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1.5 Recommendations

Introduction

In the light of all the evidence available to the Inquiry, and the submissions made to it, I have a number of recommendations to make. There is a danger in inquiries making too many recommendations: it becomes difficult to see whether action is truly being taken to avoid the errors of the past being repeated. Of the many recommendations which might have followed, therefore, this Report will concentrate upon a small number. I acknowledge that some participants may regret that I may not have chosen one which is their particular concern. Some of the lessons to be learned which were set out in the previous chapter *Lessons to be Learned* might also have resulted in additional recommendations made formally by the Inquiry. This should not, however, prevent anyone from applying the lessons identified there, avoiding in future the mistakes which have been identified, and using the content of that chapter as a basis for taking further action, and does not diminish the importance of learning those lessons.

1. Compensation

My principal recommendation remains that a compensation scheme should be set up now.

The Government accepted the moral case for compensation in December 2022 and my recommendations for compensation were made in the Inquiry's Second Interim Report of 5 April 2023.[53]

2. Recognising and remembering what happened to people

The scale of what happened, famously and accurately termed "*the worst treatment disaster in the history of the NHS*", requires recognition and a tangible reminder for future generations. Too many people have lived for too long in the shadows of infected blood. Society needs to show that it now sees what happened to them in its proper light.

Such public recognition involves a formal act of apology from those who had responsibility for what happened, and for failures of response to it. This should be meaningful: an apology on its own will be thought hollow if it does not give sufficient detail as to what the apology is for. It may not be enough (for example) for the Government, or NHS bodies, to say that they apologise for the suffering which has happened. This is an apology, true, but unless more is said, there is insufficient recognition in the words "we apologise" that the suffering is the result of errors made, wrongs done, and delays incurred – first in respect of what happened and why, and second in respect of what then happened by way of organisational response. There have (rightly) been said to be "*three components of full apologies: affect*

53 Hansard parliamentary statement on Infected Blood Inquiry 15 December 2022 p2 COLL0000022, Infected Blood Inquiry Second Interim Report 5 April 2023 INQY0000453

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(regret, remorse), affirmation (admission of fault), and action (compensation, reparation). Expressing sorrow or regret, whilst an important part of the healing process, is at best a partial apology."[54]

An apology should not only give some detail as to what is being apologised for, but to be understood by those to whom it is addressed as sincere and meaningful, it should lead to action. Compensation is part of this. Setting up a compensation scheme and making compensation payments this year, including interim payments as recommended in the Inquiry's Second Interim Report, would be a powerful statement underpinning the sincerity of an apology.

It is so obvious that an apology should be given that the risk of it being seen as given because it was formally recommended might detract from the force of the apology. I have not therefore listed it below, because though I expect one I do not think I need to say any more about it than I have.

In order to provide the public recognition and tangible reminder that is so obviously required, there should be a suitable national memorial. Funds have already been raised in Scotland with a view to there being such a memorial there. I recommend that a steering committee be formed to decide what memorials should be provided, and where, at public expense.[55] Essential voices which should be heard amongst the members of such a steering committee are people who have been infected and affected. The membership should reflect all routes of transmission; it will necessarily contain representatives of the governments of the nations of the UK. The memorial has to be meaningful, and its position appropriately prominent to act as a proper memorial and focus for those who survive, and for people who have been or are carers or who have been bereaved by infection, as well as being capable of being a public reminder.

I recommend that there should also be a memorial dedicated specifically to the children infected at Treloar's school. The memorial should be agreed with those who were pupils at Treloar's and should also be funded at public expense.

Funding should be made available for a biannual networking/support event for those infected and affected, to be organised by a working party of similar composition to the memorial steering committee, save that, although government will no doubt need to have input as to the overall funding, any government representatives should only be part of the working party at the invitation of the other members. Funding should be for a period of at least three events after the publication of this Report.[56] One of the aspects of the operation of the Macfarlane Trust which many found helpful was that in its first few years it organised

54 Quick *Duties of Candour in Healthcare: The Truth, the Whole Truth and Nothing but the Truth?* Medical Law review 2022 p11 RLIT0002448. Professor Oliver Quick quotes the words of Professor Gijs van Dijck as having "*neatly summarised*" the proposition.

55 Though there should remain a place for public subscription by those individuals or organisations who wish to contribute or who already have done so for a memorial in Scotland

56 This recommendation was put forward to the Inquiry by the clients of Collins solicitors and is similar to one put forward by the clients of Leigh Day solicitors for a forum where people can continue to meet virtually and in-person and share their experiences. Submissions on behalf of the core participants

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occasional weekend events which brought registrants of the Trust together. Though there was little professional psychological support given at the time, many have said that they valued the mutual support given by these. The time that people have been able to spend meeting others who have been similarly affected at, and in the margins of, the Inquiry, has also been important to many. The opportunity to stay in contact remains important now, since a large number of people who have been impacted by what happened otherwise live in isolation.

The working party may wish to consider the suggestion made by Collins Solicitors on behalf of their clients that such an event could "*usefully be combined with a public presentation/ update as to the ongoing process of providing compensation and implementing the other recommendations.*"[57]

Accordingly, I recommend:

2. Recognising and remembering what happened to people

(a) A permanent memorial be established in the UK and consideration be given to memorials in each of Northern Ireland, Wales and Scotland. The nature of the memorial(s), their design and location should be determined by a memorial committee consisting of people infected and affected and representatives of the governments. It should be funded by the UK government.

(b) A memorial be established at public expense, dedicated specifically to the children infected at Treloar's school. The memorial should be such as is agreed with those who were pupils at Treloar's.

(c) There should be at least three events, approximately six months apart, drawing together those infected and affected, the nature and timing of which should be determined by a working party as described above, facilitated by some central funding.

3. Learning from the Inquiry

The previous chapter *Lessons to be Learned* draws attention to a number of lessons which are not necessarily intuitive. They are starkly obvious to anyone who has read the rest of the Report, but few people in training for a career in medicine may take that opportunity. A very real danger is that the lessons of the past are forgotten when a fresh history is being made in the years to come, and only then, after another disaster, are remembered. All those responsible for medical education should take steps to ensure that those "lessons to be learned" which relate to clinical practice do indeed become part of every doctor's

represented by Collins Solicitors December 2022 p202 SUBS0000063, Recommendations on behalf of the core participants represented by Leigh Day 17 June 2022 pp22-23 SUBS0000003

57 Closing Submissions on behalf of the core participants represented by Collins Solicitors December 2022 p202 SUBS0000063. Initial submissions on behalf of the Core Participants represented by Collins Solicitors on non-financial recommendations June 2022 p5 SUBS0000015. They had in mind that the minister then responsible should give this, since it would underline the apology.

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training. However, it is above all the hard and awful facts of what happened that doctors need to understand so that the errors are not repeated. A package of training materials, with excerpts from oral and written testimony would underpin what can happen in healthcare, and must be avoided in future.

It has been pointed out by Christine Braithwaite, director of standards and policy at the Professional Standards Authority for Health and Social Care, that:

> "*We have noted in the course of our work that once a review or inquiry is complete, usually after publication, that the secretariat tends to be disbanded. The publication of an inquiry's findings, conclusions and recommendations can bring to light information that others may need to act on. In particular, professional regulators may want to obtain information to help them identify people described anonymously in a report, if there is evidence that calls into question their conduct or competence. This becomes challenging if a review/inquiry team is no longer operational. An example of this is the review into failings at Shrewsbury and Telford Matenity Services*[58] *which reported* [in March 2022]".[59]

The real problem here is access to the material which an Inquiry will have considered in the course of drawing its conclusions, and making its recommendations. Christine Braithwaite's words are a powerful reason for ensuring that the key documents considered by the Inquiry remain available and accessible at no cost to any person who wishes to access them. The material uncovered by the Inquiry (as will be seen by the copious references throughout this Report) underpins conclusions about safety and "next steps", and though maintaining it in a usable form will not be without some cost, it is a small price to pay if by doing so the cause of future patient safety can be advanced. Accordingly, I recommend that the Inquiry website is maintained with full functionality online. Thus I recommend:

3. Learning from the Inquiry

(a) The General Medical Council, and NHS Education for Scotland, Health Education and Improvement Wales, Northern Ireland Medical and Dental Training Agency and NHS England, should take steps to ensure that those "lessons to be learned" which relate to clinical practice should be incorporated in every doctor's training.

(b) They should look favourably upon putting together a package of training materials, with excerpts from oral and written testimony, to underpin what can happen in healthcare, and must be avoided in future.

(c) The Inquiry website is maintained online.

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58 Ockenden Report – Findings, Conclusions and Essential Actions From the Independent Review of Maternity Services at The Shrewsbury and Telford Hospital NHS Trust 30 March 2022 WITN7523009

59 Written Statement of Christine Braithwaite para 12 WITN7523001

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4. Preventing future harm to patients: achieving a safety culture

The account in the chapters of this Report sets out the history of a failure to focus on risk, a failure to put safety first, a failure to listen to voices advising a different course. It also contains a history of systemic failures – a large number of committees, advisory bodies and working groups, many of which seemed partly to cover the same ground as each other, and lacking executive power or sufficient status to demand the ear of those who did have that power. It describes widespread failures of record keeping. The recommendations which follow thus arise out of the Inquiry's Terms of Reference – but it is noticeable that similar failings have been identified throughout healthcare in other inquiries and suggest a wider problem still.

In the NHS there are three particular aspects which demand action:

- First, **changing the culture**, such that safety is embedded as a first principle, and is regarded as an essential measure of the quality of care. Though performance, efficiency, and expense are all important, it should be the safety of care in any health institution that is the aspect in which all its staff take particular pride.
- Second, a **more rational approach to regulation and safety management**, resolving the problems created by the current systems for trying to deliver safer care: which are fragmented, overlapping, confusing, and poorly understood.
- Third, **ensuring a coherent approach to data** – for patients to whom that data relates, and by a body (preferably just one, but if more than one is necessary, then as few as possible) which, with the appropriate consent of the patients concerned, can make use of that data to help identify threats and trends, and better inform protection for others.

To understand the link between these three, it is important to recognise: first, that there have, over the last five decades, been multiple high profile failures of care which have themselves been the subject of earlier public inquiries and recommendations;[60] and second, that it has long been pointed out that the regulatory framework for the NHS is overly complex and disjointed. Thus, for example, in 2002 Professor Kieran Walshe argued that "*Current regulators vary widely in their statutory authority, powers, scope of action, and approach. The resulting mosaic of regulatory arrangements is highly fragmented and some roles are duplicated.*"[61]

60 There is a useful snapshot of some of these inquiries in the period up to 2001 in: Walshe and Higgins *The use and impact of inquiries in the NHS* British Medical Journal 19 October 2002 pp1-2 RLIT0002403. Some of the more recent inquiries, such as the inquiry into the Mid Staffordshire NHS Foundation Trust, are referred to in the main text of this chapter.

61 Walshe *The rise of regulation in the NHS* British Medical Journal 20 April 2002 p2 RLIT0002387. In 2016 the chief executive of the Nuffield Trust argued that "*oversight from so many different bodies creates the potential for confusion and the risk of the 'problem of many hands', in which accountability is distributed and it is not clear who is responsible for key actions*." Edwards *Burdensome regulation of the NHS* British Medical Journal 20 June 2016 p1 RLIT0002413

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By 2019, it was revealed just how much further this fragmentation and duplication had gone when Professor Charles Vincent and others set out in an attempt (for the first time) to describe and understand what body regulated what process within the NHS in England, to what extent, and with what powers. Their study showed that there were then over 126 organisations which exercised some regulatory influence on NHS provider organisations. Three were national overseeing bodies; 18 were statutory regulators. They commented:

> "*The multitude of organisations that are simultaneously involved in various types of activities overseeing healthcare is striking … There is no reason to think that all these organisations should do exactly the same thing, but the variability in approach and overlapping functions suggest that there is no overall integrated regulatory approach … Evidence of overlapping responsibilities, duplication, practical challenges in coordinating regulatory compliance and providing assurance have been extensively documented.*"[62]

There seems an inevitability about the conclusion that:

> "*The regulatory system of the NHS has evolved rather than been designed and is not fully understood even by professional regulators and it is almost impossible for the general public to navigate the system. Regulation is important and the actions of thoughtful and well-intentioned regulatory organisations have the potential to improve health service standards. However, the overall impact of the regulatory system hinders the effectiveness of regulatory actors and can be challenging for NHS providers detracting from safety and quality improvement initiatives.*"[63]

If safety is to be regulated properly, it needs to be easy for an ordinary user of the system to know to whom they can express any concerns they may have about it, who will take up their cause, and what they can expect from them. At the same time, those who are busy working within the system, especially those in leadership roles or on the boards of hospital trusts and health boards, need to have clarity as to what, precisely, is expected of them.

Yet, so far as England is concerned, the Parliamentary and Health Service Ombudsman,[64] Rob Behrens, as recently as 17 March 2024 drew attention (amongst other matters) to the difficulties of navigating the regulatory system. He also saw another problem caused by the current system – he is quoted as saying that there are now "*too many regulators in the health service – too many bodies doing roughly the same thing – [and] they're not sufficiently joined up, which means that decisive action which should be taken isn't taken, because ministers aren't getting one voice about what should happen.*"[65]

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62 Oikonomou et al *Patient safety regulation in the NHS: mapping the regulatory landscape of healthcare* BMJ Open 9 July 2019 pp6-8 RLIT0001735

63 Oikonomou et al *Patient safety regulation in the NHS: mapping the regulatory landscape of healthcare* BMJ Open 9 July 2019 p8 RLIT0001735

64 Each of the four nations has its own ombudsman: the others are the Scottish Public Services Ombudsman, Public Services Ombudsman Wales and Northern Ireland Public Services Ombudsman.

65 The Guardian *NHS ombudsman Rob Behrens: 'There are serious issues of concern'* 17 March 2024 p2 RLIT0002366

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The Professional Standards Authority for Health and Social Care, which has a remit to oversee the statutory regulators of health professionals (including the General Medical Council and the Nursing and Midwifery Council which respectively regulate doctors and nurses across the UK)[66] pointed out that "*the Paterson, Cumberlege, and Ockenden reports describe a fragmented system with patient safety concerns falling through the gaps and the patient voice being lost*"[67] in its report "*Safer care for all*" published in September 2022. The Professional Standards Authority concluded that "*The health and social care safety system, of which inquiries and reviews are an integral part, is made up of a complex jigsaw of institutions. Each has a specific remit, and no single body is tasked with ensuring that together they create an effective safety system that protects patients and service users.*"[68] The Authority considers that there is a problem with:

> "*Harm and risk of harm going unaddressed because:*
>
> - *patients and service users are not listened to*[69]
> - *data is not collected*
> - *information/ intelligence/ data is held in the wrong place and/or not shared with the appropriate bodies*
> - *the extent of a risk is not identified because bodies are not pooling their intelligence/data*
> - *trends that can only be spotted by taking a bird's-eye view are not identified*
> - *a joined-up response is required but none is forthcoming as a result of remit apathy ('not my responsibility') and/or lack of accountability for joint working.*"[70]

The solution proposed by the Professional Standards Authority for Health and Social Care was that there should be a Safety Commissioner in each nation with an overarching role

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66 The remit of the Professional Standards Authority for Health and Social Care encompasses the statutory bodies that regulate health professionals across the UK, and the statutory body that regulates social workers in England.

67 Professional Standards Authority for Health and Social Care *Safer care for all: Solutions from professional regulation and beyond* September 2022 p6 RLIT0001837

68 Written Submission of Professional Standards Authority January 2024 p1 RLIT0002406

69 The examples given were Mid Staffordshire, Cumberlege, and Morecambe Bay. These inquiry and investigation reports are as follows: Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry RLIT0001757, First Do No Harm: The report of the Independent Medicines and Medical Devices Safety Review RLIT0001379, The Report of the Morecambe Bay Investigation WITN7523007

70 Written Statement of Christine Braithwaite para 11 WITN7523001. Christine Braithwaite identified a lack of candour with patients and families (giving as examples Bristol, Mid Staffordshire, Morecambe Bay, Cumberlege – two of which predated the statutory duty of candour becoming law); and gave examples of inquiries which had shown that data was not shared or acted upon (Paterson, Cumberlege, Shrewsbury and Telford). Written Statement of Christine Braithwaite para 15 WITN7523001. The other inquiry and investigation reports are as follows: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995: Learning from Bristol July 2001 DHSC5030766, Report of the Independent Inquiry into the Issues raised by Paterson February 2020 WITN7523006, Ockenden Report – Findings, Conclusions and Essential Actions From the Independent Review of Maternity Services at The Shrewsbury and Telford Hospital NHS Trust March 2020 WITN7523009

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focussed on ensuring that the various bodies charged with protecting the public work together as an effective system, rather than as a collection of disparate institutions and activities. In its view, the remit should not simply be limited to medicines and devices, for this was likely to add a further layer of complexity to an already fragmented system – what it saw as needed was an overall, independent, transparent body concerned with all aspects of patient safety.[71]

There is now a Patient Safety Commissioner for England. Dr Henrietta Hughes began her role with effect from September 2022. However, her role is by statute one in relation to the safety of medicines and medical devices, not overall patient safety. She nonetheless was able to say in a report on her first 100 days that it was clear from what she had been told by patients, healthcare professionals and senior leaders that "*the focus of the health service is on productivity, operational performance, and financial control. Medicine is industrialised when it needs to be humanised. As well as asking 'What's the matter with you?' we should be asking 'What matters to you?' so that healthcare is personal, meaningful, and safer.*"[72]

There is provision, too, in Scotland for a Patient Safety Commissioner.[73] In Scotland the powers are not focussed on medicines and medical devices, but being "*Independent of Government and the NHS and accountable to the Scottish Parliament, the commissioner will have complete freedom to consider or investigate any issue they believe to have a significant bearing on patient safety in healthcare, and will be able to hear from patients and their families as well as gather information from healthcare providers, to inform their work.*"[74] The Act establishing this post became law on 7 November 2023.[75] It has yet to be seen how this works in practice, though on the face of it the remit provides for a wider responsibility than that of the English equivalent.

Simplification of the structures by which safety is promoted or supervised with the NHS is (obviously) highly desirable. One means of moving in this direction would be a coherent safety management system which those who work within the NHS and the patients whose choices of treatment inform healthcare can buy into.[76]

There is little time to waste. Dr Henrietta Hughes, Patient Safety Commissioner in England, said in the report reflecting on her first 100 days in post that "*It is clear that the culture is getting worse and unless leaders set out a strategic intention to listen and act, we are*

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71 Professional Standards Authority for Health and Social Care *Safer care for all: solutions from professional regulation and beyond* September 2022 p14 RLIT0001837, Written Statement of Christine Braithwaite para 18, para 40 WITN7523001

72 Patient Safety Commissioner *100 Days Report* 2 February 2023 p2 RLIT0002394

73 There are presently no plans for a Patient Safety Commissioner in Northern Ireland. On 27 February 2024 the Minister for Health and Social Services in Wales stated he had no plans to introduce such a role in Wales. Senedd Cymru answer given on 27 February 2024 RLIT0002458

74 Law Society of Scotland *Patient Safety Commissioner Bill passes final stage* 28 September 2023 RLIT0002428

75 Patient Safety Commissioner for Scotland Act 2023 RLIT0002436

76 Written Statement of Dr Rosie Benneyworth paras 34-40 WITN7689001, Written Statement of Dr Rosie Benneyworth WITN7689012. Dr Benneyworth is chief executive officer of the Health Services Safety Investigations Body.

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heading straight back to the days of Mid Staffs and other health scandals, severe harm, and death."[77] Over a year has passed since then.

Similarly, on 26 March 2024 Patient Safety Learning (a charity and independent voice for improving patient safety) published a report entitled *We are not getting safer: Patient safety and the NHS staff survey results.* This considered the NHS Staff Survey 2023 for England, and saw in it a need to raise awareness of the urgency of action to create a patient safety culture.[78]

The culture will not change unless candour is ensured as best we can.

