



**LETTER OF INSTRUCTION TO THE
PUBLIC HEALTH AND ADMINISTRATION EXPERT GROUP**

20.12.2021

Lord Michael Bichard

Professor Charles Vincent

Dear Lord Bichard and Professor Vincent

Re: The Infected Blood Inquiry

1. I am writing on behalf of the Chair to the Infected Blood Inquiry, Sir Brian Langstaff, with instructions for the preparation of a report from an expert group specialising in matters relating to public health and administration (“the Group”). You have kindly agreed to convene this Group, and to act as a point of contact between the Group and the Inquiry. The other members of the Group are: Professor David Armstrong, Professor Anne-Maree Farrell, Sir Ian Magee, Dr Margaret McCartney, Professor Jane O’Hara, Professor Allyson Pollock, Mr Dave Prentis, Ms Clare Salters, Mr Nicholas Timmins, and

Professor Kieran Walshe. I have provided copies of this letter to all members of the Group.

2. Throughout this letter I refer to the production of “a report” by the Group. However, it may be that during the course of your work you feel it is appropriate to produce a series of reports. You should feel free to adopt this approach. Any reference to “the report” in this letter should be read as including the possibility that more than one report will be produced.
3. The purpose of the report is to provide evidence about matters within the expertise of the Group that may assist the Chair in fulfilling the Inquiry’s Terms of Reference. I set out in more detail below the topics and questions that the Chair asks you to address. The report will be provided to the Core Participants to the Inquiry and will be published on the Inquiry’s website.
4. In due course, I may ask members of the Group or the Group as a whole to undertake further work to assist the Inquiry. This may include: answering questions raised by Core Participants; preparing further reports; conducting discussions with, or providing opinions to, other expert groups instructed by the Inquiry; giving oral evidence at the Inquiry’s public hearings; and carrying out other duties appropriate to the role of an expert to this Inquiry as directed by the Chair through me. In the first half of 2022 the Inquiry expects to receive suggestions from Core Participants about recommendations which the Chair should consider making and the Group may be invited in due course to consider those suggested recommendations.

Background

5. As you are aware, the Infected Blood Inquiry has been established to examine the circumstances in which people treated by the National Health Service in the United Kingdom were given infected blood and infected blood products. It is an independent public inquiry under the Inquiries Act 2005.
6. The provision of such blood and blood products led directly to people becoming infected with Hepatitis B virus (“HBV”), Hepatitis C virus (“HCV”), Human Immunodeficiency Virus (“HIV”) and other diseases. Other people were indirectly infected. People have also been informed that they may be at risk of developing vCJD.
7. The Inquiry’s Terms of Reference require it to consider and report upon a wide range of issues. These include:

“To examine the circumstances in which men, women and children treated by National Health Services in the United Kingdom (collectively, the “NHS”) were given infected blood and infected blood products, in particular since 1970, including:

- a. the treatment of men, women and children who were given infected blood or infected blood products through transfusion or other means;*
- b. the treatment of men, women and children with haemophilia or other bleeding disorders who were given infected blood products (recognising that the position of those with mild, moderate and severe bleeding disorders may require separate consideration during the Inquiry);*
- c. what was, or ought to have been known, at any relevant time about the risks of infection associated with blood donations and blood products, by Government (in particularly the Department of Health), pharmaceutical companies, any relevant licensing authorities, NHS*

bodies, the medical profession, and other organisations or individuals involved in decision-making in relation to the use of blood and blood products;

- d. to what extent people given infected blood or infected blood products were warned beforehand of the risk that they might thereby be exposed to infection, and if so whether such warnings as were given were sufficient and appropriate;*
- e. the adequacy of the systems adopted for the screening of donors, and the collection, testing, licensing and supply of blood and blood products for use by the NHS;*
- f. the United Kingdom's failure to become self-sufficient in the production of blood products (and consideration of any relevant differences in terms of self-sufficiency between England, Wales, Scotland and Northern Ireland);*
- g. the actions of Government (in particular the Department of Health), pharmaceutical companies, licensing authorities, NHS bodies, the medical profession, and other organisations or individuals involved in decision-making in relation to the use of blood or blood products;*
- h. why people were given infected blood or blood products, including the nature and extent of any commercial or other interests which may have affected decision-making;*
- i. the extent to which the supply of infected blood or blood products could, and if so, should have been avoided or stopped earlier, and if so how best this might have been achieved”.*

...

