual clinicians to individual patients, which has been addressed by the Inquiry's Medical Ethics Group in its [report](#) and [oral evidence](#).

35. Please comment on how the practice and principles of warning of risk have developed, identifying any significant changes that have taken place in the time period of relevance to this Inquiry.

The duty of candour, transparency, accountability and redress when mistakes are made

36. Please explain the current principles underlying duties of candour relating both to medical accidents, errors or harm and to poor practice or failings in public administration more broadly.¹ In particular, please comment on:
 - a. The principles underlying a duty of candour in respect of the UK government and the devolved administrations.
 - b. The principles underlying a duty of candour in respect of NHS bodies.
 - c. The principles underlying a duty of candour in respect of individual doctors, civil servants, NHS executives/administrators, and ministers.
 - d. Whether the duties of candour discussed include a duty to apologise.
 - e. How the relevant duties of candour are monitored, judged and enforced.

¹ When considering the issues raised in this section, please define "medical accidents and poor practices" so as to include near-miss events.

37. Please comment on any shortcomings or recommendations the Group identifies in this area.
38. Please explain how the principles underlying the duty of candour (and any associated duty to apologise) have developed, identifying any significant changes that have taken place in the time period of relevance to this Inquiry.
39. Please comment on the role and significance of reflective learning in achieving best practice in the provision of healthcare and decision-making regarding public health risks. Please consider how, if at all, such reflective learning applies to those within relevant government departments (i.e. ministers and civil servants) and to those working within the NHS.
40. How effective have government and the NHS been in learning from past errors, failings and poor practice and why? Please comment on what improvements the Group feel could be made in this area, and provide recommendations on how such improvements could be achieved.
41. Please explain what if any mechanisms are currently in place to provide for (i) transparency and (ii) accountability, when mistakes are made in the provision or regulation of healthcare or the response to public health risks in the United Kingdom.
 - a. Please comment on how such mechanisms have developed, identifying any significant changes that have taken place in the time period of relevance to this Inquiry.
 - b. Please identify any mechanisms or examples that the Group consider to have been particularly successful or unsuccessful in this area (including examples of good practice drawn from elsewhere in the world, if relevant).
 - c. Please comment on any shortcomings or recommendations the Group identifies in this area.
42. Please comment on mechanisms that might be used to ensure that those (whether they are private or public bodies) who might be partially responsible for medical accidents, errors or harm and/or for poor practice/failings in public administration, would contribute to the costs of dealing with the consequences. In doing so, please consider:
 - a. Any mechanisms that are currently in place in the United Kingdom and, where the Group considers them to be of relevance, in other countries.
 - b. Whether other mechanisms in other fields could usefully be implemented, or considered for implementation, in respect of healthcare in the United Kingdom.
43. Please outline what avenues of redress or support (outside of individual legal action) are available for those affected by medical accidents, errors or harm or by poor practice and failings in public administration. Please comment on any shortcomings or recommendations the Group identifies in this area.

Record keeping

44. What principles do and/or should govern the approach to record keeping and archiving by:
 - a. Government departments;
 - b. NHS bodies; and
 - c. regulatory or other bodies concerned with healthcare?
45. Please comment on how those principles have developed, identifying any significant changes and/or omissions that have occurred in the time period of relevance to this Inquiry.
46. What principles and practices govern the access that individuals have or should have to their own medical records (including medical information relating to them held by non-NHS organisations)? Please comment on how those principles and practices have developed, identifying any significant changes that have taken place in the time period of relevance to this Inquiry.
47. What principles and practices govern the ability that individuals have or should have to seek the amendment or correction of their own medical records (including medical information relating to them held by non-NHS organisations)? Please comment on how those principles and practices have developed, identifying any significant changes that have taken place in the time period of relevance to this Inquiry.

Priority treatment for those injured as a result of NHS treatment

48. An issue that has been raised for consideration by the Inquiry is whether an individual who is injured as a result of NHS treatment should thereafter be offered priority treatment, or priority access to specialists, by the NHS. Please consider the circumstances in which it might be appropriate for patients harmed by NHS treatment to be treated differently from other NHS patients (e.g. in respect of priority for remedial treatment, or access to psychological support and/or tailored treatment for the particular needs of a group of patients harmed).