The duty of candour

On 6 December 2023 the Lord Chancellor Alex Chalk announced to Parliament that the Deputy Prime Minister Oliver Dowden had that day signed what was to be known as the "Hillsborough Charter" on behalf of the Government. The Charter had been proposed by Bishop James Jones, former Bishop of Liverpool, in his report on the Hillsborough disaster, entitled *The patronising disposition of unaccountable power*.[79] Alex Chalk acknowledged in his response on behalf of the Government that it had taken too long for the Government to respond.[80]

Bishop James Jones had written:

> "*The experience of the Hillsborough families demonstrates the need for a substantial change in the culture of public bodies. To help bring about that cultural change, I propose a charter drawn from the bereaved families' experiences and made up of a series of commitments to change – each related to transparency and acting in the public interest.*"[81]

There are six undertakings in the charter. Apart from the first (which relates to a public tragedy of the kind which happened at Hillsborough) all are applicable to the subject of this Report. They are:

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77 Patient Safety Commissioner *100 Days Report* 2 February 2023 p3 RLIT0002394

78 Amongst its findings in relation to this survey were: "*Turning to questions on clinical safety, the responses to this year's survey show that the percentage of staff who feel secure raising such concerns is now at a five-year low. We note that it is difficult to imagine that such figures in other safety critical industries, where the consequences of incidents may also be serious injury or loss of life, would be deemed acceptable*" and that "*Overall, the results in this section of the survey are a clear indication that we remain far away from the NHS vision of creating a patient safety culture throughout the health service*." Patient Safety Learning *We are not getting safer: Patient safety and the NHS staff survey results* 26 March 2024 p4, p11 RLIT0002386

79 The report had been produced six years earlier. The Right Reverend James Jones *The patronising disposition of unaccountable power: A report to ensure the pain and suffering of the Hillsborough families is not repeated* 1 November 2017 COLL0000025

80 Hansard parliamentary statement on Hillsborough: Bishop James Jones Report 6 December 2023 p2 RLIT0002396

81 The Right Reverend James Jones *The patronising disposition of unaccountable power: A report to ensure the pain and suffering of the Hillsborough families is not repeated* 1 November 2017 p13 COLL0000025

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> "*2. Place the public interest above our own reputation.*
>
> *3. Approach forms of public scrutiny … with candour, in an open, honest and transparent way, making full disclosure of relevant documents, material and facts. Our objective is to assist the search for the truth. We accept that we should learn from the findings of external scrutiny and from past mistakes.*
>
> *4. Avoid seeking to defend the indefensible or to dismiss or disparage those who may have suffered where we have fallen short.*
>
> *5. Ensure all members of staff treat members of the public and each other with mutual respect and with courtesy. Where we fall short, we should apologise straightforwardly and genuinely.*
>
> *6. Recognise that we are accountable and open to challenge. We will ensure that processes are in place to allow the public to hold us to account for the work we do and for the way in which we do it. We do not knowingly mislead the public or the media.*"[82]

This is aimed at organisations: the language ("*we*" and "*our*") is that of the organisation which signs up to the charter, as the UK Government and a number of other organisations (including the police forces in England and Wales) have done. In responding, Alex Chalk said that Bishop James Jones had made it clear that he wanted to "*help bring about cultural change*" through commitments to change "*related to transparency and acting in the public interest.*"[83]

The Hillsborough report and charter derived from a disaster of a very different kind from that which has been the subject of this Report. However, in both there have been allegations of cover-up, and a lack of frankness or desire to tell the truth, a hiding of documents, and a making of assertions for which there was no proper basis in fact – or which, as likely to be read, would in practice be misleading.[84] Bishop James Jones' approach applies with equal force to disasters in the health context, which are likely to arise out of a series of individual experiences revealing some systemic or individual failing.[85]

Recommendations of previous inquiries to change the culture

It is a sad fact that very few inquiries into aspects of the health service or parts of it have ended without recognition that the culture needed to change. Over the past 50 to 60 years there have been several inquiries, of different types – but nearly all have had some such recommendation.

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82 The Right Reverend James Jones *The patronising disposition of unaccountable power: A report to ensure the pain and suffering of the Hillsborough families is not repeated* 1 November 2017 p13 COLL0000025

83 Hansard parliamentary statement on Hillsborough: Bishop James Jones Report 6 December 2023 p2 RLIT0002396

84 See the detail throughout the full Report.

85 Such as the Shrewsbury and Telford Hospital Review, the Bristol Royal Infirmary Report and the Shipman Report.

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An example is that of the Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995, optimistically entitled *Learning from Bristol*. Recommendations made by the Bristol Inquiry included:

> "*To promote a new culture within the NHS: a three-way partnership of respect, honesty and openness between:*
>
> *– NHS and public;*
>
> *– professionals and patients; and*
>
> *– professionals and professionals.*"

Thus:

> "*– The patient must be at the centre of everything which the NHS does …*
>
> *– There must be openness and transparency in everything which the NHS does …*
>
> *– The safety of patients must be the foundation of the NHS's commitment to the quality of its services;*
>
> *– Sentinel events, that is, errors, other adverse events, and near misses, which occur during the care of patients, must be seen as opportunities to learn, not just as reasons to blame.*"[86]

The Bristol Report emphasised the need for change in culture. It also recognised that there was a link between candour and safety. Being open and transparent about a "*sentinel event*" enables possible shortcomings to be treated as an opportunity to improve the quality (that is, the safety) of the NHS.[87] In short, candour is not simply a matter of ensuring trust as between patient and professional, or between both patient and professional on the one hand and the organisation of which the professional is part on the other. It is a matter, more importantly still, of ensuring safety for the future.

Following both the Bristol Royal Infirmary Inquiry report, and *An organisation with a memory* (a study by the Chief Medical Officer of England's expert group on learning from adverse events in the NHS),[88] a National Patient Safety Agency was proposed. One was set up in 2002, and was absorbed into NHS England in 2012. Professor Ian Kennedy had envisaged that it would keep a national database of sentinel events, and anticipated that the culture he proposed should contribute to sentinel events being identified.[89]

When Sir Robert Francis KC reported in the Mid Staffordshire NHS Foundation Trust public inquiry, he noted that the National Patient Safety Agency had however not been alerted to

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86 The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995: Learning from Bristol July 2001 pp444-445 DHSC5030766

87 The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995: Learning from Bristol July 2001 p270 DHSC5030766

88 Department of Health *An organisation with a memory: Report of an expert group on learning from adverse events in the NHS* 2000 RLIT0002440

89 Professor Kennedy chaired the Bristol Inquiry. The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995: Learning from Bristol July 2001 pp368-372 DHSC5030766

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the concerns which he exposed in his Report. He recommended, as recommendation 12 that "*Reporting of incidents of concern relevant to patient safety, compliance with fundamental standards or some higher requirement of the employer needs to be not only encouraged but insisted upon. Staff are entitled to receive feedback in relation to any report they make, including information about any action taken or reasons for not acting.*"[90]

I shall come back to the words "*not only encouraged but insisted upon.*"

The existing statutory and professional obligations of candour

Regulations were made in the year following the Mid Staffordshire report.[91] These were the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.[92] They cover England. Regulation 20 is headed "*Duty of candour*". It provides that "*(1) Registered persons must act in an open and transparent way with relevant persons in relation to care and treatment provided to service users in carrying on a regulated activity.*" (A *"registered person"* means, in relation to a regulated activity, a person who is the service provider, and thus includes NHS trusts; "*regulated activity*" includes treatment by the NHS of a patient; a patient is a "*service user*" for these purposes.) Regulation 20 continues: "*(2) As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a registered person must*" (in summary):

(a) notify the patient that the incident has occurred and provide them with reasonable support;

(b) give them an account of all the facts the registered person knows about the incident at the time to the best of its knowledge;

(c) say what further enquiries the registered person believes are appropriate;

(d) include an apology (though not necessarily an admission of liability); and

(e) record the notification in a written record to be kept securely by the registered person.[93]

With the exception of the provision of reasonable support, it is an offence not to comply, though the health service body has a defence if it proves that it took all reasonable steps and exercised all due diligence to prevent the breach that occurred.[94]

At the centre of this regime is a "*notifiable safety incident*" which is defined as:

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90 The report was now just over ten years ago, itself being just over ten years after the Bristol report. This recommendation followed from facts set out in chapter 2 of his report. Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry Volume 1: Analysis of evidence and lessons learned (part 1) February 2013 p246 DHSC5113232

91 The statutory authority for these was under the Health and Social Care Act 2008.

92 Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 SI 2014 No. 2936

93 Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 Regulation 20 (2) and (3) RLIT0002451

94 Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 Regulation 22 RLIT0002451

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> "*any unintended or unexpected incident that occurred in respect of a* [patient] *during the provision of* [treatment] *that, in the reasonable opinion of a health care professional, could result in or appears to have resulted in (a) the death of the service user* [the patient]*, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition or (b) severe harm, moderate harm or prolonged psychological harm to the service user*".[95]

It appears from a number of the submissions made to me that some core participants were not aware that a duty of candour existed, and in particular were unaware of the terms in which it is expressed.

The duty of candour is imposed upon the health service body, not upon an individual health care professional. (Although the word "*candour*" is used in the regulation as a heading, and it is not defined, the substance of what is meant by candour in this context appears from regulation 20, the material parts of which are set out above.)

However, so far as individual doctors, nurses and midwives are concerned, there is also a duty which may have practical consequences for them if breached. The General Medical Council and the Nursing and Midwifery Council regulate the professional standards expected of any doctor, nurse or midwife. It is unprofessional for such a person to behave without candour towards a patient. The professional obligation of a health professional is to put the patient first. That means putting self-interest to one side; it means being frank, as well as open and transparent.[96]

The Care Quality Commission has issued guidance which sums up the position: "*Both the statutory duty of candour and professional duty of candour have similar aims – to make sure that those providing care are open and transparent with the people using their services, whether or not something has gone wrong.*"[97]

It would be helpful if after the words "*open and transparent*" were added the words "*and forthcoming*": it is all very well to be open and transparent when asked by a patient about an event. It may be another thing to volunteer to the patient the question the patient might have asked, and its answer, had the patient only realised that something which the professional understood to have gone wrong had done so, even though the patient was ignorant of it. Candour is more than being open and transparent, valuable though both qualities are.

In circumstances where a patient has suffered harm or distress, the General Medical Council and Nursing and Midwifery Council express the duty as being to "*explain fully and promptly*

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95 Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 Regulation 20 (8) RLIT0002451

96 See the GMC's guidance Good Medical Practice January 2024 paras 45-46 RLIT0002452, the NMC's guidance The Code October 2018 para 14 RLIT0002453; and their joint guidance Openness and honesty when things go wrong: The professional duty of candour June 2015 RLIT0002454

97 Care Quality Commission *Regulation 20: Duty of candour* June 2022 p2 RLIT0002426

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what has happened and the likely short-term and long-term effects": this in effect equates to being forthcoming.[98]

Health is a devolved issue. The text thus far has concentrated upon the position in England – though the General Medical Council and Nursing and Midwifery Council have a UK wide remit.

The Scottish Government introduced a statutory duty broadly similar to that in England, for NHS bodies, in 2018, under the Duty of Candour Procedure (Scotland) Regulations 2018. As is the case south of the border, the duty rests on organisations, not individuals.[99]

The Duty of Candour Procedure (Wales) Regulations 2023[100] establish an equivalent duty in Wales, requiring NHS organisations in Wales to be open and honest with service users receiving care and treatment in the event of a "*notifiable adverse outcome*".[101]

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98 Though in the joint guidance (2015, predating the guidance using the word "*fully*") on "*Openness and honesty when things go wrong: The professional duty of candour*" the obligation is expressed differently – "*You should share all you know and believe to be true about what went wrong and why, and what the consequences are likely to be.*" The effect is similar.

As to "near miss" incidents, the guidance says:

"*21. … You must use your professional judgement when considering whether to tell patients about near misses. Sometimes there will be information that the patient needs to know or would want to know, and telling the patient about the near miss may even help their recovery. In these cases, you should talk to the patient about the near miss, following the guidance in paragraphs 11–17.*

22. Sometimes failing to be open with a patient about a near miss could damage their trust and confidence in you and the healthcare team. However, in some circumstances, patients may not need to know about an adverse incident that has not caused (and will not cause) them harm, and to speak to them about it may distress or confuse them unnecessarily. If you are not sure whether to talk to a patient about a near miss, seek advice from your healthcare team or a senior colleague." GMC *Openness and honesty when things go wrong: The professional duty of candour* June 2015 RLIT0002454

99 The Organisational guidance says that:

"*The organisational duty of candour procedure is a legal duty which sets out how organisations should tell those affected that an unintended or unexpected incident appears to have caused harm or death. They are required to apologise and to meaningfully involve them in a review of what happened.*

When the review is complete, the organisation should agree any actions required to improve the quality of care, informed by the principles of learning and continuous improvement.

They should tell the person who appears to have been harmed (or those acting on their behalf) what those actions are and when they will happen.

The duty of candour procedure provisions reflect our commitment to place people at the heart of health and social care services in Scotland.

We recognise that when unexpected or unintended incidents occur during the provision of treatment or care, openness and transparency is fundamental. This promotes a culture of learning and continuous improvement."

Duty of Candour Procedure (Scotl248and) Regulations 2018 RLIT0002455, Organisational Duty of Candour guidance March 2018 WITN7671005

The Scottish Public Services Ombudsman has reported 12 cases between March 2021 and December 2023 which have included issues about the duty of candour not being fully observed.

100 National Health Service, Wales The Duty of Candour Procedure (Wales) Regulations 2023 WITN5712003

101 It applies "*if the care we provide has, or may have contributed to unexpected or unintended moderate or severe harm, or death*". A Summary of the Duty of Candour Procedure states:

"On first becoming aware that the duty of candour applies, the NHS must notify the service user or a person acting on their behalf. This contact should be 'in person', which means by telephone, video call or face to face.

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Northern Ireland consulted on introducing a statutory duty in 2021. The responses are currently being analysed. Legislation is not yet in place. The reasons for calling for a statutory duty given by John O'Hara QC (now Mr Justice O'Hara) in his report of The Inquiry into Hyponatraemia-related Deaths resonate with experience elsewhere:

> "*The reticence of some clinicians and healthcare professionals to concede error or identify the underperformance of colleagues was frustrating and depressing, most especially for the families of the dead children … It should not have been so. Health service guidance for 25 years and more has repeatedly recommended transparency and openness in the interests of the patient. This has proved inadequate to the problem which is why this Report must recommend a statutory duty of candour in Northern Ireland.*"[102]

Between them, the legislative duties of candour cover healthcare organisations; the professional duties and professional regulators cover individual healthcare professionals – but there remains a gap. Though there are some in leadership roles in NHS Trusts and health boards who are subject to professional duties as doctors or nurses, and though it may rightly be said that organisational duties have ultimately to be performed by individuals, there are many leaders who are as yet subject to no individual accountability for candour within their organisation.

Recent developments

When Alex Chalk responded to Bishop James Jones' charter, he said that the Government intended to conduct a review of the effectiveness of the duty of candour for health and social care providers. He said this was "*In response to recent concerns about openness*".[103] The review is intended to consider:

> "*1. To what extent the policy and its design are appropriate for the health and care system in England.*
>
> *2. To what extent the policy is honoured, monitored and enforced.*

The purpose of the 'in person' notification is to offer an apology, provide an explanation of what is known at that time, offer support, explain the next steps and provide point of contact details.

The service user or person acting on their behalf will be sent a letter within five working days, confirming what was said in the 'in person' notification.

The NHS will undertake an investigation to find out what happened and why, and how we can prevent it from happening again.

This will take place according to the NHS Wales 'Putting Things Right' Procedure.

The named point of contact provided as part of the Duty of Candour procedure will give you more information about this process and what happens next.

If you do not want us to contact you, or if you would prefer someone to act on your behalf, please let us know and we will make the necessary arrangements."

A service user guide to The Duty of Candour p2 RLIT0002446

102 The Inquiry into Hyponatraemia-related Deaths Report January 2018 p28 RLIT0002450

103 Hansard parliamentary statement on Hillsborough: Bishop James Jones Report 6 December 2023 p3 RLIT0002396, UK Home Office *A Hillsborough legacy: the government's response to Bishop James Jones' report* 13 December 2023 pp41-42 RLIT0002429

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3. To what extent the policy has met its objectives."[104]

It is to be noted that it does not grapple with how well known the duty is to the wider public: if some participants in this Inquiry were unaware there was such a duty, this indicates that the architecture of the NHS is difficult for individual users of it to navigate.

On the same day as Alex Chalk responded, to Parliament, the Parliamentary and Health Service Ombudsman for England, Rob Behrens, said:

> "*I have long called for closer openness and transparency when things go wrong in the NHS. The duty of candour was intended to reinforce this. However, a decade after its introduction, our Broken Trust report into avoidable deaths in the NHS found that the duty is not always implemented as it should be and called for a full review to assess its effectiveness … Despite it being a statutory duty to be open and honest when things go wrong with a patient's care, I know from the cases we investigate that this doesn't always happen. Patients and their families deserve better.*"[105]

What the *Broken Trust* report had found was that "*the physical harm patients experienced was too often made worse by inadequate, defensive and insensitive responses from NHS organisations when concerns were raised.*" One of the four broad themes of failings leading to avoidable death was the failure to listen to the concerns of patients or their families.[106]

The *Broken Trust* report went on to say:

> "*We also looked at the further harm – sometimes called compounded harm – that happens when families, who have already experienced the devastating consequences of losing a loved one, try to understand what has happened but are met with a poor response from NHS organisations. We identified several factors which contribute to compounded harm:*
>
> - *a failure to be honest when things to wrong*
> - *a lack of support to navigate systems after an incident*
> - *poor-quality investigations*
> - *a failure to respond to complaints in a timely and compassionate way*
> - *inadequate apologies*
> - *unsatisfactory learning responses.*"[107]

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104 Department of Health and Social Care *Duty of candour review: terms of reference* December 2023 pp4-5 RLIT0002425. The announcement said the review would be published in spring 2024 but a call for evidence was only opened in April 2024, with an indication that the review will be published "*this year*". Duty of candour review 16 April 2024 RLIT0002456

105 Parliamentary and Health Service Ombudsman *Ombudsman Rob Behrens comments on DHSC review into duty of candour* 6 December 2023 p2 RLIT0002424

106 Parliamentary and Health Service Ombudsman *Broken trust: making patient safety more than just a promise* June 2023 p8 WITN7706002

107 Parliamentary and Health Service Ombudsman *Broken trust: making patient safety more than just a promise* June 2023 p8 WITN7706002

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This is not just an English perspective. The Ombudsman in Wales published a report *Groundhog Day 2: An opportunity for cultural change in complaint handling?* in June 2023. The report described "*A lack of openness and candour*", "*clear evidence of maladministration or service failure not identified during local investigations*", "*A lack of objective review of clinical care and treatment*", and recorded that "*Sometimes, the individual clinicians who have delivered the care are involved in complaints responses.*"[108]

Over 20 years after Bristol, and over ten since Mid Staffordshire, it appears from this that too little has changed. This demonstrates how difficult it can be to change culture.

Professor Kennedy rightly observed that "*Cultural and institutional change takes time and can be slow, requiring patience and forbearance.*" Nonetheless, he anticipated that changes in the culture would follow the implementation of the recommendations he made. He had seen the recommendations as forming an interlocking whole.[109] It is a sad indictment of the system's ability to effect a change of culture over such a long timescale that the same concerns continue to surface. The concerns discussed above have been recognised in inquiry after inquiry. They have led to a strengthening of whistleblower protection, have led to a statutory duty of candour upon health service bodies in England, Scotland and Wales, have led to stern warnings from the Parliamentary and Health Service Ombudsman – but have not yet effected a change in culture.

Speaking up

In England, the role of the Freedom to Speak up Guardian was created in response to recommendations made in Sir Robert Francis KC's report "*The Freedom to Speak Up*".[110] There are now 1,000 such guardians across England, reporting through a National Guardian to the Secretary of State for Health and Social Care. This system aims to encourage a listening culture, in which people working in the health service feel free to speak up.[111]

As to whistleblower protection, the Public Interest Disclosure Act 1998 introduced provisions into the Employment Rights Act 1996 to protect a "worker" from any detriment in their employment as a result of their making a disclosure of a kind covered by the Act.[112] This

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108 Ombudsman Wales *Groundhog Day 2: An opportunity for cultural change in complaint handling?* June 2023 p15, p17 RLIT0002447

109 The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995: Learning from Bristol July 2001 p444, p446 DHSC5030766

110 Francis *Freedom to Speak Up: an independent review into creating an open and honest reporting culture in the NHS Report* 11 February 2015 RLIT0002459

111 There are Confidential Contacts as part of the Scottish Speak Up Network and the Scottish Public Services Ombudsman has taken up the role of the Independent National Whistleblowing Officer in Scotland. Healthcare organisations in Wales have a Speaking Up Safely Board Champion who is independent and an executive director as Speaking Up Safely Executive Lead.