To examine:

- a. the nature, adequacy and timeliness of the response of Government (in particular the Department of Health), 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...

...

To examine whether ...

there has been a lack of openness or candour in the response of Government, NHS bodies and/or other bodies and officials to those infected or affected.”

8. A full version of the Terms of Reference may be found on the Inquiry's website. The website also contains the Inquiry's current List of Issues, which provides more detail of the matters that may be explored during the course of the Inquiry. I have sent links to both these documents to all members of the Group.
9. The Inquiry must report its findings to the Minister for the Cabinet Office, and make any recommendations, as soon as practicable.
10. Thus far the Inquiry has examined many documents and has heard from a range of witnesses, including infected and affected individuals, clinicians, politicians, civil servants and administrators of the financial support schemes. Among the concerns and issues that have been raised during the written and oral evidence to date are the following:
 - patient safety being subordinated to, or secondary to, other concerns
 - lack of urgency in decision-making
 - a tendency toward “wishful thinking” on the part of those administering treatment, who were reluctant to adapt what they were currently doing

- a tendency to think that any recognition of risk or adaptation of response to risk was not for someone in the position they occupied but would already have been sufficiently considered by others (senior clinicians, the Chief Medical Officer, the Department of Health and Social Security, political decision makers, regulatory authorities)
- a failure to identify what was a real risk as a risk until it had materialised with sufficiently serious consequences (including confusing current incidence of harm with the risk of it happening in future)
- a tendency on the part of Government to wait for greater certainty and/or more evidence in relation to both the extent and nature of the risks and the measures that might be taken to mitigate those risks, before taking action
- decision-makers identifying some measures that might help to reduce risk, but delay in implementing them
- weakness in information sharing (both in respect of information being provided to Government and being shared across Government and in relation to information being disseminated by Government) about risk and possible mitigations
- the absence, at an early stage, of an established and formal system to identify, discuss, consider and then take action without delay in respect of the risks posed by viruses to those who might require treatment with blood, tissues and blood products
- reliance on a small group of advisors, some of whom sat on multiple advisory committees with overlapping terms of reference and no executive powers
- limited involvement of the Chief Medical Officers
- policies or strategies being adopted with insufficient challenge either from within Government or outside it

- apparent tension between Government action and clinical freedom and a reluctance on the part of Government to be seen to be interfering with clinical freedom
- weakness in planning (e.g. in relation to achieving domestic self-sufficiency in blood products) for the long-term and on a UK-wide basis
- unequal access to clinical services across the UK
- risks to patients being downplayed, with paternalism, misplaced reassurance rather than candour, failures to inform patients about their infection, statements about lack of conclusive proof of a risk (which were likely to be misinterpreted as a statement there was none to worry about), confusion between incidence and risk and deliberate decisions to withhold information to patients that they had been infected on the basis there was currently no treatment and it might make them anxious
- very late acknowledgement by Government and others that things went wrong and limited reflective learning
- limited and inadequate financial assistance
- loss or destruction of some national and patient records
- failure to invest sufficiently in research into safety of treatments
- failure to invest sufficiently into domestic production of products within the NHS believed to carry less risk of transmitting infections than similar products produced outside it which were marketed commercially
- failure sufficiently to coordinate measures across the four home nations.

It is important to emphasise that the Inquiry's examination of these factual issues is ongoing, and that whilst these are issues or allegations that have been made by core participants or which arise for consideration from the evidence heard so far, no conclusions have been reached by the Chair in

relation to them, nor will any conclusions be reached until the evidence has been heard in full and submissions from relevant participants have been made and considered.

Instructions

11. The Chair is conscious that as members of the Group you have great expertise and experience in your respective fields. The topics set out in the paragraphs that follow are intended to provide a focus and structure to the Group's work for the Inquiry. If the Group feels that the topics or questions could helpfully be rephrased, or if there are matters that it considers should be added or omitted from those set out below, then please provide suggestions in a letter to me. The Chair will consider any points that the Group raises and I will respond with his decision.

12. The topics and questions set out below are deliberately framed in broad terms. This is intended to allow the Group to approach the matters as it sees fit in light of the available evidence.