112 What is covered is: "*information which, in the reasonable belief of the worker making the disclosure, is made in the public interest and tends to show one or more of the following–*

(a) that a criminal offence has been committed, is being committed or is likely to be committed,

(b) that a person has failed, is failing or is likely to fail to comply with any legal obligation to which he is subject,

(c) that a miscarriage of justice has occurred, is occurring or is likely to occur,

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includes the disclosure of information tending to show that "*the health or safety of any individual has been, is being or is likely to be endangered.*" It is thus capable of covering the "*sentinel events*" (as Professor Kennedy in Bristol described them), and "*notifiable safety incidents*" or "*notifiable adverse outcomes*" as described in the regulations establishing the duty of candour in the health service. The disclosure is to be made to specified classes of people, depending on the circumstances.

Whistleblowers are recognised as capable of providing a valuable service. The protection given to them consists of ensuring they do not suffer a detriment for making the revelations which they do. However, the system is one in which it is almost assumed that, but for the Act, a whistleblower would otherwise be subject to blame. It is that cultural assumption which most needs to be addressed. What most needs to be valued[113] is ensuring that reporting near misses ("*sentinel events*") as well as harmful acts is prized, so that we may learn how to avoid them next time a similar situation occurs.

If a culture of learning from mistakes and near misses is to work most successfully, and if being frank and forthcoming is to be regarded as essential for patient safety then it is insufficient for me simply to add the voice of this Inquiry to an increasingly long list of those which have asked for a change of culture, but have failed to achieve it.

Something more is required if culture is to change.

There are, in my view, two aspects which are vital if culture is to change. They are "insisting upon the reporting of concerns" on the part of those in a leadership role, and the better organisation of the systems dealing with safety across healthcare.

(d) that the health or safety of any individual has been, is being or is likely to be endangered,

(e) that the environment has been, is being or is likely to be damaged, or

(f) that information tending to show any matter falling within any one of the preceding paragraphs has been, is being or is likely to be deliberately concealed."

Employment Rights Act 1996 Section 43B(1) RLIT0002435. The Act applies to Scotland, Wales and England: there are near identical provisions in an Order in Council applicable to Northern Ireland.

113 Current legislation may be seen as being complex, giving a protection in carefully delineated circumstances, which are dealt with under the provisions of Part IVA of the Employment Rights Act 1996 (ss 43A – 43L). The provisions are rightly directed at the particular circumstances that call for protection (including that the disclosure must be of information, as opposed to allegation or opinion; that the whistleblower must have a "*reasonable belief*" that the disclosure is in the public interest and that the information they are revealing "tends to show" that there has been a "*relevant failure*" – ie a criminal offence; a breach of legal obligation; a miscarriage of justice; a danger to health and safety of an individual; damage to the environment or related to a deliberate attempt to conceal any of these matters; and that information relating to any of the above has been, or is likely to be deliberately concealed. The information must in the first instance be given to the whistleblower's employer (or other responsible person as defined by s.43C). It is unnecessary for present purposes to give more detail, save to say that the legislation is not simple, and may seem to be focused more on the acts and behaviour of the whistleblower than on the direct protection of a person from harm, or other people in a similar situation in future from potential harm.

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Insisting on the reporting of concerns

I said I would return to the words which Sir Robert Francis used in recommendation 12 of his report into the Mid Staffordshire Trust. "*Reporting of incidents of concern relevant to patient safety … needs to be not only encouraged but insisted upon.*"[114]

Andrew Bragg, who was infected by treatment under the NHS and is a chemical engineer and chartered scientist by background, has a lifetime of experience working with high hazard chemicals – substances that could, in his words "*seriously impact both our employees, our neighbours and people who use* [them]".[115] He has worked with regulation all his life. It is worth quoting part of what he had to say to the Inquiry:

> "*So every time I have been with the NHS I have been a professional observer of organisational systems. So I have been looking at how the medical teams who are treating me are functioning. It is not always a very pretty picture. So there are lots of examples of where – – poor team working, poor communication, unsystematic working, working from memory – – so lots of boxes which, in my business, we would not accept but seems to be fairly routine in the Health Service. The type of things I'm looking for is not really specific to my industry. There are lots of industries where you face complex challenges which potentially put lives at risk. So the chemical industry, oil and gas industry, offshore, nuclear industry, aviation, building complex structures. In all of these, managing risk, managing personal safety, managing the safety of third parties is absolutely the core of what you do. But I see very little of that thinking in the NHS.*
>
> *So, how do we end up so good at this and perhaps NHS not so good? Well, we have external regulatory drivers that keep us honest. So in the UK we have the Health and Safety Executive. So they are responsible for managing safety for all businesses, operations in the UK. So if we have an instance or an accident which results in serious harm or death, we will be externally audited in a very rigorous way and all our failings will be exposed and we will be expected to put it right and make sure it never happens again. We also have external inquiries, like this one.*"[116]

I do not propose a culture in which there is no blame, but rather one where the blame falls in the right place. To take Andrew Bragg's example of the aviation industry. The expectation is not that people who are concerned with the safety of an airliner are blamed when fault occurs,[117] but that they are blamed for not taking steps to bring to attention their concerns that it might do so. Rather than seeing a whistleblower as needing protection from

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114 Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry Volume 1: Analysis of evidence and lessons learned (part 1) February 2013 p246 DHSC5113232

115 Andrew Bragg Transcript 17 January 2023 p164 INQY1000266. He worked for ICI, and today works as a global sustainability and regulation manager; he has been a lead auditor.

116 Andrew Bragg Transcript 17 January 2023 pp166-167 INQY1000266

117 The principle is stated broadly in the text, but there will be some occasions on which blame will necessarily follow eg where there has been a serious neglect of duty.

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retribution which would otherwise follow, the culture should be one in which the reporting of the concerns of which Sir Robert Francis speaks is recognised as a human, professional and statutory duty. The duty is to report matters which it is reasonable to think may have an adverse impact on patient safety. A failure to do so, when the substance of what might be reported is known to one or more people, but has not been reported by them, may be regarded as a breach of professional duty,[118] and might usefully underpin the statutory duty of candour. However, the duty also rests on those to whom a report is made. In the case of someone in a leadership role, they may choose to escalate a report, resolve it, or deal with it as appropriate, but in any case they should consider it properly. A failure to give the report proper consideration should be regarded as culpable.[119] Further, if any action in this context is deserving of disciplinary action by the employer it is failing to speak up, or failing to act on a report, rather than regarding a whistleblower as a maverick, or as a "tell-tale".

Incentivising change

A failure to check or tighten bolts on an aircraft wing may not lead to a crash – but it could constitute a near miss. Reporting that it has happened is valued. In the mining industry, the use of canaries in cages was largely superseded by the role of a "deputy"[120] whose job it was to ensure the mine was safe[121] before a shift began, and tell underground workers to leave the moment there was information that suggested there was a risk it might not be. This initially Victorian development to protect workers has been credited as a principal reason why the UK coal mining industry was one of the safest. Industry dealing with offshore safety; the handling of hazardous chemicals, aerospace, maritime, and nuclear power enterprises systematise safety checks, and highlight cases where they may not have been performed. These industries have each adopted a safety management system. The NHS has not.

Speaking up about a "sentinel event" (or, in terms used by Healthcare Improvement Scotland, a "significant adverse event", in Northern Ireland "serious adverse incident" or in England and Wales "patient safety events" or incidents) is a first stage. Andrew Bragg submitted that there should be a statutory responsibility to report, formally, when one has

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118 See for example the GMC's Good Medical Practice ("*You must act promptly if you think that patient safety or dignity is, or may be, seriously compromised*" and "*If patients are at risk because of inadequate premises, equipment or other resources, policies or systems, you should first protect patients and put the matter right if that's possible. Then you must raise your concern in line with your workplace policy and our more detailed guidance on Raising and acting on concerns about patient safety*.") GMC *Good medical practice* came into effect 30 January 2024 para 75 RLIT0002452. See also the GMC's guidance Raising and acting on concerns about patient safety which stipulates that "*All doctors have a duty to raise concerns where they believe that patient safety or care is being compromised by the practice of colleagues or the systems, policies and procedures in the organisations in which they work. They must also encourage and support a culture in which staff can raise concerns openly and safely*" GMC *Raising and acting on concerns about patient safety* 12 March 2012 para 7 RLIT0002457

119 Some reports may be misunderstandings, but even then misunderstandings may be shared, and it may be useful to put them right. The duty on the person to whom a concern about a sentinel event is reported should arise only if that person is identifiable as an appropriate person to whom to make such a report.

120 Later, a Regulation 12 manager.

121 From fire, flood, gas, movement of the strata, and collapse in particular.

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occurred should be required of all employees within the NHS, including those who are not medical or nursing professionals.[122] The second stage is investigation and review, to see what if any action is desirable. The third is implementation of the actions it is thought will be effective to prevent recurrence. The fourth is audit – to check that the action appears to be having the anticipated effect. Each step needs to be taken and logged: the data should be collated nationally, as Professor Kennedy suggested in his report on Bristol.[123]

Since 2003/04, the NHS in England has collated patient safety incident records uploaded from local risk management systems. NHS England now collects over 2.3 million patient safety incident records each year, which can lead to National Patient Safety Alerts.[124] NHS Wales uses Datix Cymru to gather data on all patient safety incidents, including near-misses.[125] Northern Ireland's system is called the Datix Risk Management system.[126] Healthcare Improvement Scotland has had a database of all category 1 significant adverse event reviews since 2020 and work is underway to standardise adverse event data reporting in Scotland.[127]

Where an individual is responsible for something going wrong that was, or might have been, harmful, they should not usually be blamed for "owning up" (for that enables patient safety to be better achieved), but they should certainly be blamed if they keep silent.

The existing professional duties of candour in healthcare are good starting points, so far as those currently subject to such duties are concerned. However, others who are not covered by these obligations should be subject to reciprocal duties. Reporting concerns about the healthcare being provided, or the way it is being provided, where there reasonably appears to be a risk that a patient might suffer harm, or has done so, is critical to realising risks, and

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122 Andrew Bragg Transcript 17 January 2023 p175 INQY1000266. Following his submission the Inquiry gathered written statements from organisations with roles in patient safety including:
Healthcare Improvement Scotland: Written Statement of Lynsey Cleland WITN7671001
NHS Wales: Written Statement of Judith Paget WITN5712002
Department of Health in Northern Ireland: Written Statement of Peter May WITN7461007
DHSC: Written Statement of William Vineall WITN4688083

123 The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995: Learning from Bristol July 2001 p465, p447 DHSC5030766. Professor Kennedy hoped that the changes he was recommending would lead to a change in the culture: *"Perhaps the most significant change we call for is one which does not attract a specific Recommendation. This is the change which is needed in the culture of the NHS. We see changes to that culture as being a product of the Recommendations as a whole. If the Recommendations are implemented, changes in the culture will follow*." His steps included a duty of candour, regulation, assurance and a national reporting system: matters which are reflected in these recommendations too. These remain important. Now, some of those most centrally involved with patient safety in England are exploring the contribution that a safety management system could bring in addition (see the discussion in the text): it would add significantly to the "*whole*" which Professor Kennedy envisaged.

124 Written Statement of Dr Aidan Fowler para 18, paras 32-42 WITN7717001. The devolved administrations are observers on an external stakeholder panel when National Patient Safety Alerts are issued and have access to the data and analysis generated in support of an Alert.

125 Written Statement of Judith Paget para 9 WITN5712002

126 Written Statement of Peter May para 3.1 WITN7461007

127 Written Statement of Lynsey Cleland para 19, para 23 WITN7671001

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improving safety. It should be considered a serious disciplinary matter on the part of the person in authority to whom a report of a sentinel event is reported not to consider it adequately.

The need to ensure that people in leadership roles have a duty resting upon them individually as leaders is further underpinned by observations of the Independent Neurology Inquiry in Northern Ireland in 2022, which became a statutory inquiry during the course of proceedings and reported (in respect of doctors who exercised leadership roles, as well as administrators) that: "*Medical professionals were ... apprehensive in raising a concern about the practice of a colleague or querying discrepancies that arose, which did not directly touch upon the welfare of their own patient. It was clear that senior managers were too often reluctant to manage doctors and were easily deflected by the raising of any clinical dimension to an issue of concern. Correspondingly, many doctors who took on a management role were accustomed to operating collegially and consensually and found the responsibilities of management did not easily fit into that extant culture.*"[128]

In short, this would make whistleblowing an obligation: but more than that, it would make the person to whom a report of a sentinel event is made, accountable for what is then done in response to it. It entrenches the principle that safety is the responsibility of all. It makes patient safety a hallmark of quality care. In effect, it gives teeth to the duty of candour in healthcare.

Accountability of leadership

On several occasions during the course of the Inquiry witnesses were asked what could be done to change the culture of the NHS. Many inquiries had suggested a culture change was needed. None had achieved this.

The answer given by Professor Sir Jonathan van Tam was "*leadership*". The exchange went like this:

> *"Q: … how do you best incentivise candour and openness in the organisations which you lead and, for that matter, in the NHS?*
>
> *A: ... it boils down to a set of personal values and it boils down to me as a leader, in whatever position I am in an organisation, insisting of the people who report to me, and who are also in leadership positions, insisting on certain standards and insisting upon responsibility and accountability. And insisting, in their reports, on the same and building from the very top to the bottom an insistence on quality ... I don't think this is something that can be created by a mission statement or a set of wonderful principles that are ... framed in every office in the building. I think it has to be about lived relationships and about, if you're in a position of leadership, your expectation directly of the people who report to you, and your insistence that they have the right to expect the same all the way down the system. Of course at different levels with different things that they are responsible for at different*

128 Independent Neurology Inquiry Report June 2022 p21 RLIT0002449

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> *levels in the system, but that kind of built-in ownership and accountability for what they do.*"[129]

Lord Evans of Weardale, then chair of the Committee on Standards in Public Life, emphasised the central importance of leadership in his foreword to a report in January 2023: *Leading in Practice: A review by the Committee on Standards in Public Life*.[130]

Rob Behrens identified a "*cover-up culture*" from his experience as Parliamentary and Health Services Ombudsman over the last seven years. Asked how such a culture can be ended he is quoted as saying that: "*First of all, you have to recognise that it* [a cover-up culture] *exists and secondly you have to make leaders accountable for how the culture operates*". He added that ministers, NHS bosses and the boards of NHS Trusts need to be much more proactive.[131]

Since culture is identified by seeing the way in which people behave and react, it is not something that can necessarily be directed from the top. However, it is generally true that leadership sets the tone for an organisation. It can establish the parameters within which those who work for the organisation operate. It can indicate the approach which it is acceptable to take to those whom the organisation serves, fellow workers, and third parties.

The seven principles of public life identified by Lord Nolan 30 years ago include leadership.[132] Accountability is another. Rob Behren's words encapsulate four more – objectivity, and integrity, in recognising the problems with an existing culture; openness and honesty in admitting to it. The first principle – selflessness – may also have a part to play, by not seeking to retreat into defensiveness, which is another way of describing actions which put self-interest ahead of those of others.

The importance of leadership and the possibility it can make a difference is real. An individual duty of candour, and a duty to record, and give proper consideration to reports of concerns made by healthcare staff to those in leadership roles should be provided for, enforceable first as a requirement of the job, and second underpinned by secondary legislation.

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129 Professor Sir Jonathan Van-Tam Transcript 18 November 2022 pp67-68 INQY1000265

130 He said: "*Senior leaders must ensure that values are understood and embedded into all aspects of how their organisations operate – from the way leaders communicate with employees, to the priority given to developing good decision-making, to the approach taken to recruitment and performance management. While the tone from the top is critical, leadership matters throughout an organisation. Leaders at all levels have a fundamental role in exemplifying and helping their teams live up to the Principles in their day-to-day behaviours.*" He did however caution that "*From the evidence we have heard, it is clear that there is no single right way to embed an ethical culture in organisations, but a range of possible approaches and measures*", although it was clear that an ethical culture did not happen by accident. Committee on Standards in Public Life *Leading in Practice: A review by the Committee on Standards in Public Life* January 2023 p4 RLIT0002399

131 The Guardian *NHS ombudsman Rob Behrens: 'There are serious issues of concern'* 17 March 2024 RLIT0002366. He told the Inquiry: "*Defensive cultures are a product of defensive leadership, so the behaviour of senior leaders is critical in creating an open, transparent environment where patient safety is prioritised.*" Written Statement of Rob Behrens para 19 WITN7706001

132 Lord Nolan *Standards in Public Life: First Report of the Committee on Standards in Public Life* May 1995 p18 RLIT0001795

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Organisation of a safety management system

The steps identified above require a body (preferable to one person,[133] since safety requires team effort; though having an individual in every healthcare organisation who has a designated responsibility for safety[134] can be part of the system) to oversee a safety management system, to collate reports and build a picture of the challenges to safety within the health services across the UK and the measures that are needed to meet them.

Why is the status quo not enough? The answer is that despite the focus on patient safety, there are still recurring safety risks and serious incidents in healthcare. This can be seen in repeated concerns in the last decade such as in the Morecambe Bay Investigation (Kirkup, 2015),[135] *First Do No Harm: The report of the Independent Medicines and Medical Devices Safety Review* (The Independent Medicine and Medical Devices Safety Review, 2020),[136] the Ockenden review of maternity services at Shrewsbury and Telford Hospital NHS Trust (Ockenden, 2020);[137] and *Reading the signals: Maternity and Neonatal Services in East Kent Report* (Kirkup, 2022).[138] These investigations and reports have identified similar problems to those which this Inquiry has laid bare: not only a problematic culture, which does not put patient safety first; but too many bodies, with no one having an overall role with executive power or central influence; too much fragmentation leading to a confusion of approach and paralysis of decision-making.

Dr Henrietta Hughes, the Patient Safety Commissioner for England, gave evidence that "*Overall, the patient safety landscape has arguably become too cluttered and is too confusing from the point of view of patients … Reorganisations also inherently present short term inefficiencies and delay.*"[139]

In *First Do No Harm*, Baroness Cumberlege wrote in the opening letter to the Secretary of State:

> "*We have found that the healthcare system – in which I include the NHS, private providers, the regulators and professional bodies, pharmaceutical and device manufacturers, and policymakers – is disjointed, siloed, unresponsive and*

133 The Professional Standards Authority suggested that coordination be achieved by a commissioner with an overarching role focussed on ensuring that the various bodies charged with protecting the public work together as an effective system. Though I am not averse to this, it might be better that there be a commission with one head. Professional Standards Authority for Health and Social Care *Safer care for all: solutions from professional regulation and beyond* September 2022 pp84-87 RLIT0001837

134 Provided that care is taken that this does not lead to other health professionals thinking that safety is not their problem too.

135 Kirkup *The Report of the Morecambe Bay Investigation* March 2015 WITN7523007

136 First Do No Harm: The report of the Independent Medicines and Medical Devices Safety Review 8 July 2020 RLIT0001379

137 Ockenden Report – Findings, Conclusions and Essential Actions From the Independent Review of Maternity Services at the Shrewsbury and Telford Hospital NHS Trust 30 March 2022 WITN7523009

138 Kirkup *Reading the signals: Maternity and neonatal services in East Kent – the Report of the Independent Investigation* October 2022 WITN7523008

139 Written statement of Dr Henrietta Hughes para 36 WITN7328004

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> *defensive … The system is not good enough at spotting trends in practice and outcomes that give rise to safety concerns.*"[140]

In mid October 2023 the Health Services Safety Investigations Body ("HSSIB") published a report about safety management systems for healthcare. The report said:

> "*An overall systems approach is needed – that is, one that encompasses all aspects of healthcare including non-clinical services, which can have a significant impact on patient safety. For example, a whole-system approach should consider auxiliary services such as decontamination services, facilities management or healthcare engineering. Currently, this may not be the case in healthcare. HSSIB* [Health Services Safety Investigations Body] *highlighted the importance of other services and parts of the healthcare system that may have a significant impact on patient safety and will need to be included in an overall systems approach.*"[141]

The report described the essentials of safety management systems: "*An SMS* [safety management system] *is a proactive and integrated approach to managing safety. It sets out the necessary organisational structures and accountabilities and will continuously be improved. It requires safety management to be integrated into an organisation's day-to-day activities. There is no one-size-fits-all SMS*". The report detailed that it involves:

(a) *"**safety policy** – establishes **senior management's commitment** to improve safety and outlines responsibilities; defining the way the organisation needs to be structured to meet safety goals*

(b) ***safety risk management** – **which includes the identification of hazards (things that could cause harm) and risks** (the likelihood of a hazard causing harm) and the assessment and mitigation of risks*

(c) ***safety assurance** – **which involves the monitoring and measuring of safety performance** (eg how effectively an organisation is managing risks), the continuous improvement of the SMS, and evaluating the continued effectiveness of implemented risk controls*

(d) *safety promotion – which includes **training, communication and other actions to support a positive safety culture** within all levels of the workforce.*"[142]

In summary:

> "*The purpose of an SMS is to ensure that an industry achieves its business and operational objectives in a safe way and complies with the safety obligations that apply to it. However, it is not just a paper-based or electronic system specifically*

140 First Do No Harm: The report of the Independent Medicines and Medical Devices Safety Review 8 July 2020 pp3-4 RLIT0001379

141 Health Services Safety Investigations Body *Investigation report: Safety management systems – an introduction for healthcare* 18 October 2023 p11 RLIT0002398

142 Health Services Safety Investigations Body *Investigation report: Safety management systems – an introduction for healthcare* 18 October 2023 p3 RLIT0002398. Emphasis added.

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> *developed for demonstrating compliance with regulatory frameworks. Instead, an SMS should be a dynamic set of arrangements which grows in maturity and develops as the industry evolves.*"[143]

The HSSIB recommended that "*NHS England explores, and if appropriate, supports the development and implementation of safety management systems (SMSs) through an SMS co-ordination group. This should be in collaboration with regulators, relevant arm's length bodies and national organisations, academics, patient representatives and safety leaders from other safety-critical industries.*"[144]

This is consistent with Andrew Bragg's submission discussed above that there should be a systemised approach to safety, as there is in other safety critical industries.

The Patient Safety Commissioner for England is strongly supportive of the work the HSSIB is leading, looking at how recommendations are made to the healthcare system and moving towards an agreed set of principles that national organisations and office holders (such as the Patient Safety Commissioner) with the power to make safety recommendations can sign up to – but cautions that it has to start from a detailed "*gap analysis of the current landscape*", and a danger that one body might be a recreated National Patient Safety Agency which, as noted, was absorbed into NHS England in 2012, and might be seen as the preserve of "*highly specialised 'experts' … in contrast to high reliability organisations in other sectors with SMSs, where safety is seen as the responsibility of everyone from the CEO downwards.*"[145]

The National Director of Patient Safety for NHS England told the Inquiry that "*it is right to ask what more the NHS could do in this space and what more we could learn from other industries … Understanding how SMSs might be conceived and applied in a healthcare setting is an integral step for informing further policy developments.*"[146]

The Professional Standards Authority for Health and Social Care also agrees with Andrew Bragg's view that there is a need for a body to check that the healthcare safety system is operating effectively, and that serious review findings are implemented.[147]

In summary, a powerful consensus has been building over the last three years that an appropriate safety management system is needed for healthcare in England.

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143 Health Services Safety Investigations Body *Investigation report: Safety management systems – an introduction for healthcare* 18 October 2023 p3 RLIT0002398

144 Health Services Safety Investigations Body *Investigation report: Safety management systems – an introduction for healthcare* 18 October 2023 p5 RLIT0002398

145 Written Statement of Dr Henrietta Hughes para 28, paras 30-31, para 35 WITN7328004

146 Written Statement of Dr Aidan Fowler para 18, paras 48-49 WITN7717001

147 Written Statement of Christine Braithwaite para 13 WITN7523012. The statement does, though, draw attention to some of the differences between aviation safety, where for instance planes can be grounded, and the NHS which has variable staffing, less predictable demand, where critical decisions need to be made fast, conditions may vary from shift to shift and there are multiple variables in the nature of diseases and conditions. Written Statement of Christine Braithwaite paras 11-12 WITN7523012. See also Andrew Bragg's submission: Andrew Bragg Transcript 17 January 2023 pp167-170 INQY1000266

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Dr Rosie Benneyworth of the HSSIB has set out the next steps towards this – first, investigating accountabilities for patient safety across organisational boundaries,[148] then considering how NHS staff and patients could be involved in an integrated safety management system.

In Scotland, Healthcare Improvement Scotland scrutinises and assures the quality of NHS services in Scotland but does not regulate them.[149] There is no equivalent organisation elsewhere in the UK.[150] It recognises "*the combined strength of the respective skills and expertise that each of the organisations with a role to play in safety and quality of care in Scotland currently bring, but also understand the vital importance of these organisations working together to share, consider and respond to intelligence about health and care systems, as demonstrated by our membership of the Sharing Intelligence for Health & Care Group (SIHCG) and the secretariat support we provide for this.*"[151]

The NHS Wales Executive has developed a National Quality Management System that integrates quality and safety intelligence with performance to provide "*a rounded picture of organisations which can be used as an early warning*".[152]

In Northern Ireland it is the Department of Health that manages the Serious Adverse Incident process, working jointly with the Public Health Agency.[153]

Patient records

Because moves are already under way to give patients greater access to their own records, that development in itself needs no recommendation from this Inquiry. However, the digital initiatives in England, Scotland, Wales and Northern Ireland are still works in progress, and this Inquiry is in a position to provide a unique perspective on aspects of process and outcome which may assist in achieving what patients will value most about the new landscape which is being formed. A repeated lesson from the Inquiry has been a sidelining of what patients have had to say.

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148 A report is due for publication in October 2024. Written Statement of Dr Rosie Benneyworth WITN7689012

149 Established in 2011 as a Health Body, constituted by the National Health Service (Scotland) Act 1978, as amended by the Public Service Reform Scotland Act 2010 and the Public Bodies (Joint Working) Act 2014. While Healthcare Improvement Scotland is not a special health board, it may be grouped with NHS special health boards in terms of Scottish Government initiatives such as shared services.

150 Written Statement of Lynsey Cleland paras 5-6, WITN7671001. The approach of the NHS Wales Executive is described by their chief executive. Written Statement of Judith Paget para 4, paras 14-15 WITN5712002. The position in Northern Ireland is set out by the Permanent Secretary in the Department of Health. Written Statement of Peter May paras 3.1-3.3 WITN7461007

151 The position of Healthcare Improvement Scotland is: "*We would have a strong interest in any proposals to further strengthen the safety of the health and care system in Scotland, but believe that detailed consideration needs to be given to the existing landscape, including the proposals for a Patient Safety Commissioner, in order to ensure that any new arrangements are evidence-based and do not inadvertently duplicate, complicate or dilute existing provisions.*" Written Statement of Lynsey Cleland paras 30-31 WITN7671001

152 Written Statement of Judith Paget para 14 WITN5712002

153 Written Statement of Peter May paras 3.1-3.3 WITN7461007

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The message delivered generally to the Inquiry is one of deep concern about the failings of NHS record keeping to date. It is important for there to be faith in the new system. There should accordingly be a formal audit of the success of the system, as operated in each of the four health administrations, by the end of 2027, which reports in a public forum as to its level of success in the percentage of the population who are (a) able to access their medical records online*;* (b) able to identify any corrections that need to be made to the data which has been recorded in their records, and can succeed in any reasonable case in securing those corrections; and (c) satisfied that they have sufficient control over the use of their data for purposes beyond their immediate treatment such as for research. It should also measure and report the degree of confidence which health professionals have in the degree of detail, accuracy and timeliness of any record they enter, and be able to assess that little material which should be recorded has been omitted. It should evaluate how far the savings in time which are identified in the Government strategy have been achieved in England, and whether all the national governments' digital initiatives have met their objectives and can be shown (on balance) to have improved the safety of patient care.

Because so many people who were infected trace their infections back to events which happened some time before they were diagnosed, the destruction policies of many health bodies have meant they are no longer are able to see, by looking back through their records, what was recorded as having happened, and be able to show to others (if necessary) what it led to in earlier years. Patients have a medical past which may help to inform diagnosis and treatment options today: where diseases may incubate over long periods, and attendances at medical centres may be sporadic, this may be important to them. Destruction policies should therefore be kept under review.

Professor David Armstrong drew attention in his evidence to problems caused because of a lack of interoperability of the digital systems currently in use in hospitals, both as between many hospitals, and as between hospitals and GPs.[154] There is plainly a danger that the systems to be adopted in England, Scotland, Wales and Northern Ireland may not be capable of interoperability, which could affect patient care given the regular movements of populations within the UK, and the resultant risks of gaps in personal health records (and the consequences of those risks).

The above analysis, considered in the light of all the material the Inquiry has reviewed, leads me to make the following recommendations:

4. Preventing future harm to patients: achieving a safety culture

(a) Duty of candour

(i) A statutory duty of candour in healthcare should be introduced in Northern Ireland.

154 Professor David Armstrong Transcript 14 September 2022 pp141-145 INQY1000240. Professor David Armstrong is professor of medicine and sociology at King's College London.

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(ii) The operation of the duties of candour in healthcare in Scotland and in Wales should be reviewed, as it is being in England, to assess how effective its operation has been in practice. Since the duty was introduced in 2023 in Wales, the review there need not be immediate, but should be no later than the end of 2026.

(iii) The review of the duty of candour currently under way in England should be completed as soon as practicable.

(iv) The statutory duties of candour in England, Scotland, Wales (and Northern Ireland, when introduced) should be extended to cover those individuals in leadership positions in the National Health Service, in particular in executive positions and board members.

(v) Individuals in leadership positions should be required by the terms of their appointment and by secondary legislation to record, consider and respond to any concern about the healthcare being provided, or the way it is being provided, where there reasonably appears to be a risk that a patient might suffer harm, or has done so. Any person in authority to whom such a report is made should be personally accountable for a failure to consider it adequately.

Success in implementation will be measured by the extent to which there is an increase in the number of reports made of near miss incidents to the designated data collector; and a decline in the number of widespread or significant healthcare failures.

(b) Cultural change

(i) That a culture of defensiveness, lack of openness, failure to be forthcoming, and being dismissive of concerns about patient safety be addressed both by taking the steps set out in (a) above, and also by making leaders accountable for how the culture operates in their part of the system, and for the way in which it involves patients.

(c) Regulation

(i) That external regulation of safety in healthcare be simplified. As a first step towards this, there should be a UK wide review by the four health departments of the systems of external regulation, with the aim of addressing all the points made earlier in this Report and in other reports since 2000.

(ii) That the national healthcare administrations in England, Northern Ireland, Scotland and Wales explore, and if appropriate, support the development and implementation of safety management systems ("SMS"s) through SMS coordination groups (as recommended by the HSSIB), and do so as a matter of priority.

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Success in implementation will be measured by the percentage of patients who know to whom they can express any concerns they may have about safety, who will take up their cause, and what they can expect from them. At the same time, it will be measured by the extent to which those who are busy working within the system, especially those in leadership roles, have clarity as to what, precisely, is expected of them, from whom. It should also be measured by a reduction in avoidable harm from both errors and systemic issues.

(d) Patient records

(i) Before the end of 2027 there should be a formal audit, publicly reported, of the extent of success of digitisation of patient records in each of the four health jurisdictions of the UK, measuring at least the levels of patient access to their personal records, their ability to identify and correct apparent errors in them, their interoperability, and the confidence of health professionals in the detail, accuracy and timeliness of any record they enter, and that little material which should be recorded has been omitted. Next steps should be identified.

(e) Consideration should be given by the national healthcare administrations in England, Scotland, Wales and Northern Ireland, to further coordination of their approaches particularly to ensure that patterns of harm, or trends, are identified and any response which for the sake of patient safety would be better coordinated than left to each individual administration can collaboratively be agreed and implemented.

5. Ending the defensive culture in the Civil Service and government

A duty of candour on civil servants and ministers

The Inquiry has a particular perspective to bring to the debate about whether to extend the duty of candour, on which the Lord Chancellor Alex Chalk said the Government was keeping related duties and obligations under review: "*we will not rule out taking further action if it is needed.*"[155] The chapter on *Lines to Take* lays out clearly the consequences of civil servants and ministers adopting lines to take without sufficient reflection, when they were inaccurate, partial when they should have been qualified, had no proper evidential foundation, ignored findings made by courts which were inconsistent (or flatly contradictory of) the lines adopted, or made unrealistic claims that treatment had been the best it could be. The commentary to that chapter reflects how:

155 Hansard parliamentary statement on Hillsborough: Bishop James Jones Report 6 December 2023 p3 RLIT0002396

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> "*In relation to Hepatitis C, Ministers took on faith what civil servants said; civil servants took on faith what the files said. No one stood back and reflected. No one asked questions – could this really be right? How could the best treatment available lead to the infection of so many?*"[156]

It records how a "*line, which was wrong from the very outset, then became entrenched for around twenty years: a dogma became a mantra. It was enshrined. It was never questioned.*"[157] "Lines" are particularly important because they are set out to express underlying policy and, especially when in place over many years, then affect or hinder the development of new policies.

In respect of three of the "lines to take", the consequences are described as cruel:

> "*The cruelty, for those infected and affected, of hearing, over and over, that they had received the best treatment available, that testing had been introduced as soon as possible, that they had been inadvertently infected, should not be underestimated.*"

The use of the lines contributed to delay in there being a public inquiry; it almost certainly meant that those infected and affected did not get the financial and psychological support they would otherwise have received; it contributed to a loss of trust in the health service and in the ability of government to understand and respond to genuine concerns and complaints.

In the light of findings such as are concentrated in the chapter on *Lines to Take*, the Inquiry has a particular perspective on how the existence of a clearer, more emphatic, duty of candour among civil servants might have altered the nature of the government response. It might have avoided compounding the suffering which had already occurred.

I doubt that the last word has yet been said on whether a statutory personal duty of candour should be introduced across the Civil Service. No one can sensibly dispute that people in public life should observe basic moral principles: they are as applicable to government ministers and officials as they are to clinicians.[158] The principles of public life may have

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156 See the chapter on *Lines to Take*.

157 See the chapter on *Lines to Take*.

158 As was clear from the evidence of the expert group on Public Health and Administration, the attributes of integrity, honesty, objectivity and impartiality form the bedrock upon which the Civil Service was built; and ministers were expected to behave with objectivity, openness and honesty, even before Lord Michael Nolan articulated those principles as part of the seven principles of public life. Public Health and Administration Expert Panel Transcript 3 October 2022 pp6-9 INQY1000251. Expert Report to the Infected Blood Inquiry: Public Health and Administration August 2022 pp8-12 EXPG0000048. The Seven Principles of Public Life are:

1. Selflessness (requiring holders of public office to act solely in the public interest)
2. Integrity
3. Objectivity
4. Accountability
5. Openness
6. Honesty
7. Leadership

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become known as the Nolan Principles in 1995,[159] but they articulate what was already well understood, and went beyond the "*basic moral principle of our society that we should tell the truth*."[160] Yet they did not prevent what the chapters on the government response describe. I said in the chapter *Lines to Take* that it is ironic that these Nolan principles were articulated in their present form at a time when for six years an over-confident line with no proper evidential foundation had been repeated by civil servants, adopted by them as having the status of a "given" through a form of groupthink, and was to go on being used repeatedly. It is more than ironic: it shows that without statutory underpinning the principles of Lord Nolan and the Civil Service Code are not in themselves sufficient to prevent this happening.

It must be a concern that unless a duty of candour "has teeth" it might similarly be broken in future; and it is my concern that unless I draw attention to this I shall not be fulfilling my duty of making appropriate recommendations to the Government.

In addressing how best patient safety in future can be ensured in healthcare, and what "teeth" might be effective in achieving the long sought-after change of culture, I have proposed that leaders should be made accountable for failures of candour in their organisations; that no blame should fall on those who admit to making honest mistakes, or to a "near miss", but instead on those who hide them (either in themselves or others), and that reliable data will enable a proper record so that leaders and the public are informed accurately about progress towards safer care.

Though the Civil Service does not itself deal directly with patient care, its actions, and those of the ministers it supports can compound any failures of care, especially where they do so by expressing mistaken, inadequate, or ill-considered views of the facts, or simply by delaying responses to concerns or fresh information. Taking a wider view, there is a duty to the public served by civil servants: citizens deserve honesty rather than ill-placed defensiveness.

Dame Una O'Brien, who was formerly Secretary to the Bristol Inquiry and later Permanent Secretary at the Department of Health and Social Care, and thus worked in a part of the Civil Service closely linked to the issues arising in this Inquiry, wrote an article in April 2023, entitled "*Silence is not golden: The civil service must enable a 'speak-up' environment*". In it she described the problem which led to the title of the article – "*will I be heard respectfully without negative consequences? The policies and procedures might look polished and inviting, but sometimes, especially in the civil service, a culture of hierarchy and dismissiveness can cause us to hold back.*" She pointed to the examples of "*Sue Gray's report regarding No.10: 'Some staff had witnessed or been subjected to behaviours at work which they had felt concerned about but at times felt unable to raise properly'*" and to "*the Foreign Affairs Committee's report on the withdrawal from Afghanistan, where they point to the absence of an adequate process for officials to express concerns about policy without fear of damaging their careers.*" Both showed that (despite the Civil Service Code and Nolan

159 Lord Nolan *Standards in Public Life: First Report of the Committee on Standards in Public Life* May 1995 RLIT0001795

160 The words of Professor Kennedy in his 1980 Reith Lectures *Unmasking Medicine* Transcript 26 November 1980 p3 RLIT0000620

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Principles) people found it difficult to express concerns. She then turned to the "*mature good practice*" of the nuclear and airline industries for inspiration as to the best way of addressing this. Her solution was, as it had been in those industries, to develop "*systems that counter deference and encourage staff at all levels to speak up with concerns.*" She thought that part of achieving this was "*leadership*", and a culture of trust and respect.[161]

What she says echoes what the Inquiry has found of the period leading up to today; and the solutions she suggests for the Civil Service are consistent with mine for healthcare: ensure the accountability of leadership, and put blame not on those who raise concerns, but on those who knowing of a matter of concern do not then raise it or who ignore concerns raised.

In the House of Lords debate on whether to accept an amendment to the Victims and Prisoners Bill which proposed a statutory duty of candour, the following exchange took place. Baroness Brinton asked the Parliamentary Under-Secretary of State, Lord Bellamy, "*there is an issue about the personal duty of candour that changes behaviour. Does he recognise that?*" His answer was: "*Yes, the Government recognise that up to a point. What we are discussing is the right way to get there. The Government are not convinced that this statutory amendment is the right way.*"[162]

It is plain that the objective of those who support a statutory duty is the same as those in government who do not – that there needs to be a change of culture to one which values personal candour and rejects defensiveness. The question is what best achieves this.

Part of the view of the Government has been that the introduction of an independent advocate for victims of major incidents will go a considerable way in addressing what might otherwise be achieved by enacting a statutory duty of candour. The addition of an independent advocate to support victims of a major incident is indeed valuable. The Bill regarding the role of independent advocates has, at the time of writing, not yet reached the statute book. As currently drafted, it is very much a supportive one, in effect to act as a knowledgeable intermediary, in response to a "*major incident*". The independent advocates will have no powers themselves to investigate; nor powers to require the provision of, or even to see, documents. It is difficult to see that the role would have made a material difference to the way in which governments reacted to what had happened to infect people through blood and blood products. It is not at all easy to see that it would have encouraged a more reflective approach within the Civil Service, or a more curious approach from ministers.

It is unlikely that the role, important and valuable though it is, will have any significant part in achieving the culture change which is needed to prevent a future recurrence of the apparent deafness and defensiveness of government to concerns about what had happened to cause infections by blood and blood products.

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161 Civil Service World *Silence is not golden: The civil service must enable a 'speak up' environment* 6 April 2023 RLIT0002432

162 Hansard debate on Victims and Prisoners Bill 26 February 2024 pp5-6 RLIT0002433

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I well understand that a duty of candour cannot be drafted so widely as to oblige each individual civil servant of whatever rank to consider separately in the aftermath of a major incident whether they need to disclose a document they have seen or information of which they are aware. This would, as Lord Bellamy suggests, be unworkable.[163] Government is entitled to formulate its policy in a "safe space" if it is to work effectively. However, those in a leadership role (as opposed to more junior civil servants) are well placed to know what documents and information may and should be disclosed without encroaching on such a safe space.

Equally, a duty should not be so limited as to apply only when concerns have developed so far as to lead to an inquiry, or to a claim by way of judicial review, or a court case.

If and when, however, serious concerns are raised with or come to the attention of government departments (as they were in relation to infected blood) there is a very real place for a statutory requirement of candour to bite. This will first and foremost place requirements on those who lead – for they should be accountable by statute for the honesty, objectivity and completeness of what is said by them, or given to ministers to say. They should be responsible too for ensuring that a candid response is forthcoming, which should draw attention to any document or reliable information reasonably to be regarded as relevant to the concern being raised telling not just the truth, but **the whole truth**, and nothing but the truth. Those in a department who are not themselves in a leadership role should be obliged to tell those to whom they report of any concern they have that a response (or proposed response) is lacking or inaccurate – and to record that they have done so.

I have recommended that those in leadership positions in the health service, who would not otherwise be within the scope of a statutory duty of candour, should be made subject to it, and made accountable for their personal handling of concerns about the safety of healthcare amongst those they lead. Recognition of a corresponding duty of leaders in the Civil Service is also recommended.