13. The Chair's intention in instructing this Group is, primarily, to explore matters of relevance to public health and public administration today, and to inform any recommendations that he might make in respect of such matters. However, it is recognised that the Group may also assist in providing evidence about the development over time of relevant principles and practices in this area. This is reflected in some of the questions that follow. It is emphasised that the Group is not asked to provide an historical account, or to make findings of fact on contentious events. Instead, the Group is invited, where relevant and within its expertise, to set the current situation

within its broad historical context and/or to draw on its knowledge of earlier responses to health risks in addressing the questions below.

14. The Inquiry is primarily concerned with matters relating to the United Kingdom. However, where the Group considers that evidence drawn from other countries may assist in answering the questions posed, please include this in the report.

General principles concerning public administration

15. Please:

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

General principles concerning public health

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

17. Please explain, in broad terms, how public health expertise and institutional arrangements have been, and are, funded, structured, organised and utilised by the governments and the NHS in the United Kingdom. To the extent that you are able to, please:

- a. identify any particularly significant historical developments; and
- b. address the development of the Public Health Laboratory Service and the Communicable Disease Surveillance Centre and their role in assessing risk.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Devolution within the United Kingdom

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

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

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

The role of patients and patient representative organisations in healthcare policy

31. Please explain the current role played by patients and patient representative organisations in informing and shaping health policy, including in response to emerging health risks, in the United Kingdom. In particular:

- a. Please explain the principles underpinning the role played by patients and patient representative organisations.
- b. Please comment on any shortcomings or recommendations the Group identifies in this area.

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

The communication of risk in the provision of healthcare

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

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

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

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

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

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

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

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

36. Please explain the current principles underlying duties of candour relating to both to medical accidents, errors or harm and to poor practice or failings in public administration more broadly.¹ In particular, please comment on:

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

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

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

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

40. How effective have government and the NHS been in learning from past errors, failings and poor practice and why? Please comment on what

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

improvements the Group feel could be made in this area, and provide recommendations on how such improvements could be achieved.

41. Please explain what if any mechanisms are currently in place to provide for (i) transparency and (ii) accountability, when mistakes are made in the provision or regulation of healthcare or the response to public health risks in the United Kingdom.

- a. Please comment on how such mechanisms have developed, identifying any significant changes that have taken place in the time period of relevance to this Inquiry.
- b. Please identify any mechanisms or examples that the Group consider to have been particularly successful or unsuccessful in this area (including examples of good practice drawn from elsewhere in the world, if relevant).
- c. Please comment on any shortcomings or recommendations the Group identifies in this area.

42. Please comment on mechanisms that might be used to ensure that those (whether they are private or public bodies) who might be partially responsible for medical accidents, errors or harm and/or for poor practice/failings in public administration, would contribute to the costs of dealing with the consequences. In doing so, please consider:

- a. Any mechanisms that are currently in place in the United Kingdom and, where the Group considers them to be of relevance, in other countries.
- b. Whether other mechanisms in other fields could usefully be implemented, or considered for implementation, in respect of healthcare in the United Kingdom.

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

Record keeping

44. What principles do and/or should govern the approach to record keeping and archiving by:

- a. Government departments;
- b. NHS bodies; and
- c. regulatory or other bodies concerned with healthcare?

45. Please comment on how those principles have developed, identifying any significant changes and/or omissions that have occurred in the time period of relevance to this Inquiry.

46. What principles and practices govern the access that individuals have or should have to their own medical records (including medical information relating to them held by non-NHS organisations)? Please comment on how those principles and practices have developed, identifying any significant changes that have taken place in the time period of relevance to this Inquiry.

47. What principles and practices govern the ability that individuals have or should have to seek the amendment or correction of their own medical records (including medical information relating to them held by non-NHS

organisations)? Please comment on how those principles and practices have developed, identifying any significant changes that have taken place in the time period of relevance to this Inquiry.

Priority treatment for those injured as a result of NHS treatment

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

Further Information

49. If there are issues on which the Group considers that it requires further information before being able to reach a conclusion on some of the topics above, then please set that out in the report or in a separate letter to me. Where practicable, the Inquiry will seek to obtain and provide such information as the Group requires.

50. Where appropriate, the Group should provide provisional answers to the questions set out above, qualifying them as necessary with reference to further evidence or research that may be required to provide a more complete answer.