The duty of ministers is to be properly reflective, curious and prepared if need be to be critical of advice. What they say should, of course, be candid (subject to overriding issues of public interest) but they also have a role in helping to ensure that Government as a whole is candid.

It follows that I recommend that:

5. Ending a defensive culture in the Civil Service and government

(a) The Government should reconsider whether, in the light of the facts revealed by this Inquiry, it is sufficient to continue to rely on the current non-statutory duties in the Civil Service and Ministerial Codes, coupled with those legal duties which occur on the occasions when civil servants and ministers interact with courts, inquests and inquiries, as securing candour.

163 Hansard debate on Victims and Prisoners Bill 26 February 2024 p5 RLIT0002433

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(b) If, on review, the Government considers that it is sufficient to rely on the current non-statutory duties in the Civil Service Code, it should nonetheless introduce a statutory duty of accountability on senior civil servants for the candour and completeness of advice given to Permanent Secretaries and Ministers, and the candour and completeness of their response to concerns raised by members of the public and staff.

(c) The Government should consider the extent to which Ministers should be subject to a duty beyond their current duty to Parliament under the Ministerial Code.

6. Monitoring liver damage for people who were infected with Hepatitis C

In February 2020 at the end of the hearings with the expert groups I said:

> "*I would like to draw the attention publicly now of NHS England and hospital trusts and boards throughout the country to the fact that the need for specialist treatment by professionals who have a special understanding of infected blood and blood products has not gone away, now that there is greater success in treatment of the underlying conditions, that there is a need to ensure that the standards of follow-up of those who have cleared Hepatitis C but have been left with a compromised liver are maintained in accordance with what the experts have set out this week*".[164]

One of the most important issues to participants in relation to their treatment is their ability to access monitoring and follow up care for Hepatitis C (and related symptoms and conditions) after they achieve sustained virological response ("SVR"). This arises because of their very reasonable anxieties about the harm long-untreated Hepatitis C may have done to their bodies. Even if "cured", in the sense that the disease process itself is no longer active, it has left an increased risk of developing end-stage liver disease or liver cancer if they had developed fibrosis or cirrhosis before treatment.[165] Witnesses told the Inquiry that they had simply been discharged from any ongoing care or monitoring following achievement of SVR. Currently there is no consistent clinical practice, and some patients receive no clinical surveillance.

The prognosis and progression to cirrhosis and hepatocellular cancer is variable as between patients,[166] with the major factor determining any long-term impact being the degree of liver fibrosis at the time the person's Hepatitis C PCR test became negative.[167] That has treatment and monitoring implications. Although there is evidence that treatment intervention, even at

164 Sir Brian Langstaff Transcript 28 February 2020 pp177-178 INQY1000054

165 Hepatitis Expert Panel Transcript 26 February 2020 pp173-181 INQY1000052, Expert Report to the Infected Blood Inquiry: Hepatitis January 2020 p58, pp67-68 EXPG0000001

166 Expert Report to the Infected Blood Inquiry: Hepatitis January 2020 p30 EXPG0000001

167 Expert Report to the Infected Blood Inquiry: Hepatitis January 2020 p58 EXPG0000001

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late stages of fibrosis, will change the risk of liver failure dramatically, successfully treated patients still carry risks of progressing to cirrhosis.[168] Further, evidence from Scotland has shown that after successful treatment, the risk of cancer fell but did **not** return to normal after a three year period.[169] The extent to which SVR is associated with a reduction in the risk of Hepatitis C-related damage (note, this is a reduction, not an eradication) depends on the time Hepatitis C has been left to progress untreated and to what extent fibrosis or cirrhosis has already occurred. There is thus a long term risk of those infected by NHS treatment – the vast majority of whom were left untreated for years or even decades – developing liver cancer even for those who have not reached liver failure.[170] Liver cancer is such that surveillance is crucial for identifying it at an early stage. The tumour is "*very variable … and some patients despite screening may be diagnosed at a late stage, even though they've been undergoing tests.*"[171]

It is possible in theory for HCV to "*reactivate*" following immunosuppression, for example associated with cancer treatment, if the assumed SVR did not in fact amount to full clearance of the virus. "*You can think you have got rid of a virus infection in a human host and then you do something to them and if there is any residual virus it may reactivate.*"[172] Though confirmed as a theoretical possibility in the Expert Report to the Infected Blood Inquiry: Virology (Hepatitis Supplementary), which also confirms that there is "*no perfect test to establish* [complete eradication]" of Hepatitis C it should be noted that the Expert Group says that rates of recurrence are very low (if it has not occurred within 12 weeks of finishing therapy) and it is rare after 24 weeks.[173]

In the chapter on *Access to Treatment*, I recorded the recommendations of Professor Michael Makris. These relate to people with an inherited bleeding disorder infected with Hepatitis C, but they are equally applicable to those who have been infected by transfusion. He recommends that those who are infected, including those who have successfully cleared the virus, should be reviewed by a liver specialist at least once. He explains that many of the patients with bleeding disorders treated over the last 35 years, especially prior to the last decade, will have been treated through haemophilia centres rather than by an hepatologist. Studies have shown that successful Hepatitis C treatment does not eliminate the risk of liver-related complications in persons with infected bleeding disorders. Due to higher baseline risk, incidence was higher after direct-acting antivirals than interferon-based SVR – since people were being treated later.[174]

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168 Hepatitis Expert Panel Transcript 26 February 2020 pp96-97 INQY1000052

169 Hepatitis Expert Panel Transcript 26 February 2020 pp96-97 INQY1000052

170 Expert Report to the Infected Blood Inquiry: Hepatitis January 2020 p56 EXPG0000001, Hepatitis Expert Panel Transcript 26 February 2020 pp170-171 INQY1000052

171 Hepatitis Expert Panel Transcript 26 February 2020 p119 INQY1000052

172 Professor Richard Tedder Transcript 14 October 2022 p75 INQY1000256

173 Only 1 out of 384 patients suffered a recurrence 60 weeks after completing therapy. Expert Report to the Infected Blood Inquiry: Virology (Hepatitis Supplementary) December 2022 pp8-9 EXPG0000131

174 Written Statement of Professor Michael Makris WITN4033023. See the chapter on *Access to Treatment*.

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He recommends that patients with advanced fibrosis or cirrhosis are entered into an hepato-cellular screening programme, with six-monthly ultrasound scans and regular hepatology follow-up to detect early signs of liver failure because "*The chances of success in the treatment of hepatocellular carcinoma depends on how early it is diagnosed, so every attempt should be made for early identification.*" He notes that "*If surveillance is required, there should be a named doctor/team responsible for making sure it takes place on time*" and that those with an inherited bleeding disorder who have had Hepatitis C should be seen by a consultant hepatologist, rather than a more junior member of staff.[175]

I said in the course of the hearings, and repeat here, that given the particular complexities infected people with inherited bleeding disorders present, and a need to have some understanding of the historical context, I agreed with what Professor Makris was saying.

In respect principally of people infected with Hepatitis C as a result of transfusion, the participants represented by Leigh Day[176] recommended in essence what Professor Makris had set out. Since I consider their recommendations to be justified by the evidence, my recommendations use their words as my own, with the addition of two further points.

The first is point (v) to accord with Professor Makris' recommendations in respect of the involvement of a consultant hepatologist.

The second reflects the commentary at the conclusion of the section on *Treatment of Hepatitis C* in the chapter on *Access to Treatment*, where I said that: "*The consistent delivery of appropriate follow-up monitoring is a legitimate concern. For this reason, I recommend that those bodies responsible for commissioning hepatology services in each of the home nations should publish the steps they have taken to satisfy themselves that the services they are commissioning meet the particular needs of this group of people harmed by NHS treatment, including those with bleeding disorders whose treatment for Hepatitis C was not managed by hepatologists.*"

I therefore recommend:

6. Monitoring liver damage for people who were infected with Hepatitis C

(a) All patients who have contracted hepatitis via a blood transfusion or blood products should receive the following care:

(i) those who have been diagnosed with cirrhosis at any point should receive lifetime monitoring by way of six-monthly fibroscans and annual clinical review, either nurse-led, consultant-led or, where appropriate, by a GP with a specialist interest in hepatitis

175 Written Statement of Professor Michael Makris p4 WITN4033023. See the chapter on *Access to Treatment*.

176 This was a group which consisted largely of those who had been infected by transfusion, the majority of whom were infected by Hepatitis C. Final Submissions on behalf of Leigh Day Participants 16 December 2022 pp202-203 SUBS0000059. This is consistent with the advice of the expert group on hepatitis. Expert Report to the Infected Blood Inquiry: Hepatitis January 2020 pp67-68 EXPG0000001

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(ii) those who have fibrosis should receive the same care

(iii) where there is any uncertainty about whether a patient has fibrosis they should receive the same care

(iv) fibroscan technology should be used for liver imaging, rather than alternatives

(v) those who have had Hepatitis C which is attributable to infected blood or blood products should be seen by a consultant hepatologist, rather than a more junior member of staff, wherever practicable

(vi) those bodies responsible for commissioning hepatology services in each of the home nations should publish the steps they have taken to satisfy themselves that the services they are commissioning meet the particular needs of the group of people harmed by NHS treatment

7. Patient Safety: Blood transfusions

The measures taken to reduce the risk of transmission of infection by the blood services have greatly changed the risk-profile of blood transfusion. The majority (>80%) of reports to the Serious Hazards of Transfusion scheme ("SHOT") are now due to errors or mistakes in the clinical transfusion process. The biggest risks are receiving the wrong blood (either the wrong component is transfused or specific requirements are not met), receiving too much blood too quickly and developing transfusion associated circulatory overload ("TACO"), or not receiving blood quickly enough (blood delays).

Shared decision making and consent in clinical transfusion practice was recommended by the Advisory Committee on the Safety of Blood, Tissue and Organs ("SaBTO"), by NICE in their blood transfusion guidance (and supported, in Scotland, by Realistic Medicine) yet successive audits, including a recent audit against the NICE Quality Standards, has demonstrated less than universal compliance.

Though NHS hospitals and staff continue to be under exceptional pressure, perhaps never more so than over the past few years, most of these are systems errors preventable with the right processes, knowledge and training as well as implementation of enhanced electronic clinical systems which promote and support best practice in the laboratory and at the bedside.

Professor Cheng-Hock Toh, chair of the National Blood Transfusion Committee, asked readers of the *British Medical Journal* the question "*How can we ensure that the right patient gets the right blood at the right time*?" He summed up his answer by saying "*Preventing ... avoidable harm is not difficult – it needs clear leadership and resolve to make the right decisions to use blood effectively and for the right blood to be transfused in a timely manner*."[177]

177 Cheng-Hock Toh *How can we ensure that the right patient gets the right blood at the right time?* British Medical Journal 23 October 2023 RLIT0002235

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What he says resonates with the evidence there has been before the Inquiry, and leads to six improvements which will help to avoid harm.

The first is in respect of how best to avoid blood transfusions which though very safe indeed (nowadays) nonetheless always come with risks, some of which, as of now, may be unknown.

Tranexamic acid

There is a substantial body of evidence which shows that patients who receive tranexamic acid[178] have significantly less life-threatening bleeding, major bleeding or bleeding into a critical organ within the 30 days after treatment. There is no difference in the risk of unwanted thrombosis. Large surgical trials have shown that tranexamic acid resulted in a lower incidence of postpartum haemorrhage amongst patients undergoing caesarean section, and a lower incidence of haemorrhage resulting in re-operation among patients undergoing cardiac surgery.[179]

Its use is supported by NICE. In 2015 NICE issued a guideline recommending that tranexamic acid be offered to adults undergoing surgery who are expected to have at least moderate blood loss; and that tranexamic acid be offered to children undergoing surgery as well, if they are expected to have at least moderate blood loss (ie greater than 10% blood volume). Tranexamic acid is not expensive. There is strong evidence that it is clinically effective and that its use will reduce mortality and costs. Yet it was noted that clinical opinion was that usage might have been as low as 10%-20% at that point.[180]

It became a NICE quality standard in December 2016.[181] By 2021 a national comparative audit showed that 67.5% of eligible surgical patients were given tranexamic acid, though potentially all were eligible to receive it.[182] It appears there is a NICE quality standard that is not being well implemented.

Patients at risk of a blood transfusion could have been offered it too, and in Professor Roberts' view should have been. He said: "*if I had surgery and woke up to find I'd received blood and I hadn't been given tranexamic acid, I'd be really annoyed* …"[183] So he and Professor Mike Murphy (of NHSBT and professor of blood transfusion medicine at the University of Oxford) formed an ad-hoc group with representation from the Royal College of Surgeons of England, the Royal College of Anaesthetists and the Royal College of Physicians, and "*we wrote an editorial and said ... the status quo isn't adequate and we're going to try and*

178 Tranexamic acid prevents the natural process of clot breakdown, allowing the clot to stay in place. The body is therefore more likely to clot successfully, to stem bleeding.

179 Devereaux et al *Tranexamic Acid in Patients Undergoing Noncardiac Surgery* New England Journal of Medicine April 2022 RLIT0001825, Professor Ian Roberts Transcript 10 November 2022 pp70-79 INQY1000259

180 NICE Guideline on Blood Transfusion 18 November 2015 p10, p22 RLIT0001793

181 NICE Quality standard on Blood Transfusion 15 December 2016 RLIT0001794

182 NHS Blood and Transplant *2021 National Comparative Audit of NICE Quality Standard QS138* February 2022 p9 WITN7001061

183 Professor Ian Roberts Transcript 10 November 2022 p86 INQY1000259. Professor Roberts is a professor of epidemiology at the London School of Hygiene and Tropical Medicine.

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change things, and we made some suggestions of what we think needed to be done and we are still in the process of trying to carry those things out."[184]

They have recently pointed out that the 2023 audit of the NICE Quality Standards for Blood Transfusion produced nearly identical results to the 2021 audit.[185] The actions thus far taken have been ineffective, despite the Royal College of Surgeons (England) and the Royal College of Anaesthetists having highlighted its use, and aimed to ensure that "*consideration of tranexamic acid use*" is included in the safe surgery checklist of all NHS hospitals.[186]

The National Medical Director of NHS England, Stephen Powis, wrote in 2022 to Trust medical directors recommending the wider use of tranexamic acid to reduce bleeding in surgery.[187]

Professor Toh, wrote in the *British Medical Journal* as chair of the National Blood Transfusion Committee:

> "*The number of deaths related to blood transfusions has more than doubled since the covid-19 pandemic and the Serious Hazards of Transfusion group reports that these numbers have not returned to pre-pandemic levels, remaining at or above 35 deaths per annum since 2020.*
>
> *This is deeply concerning but not entirely surprising in an overstretched NHS, yet immediate and sustainable improvements are achievable. Firstly, we must effectively reduce blood loss and unnecessary use of blood. A huge body of evidence supports use of tranexamic acid to reduce major surgical bleeding by 25%, thus avoiding unnecessary blood use. Tranexamic acid is an inexpensive drug championed by UK Medical Royal Colleges*".[188]

He also said: "*leadership by integrated care boards in standardising and benchmarking transfusion performance between hospitals could deliver better patient blood management. This would save lives and avoid disastrous 'never events' in transfusion.*"[189]

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184 Professor Ian Roberts Transcript 10 November 2022 pp87-88 INQY1000259

185 Letter from Professor Murphy, Professor Roberts and Professor Toh to Sir Brian Langstaff 1 November 2023 p2 WITN7310003, NHS Blood and Transplant *2023 National Comparative Audit of NICE Quality Standard QS138* February 2024 p14 RLIT0002421

186 Letter from Professor Murphy and Professor Roberts to Sir Brian Langstaff 16 November 2022 p2 WITN7310002

187 Cheng-Hock Toh *How can we ensure that the right patient gets the right blood at the right time?* British Medical Journal 23 October 2023 p1 RLIT0002235

188 Cheng-Hock Toh *How can we ensure that the right patient gets the right blood at the right time?* British Medical Journal 23 October 2023 RLIT0002235

189 Cheng-Hock Toh *How can we ensure that the right patient gets the right blood at the right time?* British Medical Journal 23 October 2023 RLIT0002235

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I recommend that:

7. Patient Safety: Blood transfusions

(a) Tranexamic acid

(i) In England Hospital Transfusion Committees and transfusion practitioners take steps to ensure that consideration of tranexamic acid be on every hospital surgical checklist; that hospital medical directors be required to report to their boards and the chief executive of their Trust as to the extent of its use; and that the board report annually to NHS England as to the percentage of eligible operations which have involved its use. If the percentage is below 80% or has dropped since the previous year, this report should be accompanied with an explanation for the failure to use more tranexamic acid and thereby reduce the risk to patient safety that comes with using a transfusion of blood or red blood cells.

(ii) In Scotland, Wales and Northern Ireland offering the use of tranexamic acid should be considered a treatment of preference in respect of all eligible surgery.

(iii) Consideration be given to standardising and benchmarking transfusion performance between hospitals in order to deliver better patient blood management.

The recommendations which follow closely follow recommendations suggested by the NHSBT in their closing submissions. Though in the way they are formulated, they relate (necessarily) to England, I note that the Welsh Blood Service "*agrees and endorses the comprehensive submissions and recommendations now advanced to the Inquiry by NSHBT ... in Wales, headways is already being made in areas which overlap some of the recommended actions, as a result of the Welsh-specific NHS Wales Blood Plan ... WBS will consider with care whatever recommendations the Inquiry makes, with a view to building on those improvements which have already started*."[190] The Northern Ireland Blood Transfusion Service "*earnestly awaits Sir Brian's recommendations to explore further ways in which to deliver improved and enhanced care to its service users.*"[191] The Scottish National Blood Transfusion Service has developed its own similar approach. In 2021 it set out a 5-year plan. The strategy comprises three main strategic goals: Education, Communication and Data & Quality Improvement.[192]

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190 Closing submissions of the Welsh Blood Service 15 December 2022 p2 SUBS0000049

191 Closing submissions of the Northern Ireland Blood Transfusion Service 16 December 2022 p23 SUBS0000051

192 In overview, these are:

Education: to continue to educate and develop a workforce to deliver person centred care with the key focus on the safe, effective and appropriate use of blood for patients in Scotland

Communication: between team members and the transfusion network to promote and share initiatives in clinical transfusion practice

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Review of progress towards the Transfusion 2024 recommendations

In 2019 in England a plan – *Transfusion 2024* – set out key priorities for clinical and laboratory transfusion practice for safe patient care across the NHS for the next five years. It was based on the outcomes of a symposium in March 2019, organised by the National Blood Transfusion Committee and supported by NHS England and NHS Improvement. The key priorities were set out under four headings in a table – Patient Blood Management, Transfusion Laboratory Safety, Information Technology, and Recommendations for further research and development – each with a number of specific actions to be taken.[193] Progress needs to be maintained – first by publicly assessing progress across the first five years, and determining what the next steps should be, including whether a further five year plan is merited.

I recommend:

(b) Progress in implementation of the *Transfusion 2024* recommendations be reviewed, and next steps be determined and promulgated; and that in Scotland the 5 year plan is reviewed in or before 2027 with a view to determining next steps.

The responsibility for this in England is that of NHS England, shared with the National Blood Transfusion Committee, the Royal Colleges (as appropriate), and NHSBT.

Transfusion laboratories

Transfusion laboratory safety is one of the key priorities expressed in *Transfusion 2024*. Though transfusion is in general conducted very safely, there are still hazards, to which SHOT draws attention in its annual reports. Most transfusion-related complications arise from mistakes in hospital transfusion laboratories.[194] Thus in 2020, 323 such complications were reported; in 2021, 266; and in 2022, the latest year for which there is a report, 296.[195]

Clinical and laboratory teams can function optimally only if adequately staffed and resourced. Inadequate staffing levels have been a common feature to which other inquiries into NHS incidents have drawn attention. They include the Mid Staffordshire Inquiry;[196] the Paterson

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Data and quality improvement: to use the unique opportunity of Account for Blood (AfB) and the Scottish Transfusion Epidemiology Database (STED) along with other healthcare datasets and dashboard capabilities to set and monitor key performance indicators and care quality indicators which continually improve clinical transfusion practice.

SNBTS Transfusion Team 5-year Strategy pp27-28 March 2021 WITN7300016

193 Allard et al *Transfusion 2024: A 5-year plan for clinical and laboratory transfusion in England* Transfusion Medicine 2021 pp2-4 WITN7001031. The seminar in March 2019 is discussed in the chapter *Blood Transfusion: Clinical Practice*.

194 Annual SHOT Report 2021 p77 SHOT0000032

195 Annual SHOT Report 2020 p73 SHOT0000031, Annual SHOT Report 2021 p77 SHOT0000032, Annual SHOT Report 2022 p73 SHOT0000033

196 Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry February 2013 RLIT0001925

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Inquiry;[197] the Ockenden Review;[198] and an inquiry into avoidable deaths and failures of care in sickle cell patients (*No One's Listening*).[199] Compliance with UK Transfusion Laboratory Collaborative ("UKTLC") standards has been accepted by the MHRA, and UK Accreditation Service as evidence to support their inspections for laboratories: the UKTLC has concluded that a significant proportion of the errors were most probably related to issues of information technology, staff education, staffing levels, skill mix, training and competency issues.[200]

This material leads me to recommend, as the NHSBT suggests that I should, that:

(c) Transfusion laboratories should be staffed (and resourced) adequately to meet the requirements of their functions.

Training in Transfusion Medicine

The Inquiry has heard evidence that clinicians, particularly those without expertise in the blood transfusion field, lack sufficient training. Historically, this has led to inappropriate use of transfusion; most notably transfusion where it is unnecessary.[201]

In a context where risks inherent in blood and blood components can never be nil, it is important that inappropriate use of transfusion is avoided. In addition, avoidable errors in relation to blood transfusion remain.[202] All staff likely to be involved in blood transfusions need to have basic knowledge of blood components, indications for use, alternative options where available, risks, benefits, possible reactions, and management. In addition, such staff need to have the skills to improve patient outcomes in respect of transfusion and reduce health inequalities by involving patients in their own care and ensuring that any care takes into account the needs of patients as individuals.

NHSBT recommends that reducing risks to patients' safety in this respect involves haematology training, transfusion training, and education on the Better Blood Transfusion initiative.[203]

SNBTS says that the LearnBloodTransfusion e-learning programme started in 2004, and until recently was used throughout the UK. In Scotland it is mandated that all those in clinical

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197 Report of the Independent Inquiry into the Issues raised by Paterson February 2020 RLIT0001926

198 Ockenden review summary of findings, conclusions and essential actions 30 March 2022 RLIT0001927

199 No One's Listening: An Inquiry Into The Avoidable Deaths and Failures of Care for Sickle Cell Patients in Secondary Care RLIT0001928

200 Chaffe et al *UK Transfusion Laboratory Collaborative: minimum standards for staff qualifications, training, competency and the use of information technology in hospital transfusion laboratories 2014* Official Journal of the British Blood Transfusion Society 29 October 2014 RLIT0002437. The UK Transfusion Laboratory Collaborative was formed in 2006 in response to 30-40% of all wrong blood events reported to SHOT originating in hospital transfusion laboratories. It involves all major transfusion organisations in the UK.

201 See the chapter *Blood Transfusion: Clinical Practice*.

202 For example, see the 2022 SHOT report: *Annual SHOT Report 2022* SHOT0000033

203 In her Written Statement Dr Miflin described some of the work that NHSBT already does in respect of training in blood transfusion at the postgraduate level. Written Statement of Dr Gail Miflin paras 1480-1488 WITN0672006. See also Closing Submissions of NHSBT 16 December 2022 para 17.43 SUBS0000062

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transfusion practice complete the Safe Transfusion Practice module within the first few weeks of starting work in a Scottish hospital and compliance is monitored by the hospital transfusion committee. The SNBTS transfusion team signpost the modules to be completed by each staff group. NHSBT has now developed an alternative e-learning programme Blood Transfusion Training.[204]

I recognise that the content of training is carefully considered by those bodies whose principal concern it is. However I recommend (as invited to do by NHSBT):[205]

(d) That those bodies concerned with undergraduate and postgraduate training across the UK of those people who are, or intend to be, working in the NHS ensure that they are adequately trained in transfusion, that the standards by which sufficiency of training is measured are defined, and accountability for training in transfusion be defined.

Implementing SHOT reports

Acting on reports of near-misses and serious events is part of the tapestry of haemovigilance. The MHRA, SHOT and the National Blood Transfusion Committee now between them provide a complete picture on haemovigilance in the UK. The role and work of SHOT has been set out in evidence by Professor Bellamy.[206] He said, in compelling evidence, that mandating reporting to SHOT would help, because:

> "*we know that there is a large level of underreporting … It simply isn't credible that years go by when no hospital has a near miss … I think for near misses, there is a tendency not to report things. But if you want a system which is robust, which is going to stop the real harm from taking place, you're not going to do that by waiting until that real harm occurs. You need to recognise the patterns beforehand. You need to recognise the behaviours, the practices, the systems errors, which lead to those near misses because it's only if you get rid of all the near misses that you're going to stop the eventual actual event from happening.*"[207]

In his statement he explained that "*reporting … to the MHRA is mandatory for actual serious adverse events and reactions, but reporting to SHOT, for example, near-misses, is 'professionally mandated' but not legally mandatory, but forms part of clinical governance*

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204 para 241 SUBS0000044. SNBTS also worked with the territorial health boards through the Scottish National Blood Transfusion Committee ("SNBTC") and Haematology and Transfusion Scotland Network to develop a Scottish National Transfusion Record ("NTR") in July 2022, which guides clinicians through the consent process with a Transfusion Associated Circulatory Overload ("TACO") checklist.

NHS Lothian Transfusion Education and Training: Blood Transfusion procedure outlines the transfusion education and training requirements of staff members involved in any stage of the transfusion process. (November 2023)

205 Closing Submissions of NHSBT 16 December 2022 paras 17.41-17.43 SUBS0000062

206 Written Statement of Professor Mark Bellamy WITN7312001, Professor Mark Bellamy Transcript 16 November 2022 p182 INQY1000263. Professor Bellamy is chair of the SHOT steering group.

207 Professor Mark Bellamy Transcript 16 November 2022 pp64-65 INQY1000263

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arrangements for Trusts and Health Boards … although SHOT and MHRA use an integrated reporting portal".[208]

He thought that mandating NHS trusts and health boards to have a designated person in place to report haemovigilance matters might be possible. If such a post were not mandated, he feared that what would then be an optional position could be an early victim of cuts.[209] Professor James Neuberger was "*very much in favour*" of legally mandating reporting, and said that having someone statutorily responsible would be a "*very useful start.*"[210]

As I comment in the chapter on *Blood Transfusion: Clinical Practice*:

> "*all three of Professor Bellamy, Professor Neuberger and Dr Cave thought more reporting should be encouraged; all agreed that near-misses should be identified (indeed, the reasoning articulated for this by Professor Bellamy is compelling), and differed only on whether the effect of mandating a 'responsible person' to ensure proper haemovigilance reporting would be to incentivise others to think of reporting or lead to them thinking that it was someone else's responsibility … for my part I think that mandating trusts and health boards to have a responsible person in place, as a first step, together with a regularly audited professional requirement on doctors who are responsible for giving transfusions to include in their report not only that a transfusion was given (recording the identifiers of the unit(s)) but stating why it was given would be more likely to underpin the importance of haemovigilance than water it down.*"

SHOT is a professionally independent body making recommendations to improve blood safety to all organisations involved in blood transfusion. Reporting to SHOT is "*professionally mandated*". Thus, among other mechanisms, the regulatory framework operating around implementation of SHOT report recommendations should similarly be professionally mandated and monitored by healthcare regulators. This will produce a requirement for implementation within a system which has an in-built monitoring framework. This must not absolve healthcare providers of a separate obligation to monitor the implementation of the recommendations. In the submission of NHSBT it nonetheless retains an appropriate flexibility for good reasons and an appropriate risk assessment.[211]

I recommend:

(e) That all NHS organisations across the UK have a mechanism in place for implementing recommendations of SHOT reports, which should be professionally mandated, and for monitoring such implementation.

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208 Written Statement of Professor Mark Bellamy para 33 WITN7312001. He said *"the existing regulations are a little bit too flimsy and nebulous, whereas what is laid out for the MHRA reporting scheme and the BSQR* [Blood Safety and Quality Regulations] *is absolutely clear.*" Professor Mark Bellamy Transcript 16 November 2022 pp65-66 INQY1000263

209 Professor Mark Bellamy Transcript 16 November 2022 pp66-67 INQY1000263

210 Professor James Neuberger Transcript 16 November 2022 pp66-67 INQY1000263

211 Closing Submissions of NHSBT 16 December 2022 para 17.34 SUBS0000062

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Establishing the outcome of every transfusion

It is likely to be of significant importance to establish the outcome of every transfusion. If this had been achieved at the time of the principal events described in the Report, it seems likely that alarm bells would have rung sooner; that infections would have been detected (clinically, if they could not be established by existing tests) and advice to patients have been better informed, more quickly.

Scotland started developing the system "Account for Blood" in 2008 and it was in use from 2010. The database now covers 95-98% of blood transfusions in Scotland. The Scottish Transfusion Epidemiology Database uses the patient data from the Account for Blood system and links it with hospital inpatient records.[212] SNBTS worked with the territorial health boards through the Scottish National Blood Transfusion Committee and Haematology and Transfusion Scotland Network to develop a Scottish National Transfusion Record in July 2022, which guides clinicians through the consent process with a Transfusion Associated Circulatory Overload (TACO) checklist. The current aim, as part of a 5 year plan is to better understand the demand for blood components and how demand changes over time.

Outside Scotland the outcomes for recipients of blood components are not easily known without a national or clinical audit. *Transfusion 2024* has been mentioned above. It includes development of a system of "vein-to-vein" tracking. The plan notes that implementation of these significant schemes would be subject to finding the funds to do so.[213] However, NHSBT submits that having robust systems to understand the outcomes of people undergoing transfusion of blood components, coupled with one that allows clinical audit and research, should be an aim of the NHS. This is likely to be best achieved using the IT systems currently being developed, which have appropriate interfaces between existing systems.[214] Furthermore, if it is done correctly it should allow NHSBT to manage the blood stocks throughout the system and for experts to audit the appropriate use of blood components using simple tools of analysis rather than large complex time-taking audits, thus in itself leading to a greater likelihood of a better use of blood.[215]

I am told that the recording of, and access to, information concerning transfusion is currently difficult in the NHS in England. The lack of integration between various records is an important limitation which hampers patient access to information, and limits the ability of the blood service to undertake tracing, audit and root cause analysis.[216] Thus, a framework within existing systems should be established for proper recording of outcomes for recipients of blood components.

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212 Closing Submissions of SNBTS 16 December 2022 paras 242-245 SUBS0000044

213 Allard et al *Transfusion 2024: A 5-year plan for clinical and laboratory transfusion in England* Transfusion Medicine 2021 p3 WITN7001031

214 Simply trying to take data out of many existing systems into a new registry would be fraught with data transfer risks and potential errors and would be extremely difficult to set up and costly to maintain.

215 Closing Submissions of NHSBT 16 December 2022 para 17.57 SUBS0000062

216 Closing Submissions of NHSBT 16 December 2022 para 17.58 SUBS0000062

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Though this recommendation is focused on the blood services in England, the outcomes which are reported should be of interest to the WBS, NIBTS and SNBTS. The latter recommends the implementation of enhanced electronic clinical systems which promote and support best practice at the bedside as a major plank in preventing avoidable systems errors from harming patients. It is important that resources continue to be allocated to improve these further – and to ensure that insofar as those systems provide information on outcomes from transfusion the detail is shared, possibly through SHOT, with the other blood services of the UK.

I recommend:

(f) Establishing the outcome of every transfusion

(i) That a framework be established for recording outcomes for recipients of blood components. That those records be used by NHS bodies to improve transfusion practice (including by providing such information to haemovigilance bodies).

Success in achieving this will be measured by the extent to which the SHOT reports for the previous three years show a progressive reduction in incidents of incorrect blood component transfusions measured as a proportion of the number of transfusions given.

(ii) To the extent that the funding for digital transformation does not already cover the setting up and operation of this framework, bespoke funding should be provided.

(iii) That funding for the provision of enhanced electronic clinical systems in relation to blood transfusion be regarded as a priority across the UK.

8. Finding the undiagnosed

When doctors become aware that patients received a blood transfusion prior to 1996[217] they should immediately be offered a test for Hepatitis C (if they have not already had one). There may be limited opportunities in the usual interactions between patients and their GPs for it to be found out in normal practice that a given patient had ever had a transfusion in the past, if it is not already known. However, the opportunity arises when a new patient is registered at a practice. They should then be asked, as a matter of routine, if they had a transfusion before 1996 and, if they say they have, should be offered the opportunity of a precautionary blood test. There need be no alarm for the patient about this: rather, the offer should instil confidence that their safety is being protected by the doctor, and a substantial majority of previously untested patients may expect the reassurance of a negative test. However, if the test is positive (as it is likely it will be in some cases) then treatment with

217 The reasons for picking this date are that it is reasonably possible that some infections may have occurred from blood transfusions after universal screening was introduced in September 1991, and it was in 1996 that SHOT effectively began.

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direct acting antivirals may follow.[218] This requirement would also have the effect of raising awareness in general practice about Hepatitis C and thereby reduce the number of people diagnosed very late, some of whom have given evidence to this Inquiry.

I recommend:

8. Finding the undiagnosed

(a) When doctors become aware that a patient has had a blood transfusion prior to 1996, that patient should be offered a blood test for Hepatitis C.

(b) As a matter of routine, new patients registering at a practice should be asked if they have had such a transfusion.

9. Protecting the safety of haemophilia care

Peer review of haemophilia centres

Audits of practice are more often than not conducted internally in hospital Trusts and health boards: if shortcomings are identified, that leads to discussions and agreement as to the steps necessary to overcome them; these steps are then implemented; and then whether and how far those steps have been successful in remedying the original shortcomings is assessed. Audit of a specialist centre which is not conducted internally, but by a clinical team from other centres is probably better described as “peer review”.

A practice of peer review of haemophilia centres by haemophilia consultants from other centres has grown up since 1991 (in Northern Ireland and Scotland) and in England and Wales (1992/93), and has been refined over time. Consultant specialists help to identify service gaps against the service specification adopted at the time. Over the years since then, this too has evolved. A national service specification for haemophilia and related conditions has been developed and published.[219]

Peer review not only helps a centre to be better assured it is adopting “best practice”, or identifies where it may be falling short, but it can highlight matters of growing concern across the country. Thus, the last peer review reported inequity in the quality of care provided

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218 The Statistics Expert Group compared the age-sex bands for EIBSS claimants in England against their statistical estimates for the number of people infected with Hepatitis C through transfusions and identified three groups who appear to be underrepresented:
- people born 1975-1984 who had a transfusion as a child (at best a quarter of the number estimated feature as claimants)
- people born 1965-1974 who had a transfusion (only a third of the number estimated feature as a claimant)
- women born 1945-1964 who had a transfusion around childbirth (just over half the number estimated feature as claimants)

Expert Report to the Infected Blood Inquiry: Statistics (Supplementary) July 2023 p9 EXPG0000132

219 The Haemophilia Alliance *A National Service Specification for Haemophilia and other Inherited Bleeding Disorders* February 2006 HSOC0020872

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because of inconsistency in the provision of key staff groups especially in physiotherapy and psychosocial care.[220]

Three institutional core participants (UKHCDO, the Scottish Territorial Health Boards, and the Belfast Health and Social Care Trust) support auditing and peer review: technically, the professional assessment, against standards, of the organisation of healthcare processes and quality of work, with the objective of facilitating its improvement. The primary aim is to ensure the care provided is both safe, and of the highest quality, and that shortfalls in provision are identified. In particular, in a small specialty such as haemophilia, this enables best practice to be maintained across the UK.

However, peer review is defeated if the recommendations made as a consequence of the review are not implemented. Accordingly, I recommend:

9. Protecting the safety of haemophilia care

(a) That peer review of haemophilia care should continue to occur as presently practised, with any necessary support being provided by NHS Trusts and Health Boards; and

(b) That NHS Trusts and Health Boards should be required to deliberate on peer review findings and give favourable consideration to implementing the changes identified with a view to ensuring comprehensive, safe, care.

(c) A peer review of each centre should take place not less than once every five years.

Networks for haemophilia care

Most haemophilia centres only have a small number of dedicated specialists, since bleeding disorders are relatively rare. It can be all too easy for these small numbers to lead to a degree of isolation amongst specialists, or to create difficulties in facilitating discussion of haemophilia care during the course of busy practices, especially since these often involve other aspects of haematology. The Scottish Territorial Health Boards have found it particularly useful for there to be regional networks of clinicians providing regular forums for case and policy discussions. These networks are arranged so that they include patient involvement in policy discussions.[221]

At the moment, Scottish haemophilia centre directors meet every two months, and constitute such a network: patient input to the forums comes via the Scottish Inherited Bleeding Disorder Network.[222]

220 *Overview Report of the Inherited and Acquired Haemophilia and other Bleeding Disorders Peer Review Programme* May 2020 p5 RLIT0001937

221 Closing submissions of the NHS Scotland Territorial Health Boards pp112-113 SUBS0000058

222 Closing submissions of the NHS Scotland Territorial Health Boards p113 SUBS0000058

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To an extent, such networks already exist informally elsewhere, and with some support from the Haemophilia Society and UKHCDO. However, discussion in a multidisciplinary format, involving patients, would help to prevent one or two voices having a disproportionate influence on care over others. As the history revealed by the Inquiry has shown, the influence of one or two voices can (and did in 1983/84) have a damaging effect on the safety of patient care: the moderating effect of wider discussion, the involvement of patients, and of other clinical disciplines should help to avoid this being repeated in future.

Accordingly, I recommend that:

(d) The necessary administrative and clinical resources should be provided by hospital trusts and boards, integrated care boards, and service commissioners to facilitate multi-disciplinary regional networks to discuss policy and practice in haemophilia and other inherited bleeding disorders care, provided they involve patients in their discussions.

Recombinant factor products

In the submissions made by participants represented by Collins solicitors[223] it is indicated that people with severe von Willebrand disorder are still being treated with plasma-based factor products. I recommend (adopting wording used by the Scottish Territorial Health Boards, who also favour this proposal)[224] that, across the UK:

(e) recombinant coagulation factor products should be offered in place of plasma-derived ones where clinically appropriate. Service commissioners should ensure that such treatment decisions are funded accordingly.

National haemophilia database

There is no doubt that a database of the type which the National Haemophilia Database ("NHD") constitutes should be maintained. It helps to track the occurrence of disease, its prevalence, and clinical outcomes (in particular, mortality over time). It helps to identify needs as yet unmet in order to plan future therapeutic and organisational arrangements. Such a registry was recommended by the European Association of Haemophilia and Associated Disorders in 2008;[225] and is thought to be especially important for pharmacovigilance and planning of care including budget allocation.

It has been of considerable benefit to the Inquiry to have seen the figures and been supplied with data kept and collated by the NHD. Though there have historically been uncertainties about some of the data, and concerns about the way in which the data was collected, it has

223 Submissions on behalf of the core participants represented by Collins Solicitors p202, p222 SUBS0000063

224 Submissions on Recommendations of the NHS Scotland Territorial Health Boards p7 SUBS0000006

225 Colvin et al *European principles of haemophilia* Haemophilia 21 November 2007 HSOC0021039

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nonetheless represented a reliable means of showing trends in care and outcome in some detail. It is thus useful for historical research where that is needed.

Individuals may opt out of their data being used for research should they wish to do so: those who do **not** opt out are included in the UK National Haemophilia Research Registry, which may be used for observational research (the identity of patients is not disclosed for this purpose).

The UKHCDO, which runs the NHD, is a charity. Its members are NHS consultants who work in NHS hospitals treating NHS patients. Its objectives are to preserve, protect and relieve persons suffering from haemophilia and other inherited bleeding disorders; to advance the education of the medical profession, the nursing profession, professions allied to medicine and the general public in the knowledge of haemophilia and other inherited bleeding disorders and their treatment; and to promote or assist in the promotion of audit and research into the causes, prevention, alleviation and management of haemophilia and other inherited bleeding disorders and to disseminate the useful results of such research.[226]

Currently the NHD is funded, through the UKHCDO, by a mixture of NHS, charitable and pharmaceutical money. There is a need for additional funding if it is to become a better tool for patient-centred care, and to be enabled to encourage equity of access by generating comparative reports. Additional funding would also support additional expert statistical input (for instance, enabling a mutually beneficial collaboration with universities), and enable a review of the database structure and its migration to more up-to-date technology.

UKHCDO and the Scottish Territorial Health Boards propose that further resource should be provided to enable these steps to be taken.[227]

If more public money is to be spent in enabling these improvements to the NHD, it might be thought that the NHD should be brought within the NHS, rather than remaining technically independent of it though entirely dependent on clinicians employed in the NHS and patients treated by it agreeing to provide it with the data on which its operation entirely depends.