51. The manner in which the Group addresses the topics set out is a matter for its members, as is the way in which it expresses its conclusions and any qualifications that accompany them.
52. The report should make clear if there are any matters on which it is not, or may not be, possible to provide an expert opinion, for example due to the lack of available information. The report should give the reasons for any such limitation.
53. If there is a range of professional opinion on a particular issue covered in the report that must be made clear and the range of opinions summarised. The report should explain why the Group has reached the particular conclusion that it has.
54. If there is a disagreement between members of the Group about any matter within the report, then this too should be made clear. The report should summarise the different opinions, attribute them to the relevant individual, and provide the reasons explaining the views expressed.
55. In the event that the Group considers it appropriate that certain sections of the report be prepared by part of the group, please indicate in the report by whom each section has been prepared and why the division of the labour in this way was deemed appropriate.
56. The Inquiry has instructed other expert groups during the course of its work. Members of this Group may consult freely with members of these other expert groups, but should acknowledge in the report what, if any, material assistance their input has provided.

Expertise and Duties of an Expert

57. If, having read this letter, any member of the Group feels that they do not have the appropriate experience or expertise then please let me know immediately. You should also notify me if the Group has any queries or require any further information.

58. As expert witnesses, all members of the Group have a duty to exercise reasonable skill and care in carrying out their instructions and must comply with any relevant professional code of practice. The Group members' overriding duty is to assist the Inquiry and to provide their unbiased opinion as independent witnesses in relation to those matters that are within their expertise.

Format of the Report

59. I would be grateful if Professor Charles Vincent and Lord Michael Bichard, as convenors of the Group, would undertake to be the principal point of contact for all correspondence between the Group and the Inquiry.

60. In preparing the report please make sure that:

- a. It sets out details of each member's qualifications, and respective academic and/or professional experience.
- b. It gives details of any literature or other material upon which the Group has relied.
- c. It contains a statement setting out the substance of all facts and instructions which are material to the opinions expressed.
- d. It makes clear which of the facts stated are within the Group's knowledge.
- e. It identifies who carried out any other work used for the report. The report should give the qualifications for the individuals concerned and

indicate whether their work was carried out under the supervision of the Group or any of its members.

- f. Where there is a range of professional opinion on the matters dealt with in the report, it summarises the range of opinions and gives reasons for the opinion reached.
- g. It contains a summary of the Group's conclusions.
- h. It sets out any qualification to an opinion or conclusion provided.

61. The final report must be verified by statements from each member of the Group saying:

"I confirm that in respect of those parts of the report to which I have contributed:

- a. I have made clear which facts and matters referred to in this report are within my knowledge and which are not.*
- b. Those that are within my knowledge I confirm to be true.*
- c. The opinions I have expressed represent my true and complete professional opinions on the matters to which they refer."*

62. The convenor should let me know immediately if, at any time after producing the report and before the conclusion of the Inquiry, any member of the Group changes their views. It is also important that the convenor of the Group notifies me promptly if it is felt necessary to update the report after it has been finalised, for example because new evidence has come to light.

63. The report should be reasonably concise and expressed as far as possible in straightforward language. Where technical or clinical terms are used, and their

meaning may not be obvious, please provide a brief explanation as to their meaning, for example in a glossary.

Timetable

64. I would be grateful if the Group can provide a draft copy of the report by June 2022.

65. I ask for the report to be provided in draft in the first instance so that I can approve its format, check that the formal requirements for an expert report mentioned above are fulfilled correctly and ask for any queries to be addressed before the report is signed.

66. Once the report is finalised, a copy will be disclosed to the Core Participants and will be published on the Inquiry website. It may be that once Core Participants have reviewed this letter of instruction or the report they will identify further issues that I may wish to raise with the Group.

67. I may also provide the Group with further instructions at a later date in respect of any other matters on which we seek evidence from the Group.

Fees

68. I will correspond with the members of the Group separately about arrangements for their fees.

Next Steps

69. As I have indicated in this letter, and if the Group feels that it is appropriate, please write to me if the Group considers that the questions or topics should be amended or changed.

70. May I thank all members of the Group for agreeing in principle to assist the Inquiry. If there is anything that I can do to assist or there are any aspects of these instructions that the Group would like to clarify then please do not hesitate to contact me.

Yours sincerely,

A handwritten signature in cursive script, appearing to read "M Secker".

Michelle Secker

Infected Blood Inquiry, Secretariat