I consider that there would be little advantage in this: it would expose the NHS to greater expense (at the moment, it contributes about half the cost of running the NHD: if the NHD were incorporated fully within the NHS the cost would all then fall upon its shoulders). If the NHD were formally made a part of the NHS itself it would inevitably be subject to the natural fluctuations of the health budget, and the uncertainties that come with that.

I have been persuaded that, at least for the foreseeable future (though matters should be kept under review) the NHD should continue to be run by the UKHCDO, funded as is currently the case, but that additional resource as indicated above should be made from public funds.

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226 United Kingdom Haemophilia Centre Doctors' Organisation *Constitution* November 2013 p1 WITN4031004

227 Submissions on Recommendations on behalf of UKHCDO 16 December 2022 para 290 SUBS0000050, Submissions on Recommendations on behalf of NHS Scotland Territorial Health Boards 14 June 2022 para 14 SUBS0000006

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I therefore recommend:

(f) that the National Haemophilia Database, run by the UKHCDO, merits the support of additional central funding.

10. Giving patients a voice

One of the most striking aspects of the evidence has been a failure adequately to listen to patients and to hear what they wanted, rather than assume the "listener" already knew.

There is no easy way of ensuring that medical authorities, and government, become less defensive when patients tell them that their care could have been better, or has failed in certain respects. The recommendations made already in this Report should go some way towards meeting that challenge. However, without enabling the patient voice to be heard better those improvements will be incomplete.

Accordingly, I recommend that steps be taken to help the patient voice to be both heard and taken into account in developing clinical policies, and healthcare policies in future.

There are a number of steps which it is desirable to take to achieve this. Some may seem minor, but they are, taken together, part of a composite picture of how patients can be enabled to play a full part in what is best seen as a patient-doctor partnership in care.

The first follows on from my recommendation that multidisciplinary regional network meetings to discuss policy and practice in future haemophilia care and treatment be facilitated. It is important that they involve patients, as they already do in the Scottish regional network system. That recommendation looks to give a stronger voice to people with bleeding disorders. It therefore does not apply in the same way to the far greater number of people who were infected with Hepatitis C as a consequence of transfusion when treated for conditions other than haemophilia.

Elisabeth Buggins has the perspective of a parent of children infected at children's hospitals, as well as experience of management within the NHS. Her view is that in more recent years the policy of the NHS internal market, intended to promote healthcare competition for patients' benefit, has led to a focus on performance management concentrating on NHS institutions rather than on the clinical benefits of decisions to individuals and to the health and happiness of communities. A cultural shift from focus on the institution to the individual needs, in her view, to be systemically supported by the way in which healthcare is organised. She argues that as part of this patient-reported outcomes and experiences should be measured in the process of clinical audit: too little of (otherwise very useful) clinical audit which is currently performed in hospitals routinely includes patient-reported outcomes or experience measures. She says that:

> "*The picture cannot be complete without it. Instead, the system relies on patients feeling strongly enough to write in with thanks or complaints and much useful insight is lost. Where patients are not routinely seen, such as those with milder*

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> *conditions, the incentive to write diminishes rapidly and should problems occur some distance from treatment, the treating hospital is unlikely to be informed about it."*[228]

A number of submissions have recognised the importance to patients of organisations or bodies which can speak for them, or lobby for them. Organisations can give people voice: the evidence of campaigners speaking for various different interest groups in the Inquiry has demonstrated that. Some organisations have charitable status, often now of some pedigree.

The Hepatitis C Trust operates on a truly UK-national basis. It has earned plaudits for the information it has been able to supply, the support it has been able to give, and the signposts by which it has directed individuals to find the support that they have needed. It has been able to speak for people infected with Hepatitis C in an undemonstrative but effective manner. Its ability to help people to understand that they are not alone, to help them access support and treatment and to understand it, and to speak for them has drawn almost unanimous unstinting praise across, and for the duration of, the Inquiry.

For people with haemophilia, the Haemophilia Society has been long established. The chapter about it describes some of its past history.[229] For the future, it can continue (as it has in recent years) to realise its potential as a fully effective voice ensuring that the patient view is made known not only at national but also, because of its organisation, at regional levels. In Scotland, there is a separate charity – Haemophilia Scotland. In Scotland there is also the Infected Blood Forum ("SIBF"), focused on giving patients a voice; in Wales, Haemophilia Wales; in Northern Ireland, Haemophilia Northern Ireland. In Northern Ireland, there is an allied organisation, Families and Friends of Haemophilia Northern Ireland, which is not itself a registered charity.

Organisations which are campaign or mutual interest groups, rather than charities, have also played a very valuable role, helping to give a collective voice to different strands of opinion amongst those who were infected, or affected. They have campaigned indefatigably; have enabled people to share a collective comfort in mutual support; have kept their members informed; and have developed close connections amongst their members that have not only preceded the Inquiry but seem likely to outlive it by quite a while. The end of a six year Inquiry following years of struggle to have their views heard and considered will bring personal and emotional challenges which the continuation of these groups would help to meet, particularly in the short term. The end of the Inquiry gives an opportunity for the Government to go some way to facilitate this. To do so would underscore the sincerity of the apology that I hope and expect will be forthcoming, and would show that the government is not dismissive of the prospect that these groups will have more to offer as a compensation scheme takes shape, and would enable the patient voice to continue to be heard on the issues reflected in this Report.

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228 Closing Submission of Elisabeth Buggins 16 December 2022 para 2, para 4, para 18 SUBS0000054

229 See the chapter on the *Haemophilia Society*.

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One of the weaknesses of the evidence before the Inquiry has come from the relatively low numbers of people with thalassaemia or sickle cell disease being prepared to speak to the Inquiry about their experiences. Proportionately, they must have suffered at least the same likelihood of blood-borne disease as others – indeed, given their need for regular transfusion, it is to be expected that people with thalassaemia or sickle cell disease will have a significantly higher proportion of blood-borne disease than do most people who have had a transfusion of only a few units.

The Thalassaemia Society ("UKTS") said in its final submissions:

> "*It was disappointing yet understandable for the* [current team at the UKTS] *that despite their best efforts of trying to encourage their membership and families affected to come forward and testify, many chose not to due to the trauma of the diagnosis, the rigorous and horrific treatment regimes, experiences, stigma and fatalities … In most communities in which thalassaemia is prevalent, there is an enormous amount of social stigma associated with living with an inherited condition affecting the production of red 'blood' cells. Within some communities, the idea of someone living with thalassaemia was inaccurately categorised as them having 'bad blood'. As a consequence of this, individuals would wrongly be considered as a 'burden', 'less than' and not 'marriage material' … Unfortunately, the stigma and belief is still present today … The feelings attributed to psychosocial burden due to thalassaemia were then further reinforced by the stigma associated with Hepatitis C.*"[230]

One of the recommendations which the UKTS urged upon me was public funding for the UKTS and other charities "*who supported and continue to support individuals who were infected or affected to provide advice, education and advocacy services. Public funding would help UKTS and other charities provide ongoing assistance and campaigning to ensure horrific events like these do not occur.*"[231]

It is in my view of particular importance that where it is known (as is beyond doubt here) that there is a voice to be heard, but that it is currently speaking in a very quiet whisper, steps must be taken, as best can be done, to enable those who should listen to it to hear it far more loudly.

Patient feedback

The MHRA makes an online Yellow Card system available through the gov.uk website, in order to notify it of any adverse reaction from drugs or medicines.[232] The existence of this online opportunity to provide feedback is not well known. It deserves greater publicity. It is part of listening to what patients have to say. One way of drawing attention to it would be for a yellow banner to be put across patient data information sheets which accompany

230 Closing Submissions of UKTS paras 6-8 SUBS0000067
231 Closing Submissions of UKTS para 11 SUBS0000067
232 yellowcard.mhra.gov.uk

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medicines advising people, to say that if they feel that they have an adverse reaction, even if (and perhaps especially if) the reaction is a delayed one, they should use the online portal to report it. The action required for this would simply be to mandate it – the product data sheet is paid for by manufacturers, and this would simply be additional but mandatory content.

This – or some similar way of drawing attention to the online Yellow Card scheme – applies only to those taking pharmaceutical medication. Where patients are told, or know, that they have had a transfusion of blood or a blood component, they should as a matter of practice be told that if they have any adverse reaction as a consequence they too can, and should, report it; and that although their principal point of contact to describe an adverse reaction is likely to be the treating clinician or body, they can in addition make a report of it through the Yellow Card online scheme if they wish to do so – and it is important that they take up this opportunity.[233]

Drawing these threads together, I recommend:

10. Giving patients a voice

(a) That the patient voice be enabled and empowered by the following measures:

(i) clinical audit should as a matter of routine include measures of patient satisfaction or concern, and these should be reported to the board of the body concerned.

Success in this will be measured by comparing the measure of satisfaction from one year to the next, such that the reports to the board concerned demonstrate a trend of improvement by comparing this year's outcomes with the similar outcomes from at least the two previous years.

(ii) that the following charities receive funding specifically for patient advocacy: the UK Haemophilia Society; the Hepatitis C Trust; Haemophilia Scotland; the Scottish Infected Blood Forum; Haemophilia Wales; Haemophilia Northern Ireland; and the UK Thalassaemia Society.

(iii) that favourable consideration be given to other charities and organisations supporting people infected and affected that were granted core participant status (as listed on the Inquiry website) to continue to provide support for at least the next 18 months. Further support should be reviewed at that stage with a view to it continuing as appropriate.

(iv) particular consideration be given, together with the UK Thalassaemia Society and the Sickle Cell Society, to how the needs of patients with thalassaemia or sickle cell disease can best holistically be addressed.

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233 Dr Alison Cave is Chief Safety Officer at the MHRA and told the Inquiry that patients with adverse reactions to a transfusion could report through the Yellow Card scheme using the option "*Report something not on our list*" at yellowcard.mhra.gov.uk. Dr Alison Cave Transcript 16 November 2022 pp76-77 INQY1000263

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(v) steps be taken to give greater prominence to the online Yellow Card system to those receiving drugs or biological products, or who are being transfused with blood components.

11. Responding to calls for a public inquiry

Rationale

By 1986 the Government can have been under no illusion about the scale of what had happened to people with haemophilia – many had been infected with HIV, a virus with an exceptionally high mortality rate for which there was no known treatment. Sufferers of HIV experienced public hostility and stigma. In addition, over the five years which followed it became apparent beyond question that the non-A non-B Hepatitis with which most had also been infected was far more serious than some clinicians would have wished to believe in the early 1980s.

Calls were raised suggesting that the root cause of the problem was a failure to plan for, and achieve, self-sufficiency in the supply of blood products. The decision by the regulator not to ban imports of commercial concentrate from the United States, recognised as being in the throes of an AIDS epidemic, was controversial.

Yet more people – many more – were known to be suffering from hepatitis transmitted by blood transfusion, and some more again had been infected by AIDS as a result of blood transfusion.

The sources of blood products and blood were said to be rife with disease, that insufficient precautions had been taken, and that the risks had never been spelt out to patients receiving blood and blood products

Yet as the chapter in relation to a *Delay in Holding a Public Inquiry* records that:

> "*there is no documentary evidence to show that it occurred to anyone within Government before 1989*[234] *either that there might be an important public interest in investigating and understanding precisely how this had occurred* [ie the fact that so many people had gone into hospital for treatment and come out infected by HIV or Hepatitis B or C]*, or that those whose lives had been devastated in this way might deserve answers as to how and why it had happened. It ought to have been clear that there were lessons to be learned for the future if something similar were not to recur.*"

234 It should be noted that Lord Norman Fowler, who was in office as Secretary of State for Health and Social Services prior to June 1987, has urged that it took far too long for this Inquiry to be held, and has himself criticised the prevarication over it being held.

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Reasons for not holding a public inquiry, as recorded in that chapter, were generally defensive and uninformative. The chapter does not bear repetition here: but it is worth reflecting that there were lessons to be learned from what had happened.[235]

A number of participants have called for the adoption of a recognised process in deciding whether or not there should be a public inquiry into a matter which is potentially of public concern, or from which lessons might be learned, or both. Given the background in the present case, they are right to do so.

The question involves resolving the circumstances in which an inquiry should be held, and who should have power to determine that the criteria for holding one have been met. The Inquiries Act provides, appropriately (but with a very broad level of generality) that:

> "*A Minister may cause an inquiry to be held under this Act in relation to a case where it appears to him that–*
>
> *(a) particular events have caused, or are capable of causing, public concern, or*
>
> *(b) there is public concern that particular events may have occurred.*"[236]

This means that the minister has a discretion. It is sufficient if it "*appears to him*" that there is, has been, or might well be public concern, and that there should be an inquiry. Equally, if the opposite appears to her or him, there will be no inquiry. For matters of UK-wide concern this is in practice the Prime Minister's decision.

The facts considered by this Inquiry indicate two shortcomings in this. First, the minister most likely to understand whether there is public concern may very well be the minister for the department of state which is most concerned with the subject matter. Where the inquiry is into the performance of (for instance) a particular hospital trust, poisoning by a hostile state, or murder by a healthcare professional, the minister of the department concerned[237] may well be inclined to think that public concern merits an inquiry. By contrast, they may be less inclined to hold an inquiry if the public concern is directed more toward the way in which their department discharged its responsibilities. It would be only human for civil servants in that department to be defensive – indeed, they may already have been, when concerns were first raised; and it may be also be understandable if a minister is worried in some cases that they, the minister, might be thought unsupportive of their department if they asked for there to be an Inquiry into it, and this might make it more difficult to lead it.

In short, the first weakness of Section 1 of the 2005 Act is that it provides a discretion liable to be exercised by someone in whose interests and inclination it may be to be defensive of their own department, who may well be assured by their own department that all the facts are known and that no harm was done, such that there is nothing to be concerned about and thus nothing to be inquired into – or nothing that an inquiry might add – and thus reject calls for there to be one. Further, if an inquiry is called, sponsored by and therefore paid by or

235 See the chapter *Lessons to be Learned*.

236 s1 The Inquiries Act 2005 p1 RLIT0002405

237 In the examples chosen, the health minister, or the Home Office minister.

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through a departmental budget, there are inevitably concerns that the independence of the inquiry may be compromised. The examples in the context of this Inquiry of the way in which the report about *Self-Sufficiency in Blood Products in England and Wales: a Chronology from 1973 to 1991* was handled, or the Scottish Executive report was unsatisfactory,[238] show that there can be good reason for worrying about the ability of an internal investigation to reveal the truth.

A further problem with the wording of the power is that it arises where there is "*public concern*". This is a very flexible concept. It must, practically, be linked to some concept of sufficiency. Is there enough public concern to justify holding one? How is this to be judged? Is it truly of interest to a wider public than a group with a particular sectional interest? If the bar is set too low, then inquiries risk becoming more common at great expense. If they do, the force that their recommendations might otherwise have is lost. There may be evidence of significant numbers of people who appear to share a particular concern, without there being an objective evaluation of whether that concern might actually be justified.

These concerns suggest there might be a need to amend the Act, to set out further criteria. However, that is a process which might take some time, and the flexibility the Act provides may be valuable. In the alternative, I propose an interim measure to provide the public with reassurance that widespread calls for an inquiry, or particular focussed concerns which justify one, have been properly considered by a body independent of the government department(s) of state most centrally concerned.

My recommendation is that the same body as I recommend should review progress towards responding to, and if accepted, implementing the recommendations of this Inquiry – the Public Administration and Constitutional Affairs Committee ("PACAC") – should have the more general function of considering whether to recommend to an appropriate minister that there be an inquiry. It should exercise this when there is sufficient support in Parliament for such a course.

This mechanism allows for significant flexibility to be retained as to the precise circumstances in which there should be an inquiry – inquiries take many forms, from those which consider a one-off incident, to those which involve considering the effectiveness of systemic controls, to those which consider historic practices which have recently come to light (eg the Inquiry into organ retention), to those which consider practices at a single institution (Strangeways; Mid Staffordshire), and those which consider the appropriateness of, or lack of, provision for certain groups. Each inquiry is unique: the procedure in each will differ. There is no room for a "one size fits all" approach. The Act remains in force, and the minister continues to have discretion as to ordering one, and if so whether it should be statutory.

The mechanism I propose ensures proper respect for the democratic process – the power to call an Inquiry remains ultimately within the hands of a minister (not necessarily the minister whose department is most centrally concerned), and the process is open to all the scrutiny,

238 See the chapters on the *Self-Sufficiency Report* and *Scotland*.

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and transparency, of the select committee process. It gives more confidence that if calls for an Inquiry are rejected there are good reasons for this, capable of being examined by a cross-party body; but it also provides a safeguard against inquiries being held too readily, as might be the case if more prescriptive criteria were to be set.

An inquiry hub has now been established within the Cabinet Office. In my view it is appropriate that in any case in which the department concerned is potentially subject to criticism at the conclusion of the investigation, the inquiry should be sponsored and supported by the Cabinet Office[239] (unless the Cabinet Office is itself the subject of inquiry; and with the exception of those inquiries where it appears to the minister that the department concerned is likely neither to be a core participant itself nor potentially subject to criticism at the conclusion of the Inquiry).[240]

This leads me to recommend:

11. Responding to calls for a public inquiry

(a) that a minister should retain the power to call an inquiry as the minister sees fit, in accordance with the Inquiries Act 2005 – but where a minister does not choose to do so, then:

(b) if there is sufficient support from within Parliament for there to be an inquiry, the question whether there should be one should be referred to PACAC for it to consider the question.

(c) If it appears to PACAC that there is sufficient concern to justify a public inquiry, either because what happened and why has caused concern (as the committee sees it) or there are likely to be lessons learned which may prevent similar concerns arising in future, the committee may recommend to an appropriate minister that there be an inquiry.

(d) If the minister disagrees with the recommendation, they must set out in detail and publish reasons for this disagreement which are sufficient to satisfy PACAC that the matter has been carefully and properly considered.

239 The present Inquiry is a case in point. An initial proposal was that the Department of Health and Social Care should sponsor the Inquiry. Since many of those likely to be participants in the Inquiry considered the department to have played a significant part in the failings which led to their suffering, and the reaction of the government in response, they rightly objected to this. The sponsoring minister became the Chancellor of the Duchy of Lancaster. I have been grateful for the support given by the Cabinet Office to this Inquiry, and also that at no stage has anyone from that Department sought to interfere with the inquiry process.

240 If, for instance, the Inquiry is into the behaviour of a single medical professional, or the performance of a particular hospital trust or board, it is unlikely to be necessary for public confidence that the DHSC stand aside from sponsoring the inquiry.

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12. Giving effect to Recommendations of this Inquiry

Part of the history of the Inquiry has been (a) delay on the part of successive governments; (b) the failure to account for inaction; and in consequence (c) a consequent loss of trust in authority by those who have been infected, and those in turn affected by the harm that had happened to people who were important to them.

As a public inquiry, it is being held in the public interest. That interest is essentially in three respects:

- what happened to lead to treatment causing so many serious infections, and why;
- how authorities reacted to what had happened, and why they did so; and
- the lessons to be learned from that and recommendations to be made so that the future is better, and past mistakes are not repeated.

It is important in the public interest, therefore, that recommendations are fully and properly considered. If they are to be rejected, then that should be for good reason, and the public (in whose interest an Inquiry is conducted) should be told clearly what the reason or reasons are.

Accountability is one of the seven principles of public life which Lord Nolan recognised and articulated.[241] The first question, therefore, is how government should be held accountable for the way in which it deals with the recommendations made both here, and those that have already been made over a year ago, in the Second Interim Report of the Inquiry and have so far resulted in little tangible result for people infected and affected by this tragedy.

I propose two mechanisms. They run together.

First, a number of the submissions made by core participants endorse a submission made on behalf of those core participants represented by Milners solicitors:

> "*In our submission, Parliament's intention in passing the Inquiries Act 2005 was to give the chair of a statutory inquiry the power to scrutinise the actions of Government in accordance with its terms of reference, and to do so in a flexible and more expansive way than is available to a court considering a judicial review challenge. Indeed, it could be argued that the primary purpose of the Act and of many inquiries, is to scrutinise the decisions and actions of the Executive.*"[242]

241 Lord Nolan *Standards in Public Life: First Report of the Committee on Standards in Public Life* May 1995 p18 RLIT0001795

242 Submissions on behalf of the core participants represented by Milners Solicitors August 2023 p3 SUBS0000070. In my view, this is critically dependent upon the terms of reference: many statutory inquiries may consider the actions of public bodies such as individual NHS trusts, the police services, local authority actions, and general disasters which require scrutiny across many fields: not every inquiry is of an Arms to Iraq nature.

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Section 14(1)(a) of the Act provides: "*For the purposes of this Act an inquiry comes to an end – on the date, after the delivery of the report of the inquiry, on which the chairman notifies the Minister that the inquiry has fulfilled its terms of reference*".[243]

Focussing on the wording of this, it is said to me that an inquiry does not end with the delivery of the report, but with the chair's notification to the Minister.

There is a precedent, to show that the report of the Inquiry is not necessarily the last word. Thus, when Sir Michael Bichard presented his report to the Home Secretary on 14 June 2004 into the deaths of two children in Soham he wrote in a covering letter "*I look forward to the Government's response to my findings and to the recommendations which I make. As you know, I aim to reconvene my Inquiry in six months' time to assess progress on those recommendations which the Government chooses to accept. I am confident, as I acknowledge in my report, of the spirit in which my recommendations will be received and taken forward.*"[244] Six months later he was sent a progress report, and provided an update himself on 15 March 2005, in which he said "*I am also clear that the fact that this public review was known to be taking place has concentrated minds* ".[245] In an accompanying press release it was said "*He asked for preparatory work on these schemes to be completed by Spring 2006 and suggested that the Home Secretary should commit to publishing reviews of progress in September this year and March 2006. Sir Michael also said he hoped such reviews of Inquiries would occur as a matter of course in the future.*"[246] Though his findings and recommendations were contained entirely within his June 2004 report, his actions after June 2004 were concerned solely with the implementation of the recommendations which he had made.

The Inquiry's terms of reference cover an unusually wide period: they began at the start of the NHS. There is no specific end date. That is because the Inquiry is charged, amongst other matters, with examining the nature, adequacy and timeliness of the response of government (in particular the Department of Health and Social Care), NHS bodies, other public bodies and officials, the medical profession, the UK Haemophilia Centre Doctors Organisation, the pharmaceutical industry and other organisations (including the Haemophilia Society) to the use of infected blood or infected blood products to treat NHS patients; and "*To consider the nature and the adequacy of the treatment, care and support (including financial assistance) provided to people who were infected and affected (including the bereaved)*".[247] Though this Report (together with the Second Report which says all I have to say as to compensation) is a full report and I do not anticipate that it should be necessary to add any more to it, the Inquiry has a function to consider the appropriateness, and timeliness, of the response to the recommendations it makes.

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243 s14(1)(a) Inquiries Act 2005 RLIT0002407

244 The Bichard Inquiry Report 22 June 2004 p4 RLIT0002389, The Bichard Inquiry Final Report 15 March 2005 p6 RLIT0002390

245 The Bichard Inquiry Final Report 15 March 2005 p6 RLIT0002390

246 Submissions on behalf of the core participants represented by Milners Solicitors August 2023 p4 SUBS0000070

247 Infected Blood Inquiry Terms of Reference para 5a, para 8 INQY0000458

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There has been some concern, as anyone who has followed the proceedings of the House of Lords Statutory Inquiries Committee will be aware, as to the follow up of progress towards considering and, if accepted, implementing the recommendations of public Inquiries. The penultimate chapter in this Report considers the response of government to the recommendations made to it by Sir Robert Francis, and the recommendations made to it by this Inquiry in its Second Interim Report which followed. It has shown that assurances have been given, and not kept. It has demonstrated that the reasons for this have not been revealed in full to the public. It has led to a real and understandable fear that without a clear process or timetable there may be a dragging of feet. As I have said repeatedly in public, delay not only causes frustration, but compounds the harm and suffering many of those infected and affected have endured. In the context of this Inquiry, perhaps beyond all other, it is unconscionable to allow a state of affairs to exist in which these fears are realised. I am satisfied that I must do what I properly can within my powers to try to ensure this does not happen.

As to the timetable, I anticipate that **within** the next 12 months the Government will have considered and either committed to implementing the recommendations which I make, or has given sufficient reason, in sufficient detail for others to understand, why it is not considered appropriate to implement any one or more of them. During that period, and **before** the end of this year, the Government should report back to Parliament as to the progress made on considering and implementing the recommendations. I anticipate that at that stage I should be able to tell the Minister that the Inquiry has fulfilled its terms of reference. But I shall do so only if I am satisfied that there is no further role I can usefully play in preventing delay.

I also recommend that the Public Administration and Constitutional Affairs Committee ("PACAC") should review both the progress towards responding to the recommendations, and, if they are accepted, towards implementing them. Though the recommendations are capable of covering the work of different select committees (health, home affairs to name but two) it is essential that the response be viewed as a whole. The rationale for there being a select committee which should have these tasks is:

- The reputation for independence which select committees have, especially in recent times with the live broadcast of many of their proceedings. They are part of the Parliamentary process. The Inquiry reports to a Minister; the Minister is answerable to Parliament; select committees have the ability to scrutinise the actions (or inaction) of the Minister.
- A 2017 Institute for Government report suggested that select committees could examine annual progress updates from government on the state of implementation of inquiry recommendations;[248]

248 Institute for Government *How public inquiries can lead to change* December 2017 p6 WITN7523003

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- INQUEST proposed that there should be a National Oversight Mechanism which is structurally and operationally independent;[249]
- Dame Diana Johnson MP (herself chair of a select committee) has argued that select committees are well equipped to carry out "*detailed scrutiny*" on the adequacy of the government's proposed response to inquiry recommendations, and feels that this approach should become the norm;[250]
- The House of Commons Health and Social Care Select Committee has set up a new independent expert panel, which appears to be the first committee linked arrangement, to evaluate "*progress the Government has made against its own commitments*".[251]
  - Advice to ministers from civil servants may well be tempered by knowing that a body likely to command respect will potentially examine the outcome, apparent logic and timeliness of that advice – and will do so in public.
  - Such a process is within the general scope of Parliamentary powers, and also generally open to press and media comment. The history set out in the chapters of this Report which record the Government response to what had happened show that on a number of occasions action appears to have been prompted by impending publicity.

The rationale for recommending that, of the select committees that might have been suggested, PACAC take on this function is that its role includes the scrutiny of government operation. The committee is experienced in high profile matters of public interest. Government generally provides responses to committee recommendations, and often there are further reports and responses. PACAC is appointed by the House of Commons to examine the reports of the Parliamentary and Health Service Ombudsman which are laid before the House, and matters in connection therewith; to consider matters relating to the quality and standards of the administration provided by Civil Service departments and other matters relating to the Civil Service; and to consider constitutional issues. The members of the committee are drawn from the three largest political parties, and the committee itself publishes its results through reports and making its recommendations known to the government.

PACAC also has some experience in providing post-inquiry scrutiny of government. Following controversy over the Iraq Inquiry PACAC launched a short inquiry into the conduct of public inquiries and the machinery of government. The committee's report recommended that the government must assess, as a matter of urgency, how the Iraq Inquiry could have been carried out more quickly, and must report its findings to Parliament. In that connection

249 Inquest *No More Deaths: Learning, action, and accountability: the case for a National Oversight Mechanism* June 2023 p4 RLIT0002401

250 Johnson *How to hold the government to account on public inquiries* The Guardian 30 May 2023 RLIT0002397

251 House of Commons Health and Social Care Committee *Expert Panel: Evaluation of the Government's progress on meeting patient safety recommendations* 19 March 2024 p5 RLIT0002393

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it wrote "*We remain concerned about the lack of mechanisms for meaningful Parliamentary oversight over the establishment of both statutory and non statutory inquiries.*"[252]

The state and capabilities of the Civil Service has been a long running concern for the Committee.[253] It has considered and reported on propriety of governance in the wake of the collapse of financial services firm Greensill Capital and revelations about its closeness to government and its lobbying activities.[254]

These considerations lead me to recommend:

12. Giving effect to Recommendations of this Inquiry

(a) Within the next 12 months, the Government should consider and either commit to implementing the recommendations which I make, or give sufficient reason, in sufficient detail for others to understand, why it is not considered appropriate to implement any one or more of them.

(b) During that period, and *before* the end of this year – the Government should report back to Parliament as to the progress made on considering and implementing the recommendations.

(c) This timetable should not interfere with earlier consideration and response to the Recommendations of the Second Interim Report of the Inquiry

(d) The Public Administration and Constitutional Affairs Committee ("PACAC") should review both the progress towards responding to the Inquiry's recommendations and, to the extent that they are accepted, implementing those recommendations

(e) PACAC should accept the role in respect of any future statutory inquiry of reviewing government's timetable for consideration of recommendations, and of its progress towards implementation of that inquiry's recommendations.

The Recommendations

1. Compensation

My principal recommendation remains that a compensation scheme should be set up now.

252 Public Administration and Constitutional Affairs Committee *Lessons still to be learned from the Chilcot Inquiry* 27 February 2017 p16 RLIT0002400

253 Public Administration and Constitutional Affairs Committee *Developing Civil Service Skills: a unified approach* 30 November 2015 RLIT0002395

254 Public Administration and Constitutional Affairs Committee *Propriety of Governance in Light of Greensill* 29 November 2022 RLIT0002402

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2. Recognising and remembering what happened to people

(a) A permanent memorial be established in the UK and consideration be given to memorials in each of Northern Ireland, Wales and Scotland. The nature of the memorial(s), their design and location should be determined by a memorial committee consisting of people infected and affected and representatives of the governments. It should be funded by the UK government.

(b) A memorial be established at public expense, dedicated specifically to the children infected at Treloar's school. The memorial should be such as is agreed with those who were pupils at Treloar's.

(c) There should be at least three events, approximately six months apart, drawing together those infected and affected, the nature and timing of which should be determined by a working party as described above, facilitated by some central funding.

3. Learning from the Inquiry

(a) The General Medical Council, and NHS Education for Scotland, Health Education and Improvement Wales, Northern Ireland Medical and Dental Training Agency and NHS England, should take steps to ensure that those "lessons to be learned" which relate to clinical practice should be incorporated in every doctor's training.

(b) They should look favourably upon putting together a package of training materials, with excerpts from oral and written testimony, to underpin what can happen in healthcare, and must be avoided in future.

(c) The Inquiry website is maintained online.

4. Preventing future harm to patients: achieving a safety culture

(a) Duty of candour

(i) A statutory duty of candour in healthcare should be introduced in Northern Ireland.

(ii) The operation of the duties of candour in healthcare in Scotland and in Wales should be reviewed, as it is being in England, to assess how effective its operation has been in practice. Since the duty was introduced in 2023 in Wales, the review there need not be immediate, but should be no later than the end of 2026.

(iii) The review of the duty of candour currently under way in England should be completed as soon as practicable.

(iv) The statutory duties of candour in England, Scotland, Wales (and Northern Ireland, when introduced) should be extended to cover those individuals in

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leadership positions in the National Health Service, in particular in executive positions and board members.

(v) Individuals in leadership positions should be required by the terms of their appointment and by secondary legislation to record, consider and respond to any concern about the healthcare being provided, or the way it is being provided, where there reasonably appears to be a risk that a patient might suffer harm, or has done so. Any person in authority to whom such a report is made should be personally accountable for a failure to consider it adequately.

Success in implementation will be measured by the extent to which there is an increase in the number of reports made of near miss incidents to the designated data collector; and a decline in the number of widespread or significant healthcare failures.

(b) Cultural change

(i) That a culture of defensiveness, lack of openness, failure to be forthcoming, and being dismissive of concerns about patient safety be addressed both by taking the steps set out in (a) above, and also by making leaders accountable for how the culture operates in their part of the system, and for the way in which it involves patients.

(c) Regulation

(i) That external regulation of safety in healthcare be simplified. As a first step towards this, there should be a UK wide review by the four health departments of the systems of external regulation, with the aim of addressing all the points made earlier in this Report and in other reports since 2000.

(ii) That the national healthcare administrations in England, Northern Ireland, Scotland and Wales explore, and if appropriate, support the development and implementation of safety management systems ("SMS"s) through SMS coordination groups (as recommended by the HSSIB), and do so as a matter of priority.

Success in implementation will be measured by the percentage of patients who know to whom they can express any concerns they may have about safety, who will take up their cause, and what they can expect from them. At the same time, it will be measured by the extent to which those who are busy working within the system, especially those in leadership roles, have clarity as to what, precisely, is expected of them, from whom. It should also be measured by a reduction in avoidable harm from both errors and systemic issues.

(d) Patient records

(i) Before the end of 2027 there should be a formal audit, publicly reported, of the extent of success of digitisation of patient records in each of the four health jurisdictions of the UK, measuring at least the levels of patient access to their

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personal records, their ability to identify and correct apparent errors in them, their interoperability, and the confidence of health professionals in the detail, accuracy and timeliness of any record they enter, and that little material which should be recorded has been omitted. Next steps should be identified.

(e) Consideration should be given by the national healthcare administrations in England, Scotland, Wales and Northern Ireland, to further coordination of their approaches particularly to ensure that patterns of harm, or trends, are identified and any response which for the sake of patient safety would be better coordinated than left to each individual administration can collaboratively be agreed and implemented.

5. Ending a defensive culture in the Civil Service and government

(a) The Government should reconsider whether, in the light of the facts revealed by this Inquiry, it is sufficient to continue to rely on the current non-statutory duties in the Civil Service and Ministerial Codes, coupled with those legal duties which occur on the occasions when civil servants and ministers interact with courts, inquests and inquiries, as securing candour.

(b) If, on review, the Government considers that it is sufficient to rely on the current non-statutory duties in the Civil Service Code, it should nonetheless introduce a statutory duty of accountability on senior civil servants for the candour and completeness of advice given to Permanent Secretaries and Ministers, and the candour and completeness of their response to concerns raised by members of the public and staff.

(c) The Government should consider the extent to which Ministers should be subject to a duty beyond their current duty to Parliament under the Ministerial Code.

6. Monitoring liver damage for people who were infected with Hepatitis C.

(a) All patients who have contracted hepatitis via a blood transfusion or blood products should receive the following care:

(i) those who have been diagnosed with cirrhosis at any point should receive lifetime monitoring by way of six-monthly fibroscans and annual clinical review, either nurse-led, consultant-led or, where appropriate, by a GP with a specialist interest in hepatitis

(ii) those who have fibrosis should receive the same care

(iii) where there is any uncertainty about whether a patient has fibrosis they should receive the same care

(iv) fibroscan technology should be used for liver imaging, rather than alternatives

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(v) those who have had Hepatitis C which is attributable to infected blood or blood products should be seen by a consultant hepatologist, rather than a more junior member of staff, wherever practicable

(vi) those bodies responsible for commissioning hepatology services in each of the home nations should publish the steps they have taken to satisfy themselves that the services they are commissioning meet the particular needs of the group of people harmed by NHS treatment

7. Patient Safety: Blood transfusions

(a) Tranexamic acid

(i) In England Hospital Transfusion Committees and transfusion practitioners take steps to ensure that consideration of tranexamic acid be on every hospital surgical checklist; that hospital medical directors be required to report to their boards and the chief executive of their Trust as to the extent of its use; and that the board report annually to NHS England as to the percentage of eligible operations which have involved its use. If the percentage is below 80% or has dropped since the previous year, this report should be accompanied with an explanation for the failure to use more tranexamic acid and thereby reduce the risk to patient safety that comes with using a transfusion of blood or red blood cells.

(ii) In Scotland, Wales and Northern Ireland offering the use of tranexamic acid should be considered a treatment of preference in respect of all eligible surgery.

(iii) Consideration be given to standardising and benchmarking transfusion performance between hospitals in order to deliver better patient blood management.

(b) Progress in implementation of the *Transfusion 2024* recommendations be reviewed, and next steps be determined and promulgated; and that in Scotland the 5 year plan is reviewed in or before 2027 with a view to determining next steps.

The responsibility for this in England is that of the NHS, shared with NBTC, the Royal Colleges (as appropriate), and NHSBT.

(c) Transfusion laboratories should be staffed (and resourced) adequately to meet the requirements of their functions.

(d) That those bodies concerned with undergraduate and postgraduate training across the UK of those people who are, or intend to be, working in the NHS ensure that they are adequately trained in transfusion, that the standards by which sufficiency of training is measured are defined, and accountability for training in transfusion be defined.

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(e) That all NHS organisations across the UK have a mechanism in place for implementing recommendations of SHOT reports, which should be professionally mandated, and for monitoring such implementation.

(f) Establishing the outcome of every transfusion

(i) That a framework be established for recording outcomes for recipients of blood components. That those records be used by NHS bodies to improve transfusion practice (including by providing such information to haemovigilance bodies).

Success in achieving this will be measured by the extent to which the SHOT reports for the previous three years show a progressive reduction in incidents of incorrect blood component transfusions measured as a proportion of the number of transfusions given.

(ii) To the extent that the funding for digital transformation does not already cover the setting up and operation of this framework, bespoke funding should be provided.

(iii) That funding for the provision of enhanced electronic clinical systems in relation to blood transfusion be regarded as a priority across the UK.

8. Finding the undiagnosed

(a) When doctors become aware that a patient has had a blood transfusion prior to 1996, that patient should be offered a blood test for Hepatitis C.

(b) As a matter of routine, new patients registering at a practice should be asked if they have had such a transfusion.

9. Protecting the safety of haemophilia care

(a) That peer review of haemophilia care should continue to occur as presently practised, with any necessary support being provided by NHS Trusts and Health Boards; and

(b) That NHS Trusts and Health Boards should be required to deliberate on peer review findings and give favourable consideration to implementing the changes identified with a view to ensuring comprehensive, safe, care.

(c) A peer review of each centre should take place not less than once every five years.

(d) The necessary administrative and clinical resources should be provided by hospital trusts and boards, integrated care boards, and service commissioners to facilitate multi-disciplinary regional networks to discuss policy and practice in haemophilia and other inherited bleeding disorders care, provided they involve patients in their discussions.

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(e) recombinant coagulation factor products should be offered in place of plasma-derived ones where clinically appropriate. Service commissioners should ensure that such treatment decisions are funded accordingly.

(f) that the National Haemophilia Database, run by the UKHCDO, merits the support of additional central funding.

10. Giving patients a voice

(a) That the patient voice be enabled and empowered by the following measures:

(i) clinical audit should as a matter of routine include measures of patient satisfaction or concern, and these should be reported to the board of the body concerned.

Success in this will be measured by comparing the measure of satisfaction from one year to the next, such that the reports to the board concerned demonstrate a trend of improvement by comparing this year's outcomes with the similar outcomes from at least the two previous years.

(ii) that the following charities receive funding specifically for patient advocacy: the UK Haemophilia Society; the Hepatitis C Trust; Haemophilia Scotland; the Scottish Infected Blood Forum; Haemophilia Wales, Haemophilia Northern Ireland, and the UK Thalassaemia Society.

(iii) that favourable consideration be given to other charities and organisations supporting people infected and affected that were granted core participant status (as listed on the Inquiry website) to continue to provide support for at least the next 18 months. Further support should be reviewed at that stage with a view to it continuing as appropriate.

(iv) particular consideration be given, together with the UK Thalassaemia Society and the Sickle Cell Society, to how the needs of patients with thalassaemia or sickle cell disease can best holistically be addressed.

(v) steps be taken to give greater prominence to the online Yellow Card system to those receiving drugs or biological products, or who are being transfused with blood components.

11. Responding to calls for a public inquiry

(a) that a minister should retain the power to call an inquiry as the minister sees fit, in accordance with the Inquiries Act 2005 – but where a minister does not choose to do so, then:

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(b) if there is sufficient support from within Parliament for there to be an inquiry, the question whether there should be one should be referred to PACAC for it to consider the question.

(c) If it appears to PACAC that there is sufficient concern to justify a public inquiry, either because what happened and why has caused concern (as the committee sees it) or there are likely to be lessons learned which may prevent similar concerns arising in future, the committee may recommend to an appropriate minister that there be an inquiry.

(d) If the minister disagrees with the recommendation, they must set out in detail and publish reasons for this disagreement which are sufficient to satisfy PACAC that the matter has been carefully and properly considered.

12. Giving effect to Recommendations of this Inquiry

(a) Within the next 12 months, the Government should consider and either commit to implementing the recommendations which I make, or give sufficient reason, in sufficient detail for others to understand, why it is not considered appropriate to implement any one or more of them.

(b) During that period, and *before* the end of this year – the Government should report back to Parliament as to the progress made on considering and implementing the recommendations.

(c) This timetable should not interfere with earlier consideration and response to the Recommendations of the Second Interim Report of the Inquiry

(d) The Public Administration and Constitutional Affairs Committee ("PACAC") should review both the progress towards responding to the Inquiry's recommendations and, to the extent that they are accepted, implementing those recommendations

(e) PACAC should accept the role in respect of any future statutory inquiry of reviewing government's timetable for consideration of recommendations, and of its progress towards implementation of that inquiry's recommendations.

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