



**LETTER OF INSTRUCTION
TO ETHICS EXPERT GROUP**

20.12.2019

Professor Bobbie Farsides
Professor Emma Cave

Dear Professor Farsides and Professor Cave

Re: The Infected Blood Inquiry

1. I am writing on behalf of the Chair of the Infected Blood Inquiry, Sir Brian Langstaff, with instructions for the preparation of a report by the group of experts in fields relating to ethics in medicine ('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 Julian Savulescu, Professor Richard Ashcroft, Dr Melinee Kazarian. I have provided copies of this letter to them. The group is invited to consider which members are best placed to undertake the work outlined below and to notify the Inquiry accordingly.

2. 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 at this stage. The report will be provided to the Core Participants to the Inquiry and will be published on the Inquiry's website.

3. In due course, I may ask the group 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 the Inquiry as directed by the Chair through me. The Chair is likely to ask one or more contributors to the report to speak to its content at one of the Inquiry's public hearings.

Background

4. 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.

5. 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 v CJD.

6. 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. *whether and to what extent people were treated or tested or their infection status was recorded without knowledge or consent;*
- b. *the testing or treatment of a category of patients referred to as Previously Untreated Patients (“PUPS”).*

“To examine the adequacy of the information provided to people who were infected or affected, including:

- a. the nature, adequacy and timeliness of the information provided to those infected about their condition(s);*
- b. how the results of tests or information about their condition(s) were communicated to those infected;*
- c. whether, and if so what, information should have been provided to those most closely affected by the infection of a patient about that infection and any consequent risk to them.”*

“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.”

“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), including...

....the differing criteria for eligibility for financial assistance applied by the various Trusts and Funds, the justification (if any) for such differences and whether such differences were or are equitable;

..the appropriateness of preconditions (including the waiver in the HIV Haemophilia Litigation) imposed on the grant of support from the Trusts and Funds.”

The report which the group is being asked to produce at this stage will assist the Chair in considering these parts of the Terms of Reference.

7. A full version of the Terms of Reference may be found on the Inquiry's website. The website also contains the Inquiry's 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 the group.

8. The Inquiry must report its findings to the Minister for the Cabinet Office, and make any recommendations, as soon as practicable.

Instructions

9. The Inquiry has received and considered many written witness statements from people who have been infected (or whose partners or family members were infected) with HCV, HBV and/or HIV, some of whom have also been told of exposure to the risk of vCJD. The Inquiry has also heard a substantial amount of oral evidence from such individuals. The Inquiry is in the process of obtaining witness statements from clinicians and other health professionals who provided treatment to such individuals, and is proposing to hear evidence from clinicians and other health professionals (in particular as to the policies and practices within haemophilia centres) at a series of oral hearings in June and July 2020.

10. The written and oral evidence heard so far includes allegations that:

- a. People were not told about, or were given insufficient information about, the risks of infection from blood or blood products.
- b. Decisions about treatment with blood or blood products were taken by clinicians rather than by the patients themselves.
- c. People were not given sufficient information about, or were not offered, alternative treatments.
- d. Blood samples were frequently and routinely taken from people at haemophilia centres in circumstances where they were not told the purpose of taking the samples or the fact that samples might be stored for later testing.
- e. People were tested for HIV without their knowledge or consent.
- f. People were tested for HBV and/or HCV without their knowledge or consent.
- g. There were significant delays (frequently for months or years) between such tests being undertaken and people being informed of the results. There is evidence that on occasion a decision was taken deliberately not to tell a patient that he had been infected with HIV.

- h. People were invited to group meetings at haemophilia centres at which they were told (sometimes for the first time) about the risks of HIV. Some were asked in the group meetings if they wanted to know their test results; others have said that they were told their tests results in such meetings. On one occasion, a man who regularly attended clinics with his wife said he did not want to know, but his wife said she did.
- i. People were told they were infected with HIV or HCV or HBV in non-confidential settings and/or within earshot of others. Many were also told they should not tell anyone else of their infection.
- j. People were not provided with adequate information or advice about the virus with which they had been infected, its seriousness, its prognosis, its consequences and the treatment options.
- k. The risks of infecting others (such as partners) was not adequately explained, or misleading or inaccurate information given (for instance, that HCV was readily transmitted by unprotected sexual intercourse, whereas the position as the Chair understands it is that although this is possible it rarely happens).
- l. People were not given sufficient information about the side effects of treatments for HIV and/or HCV and/or HBV.
- m. People were told of their diagnosis or prognosis in ways that have been variously described as insensitive, casual, informal, indifferent, unsympathetic or callous.
- n. People (or their children) were involved as subjects of research without their knowledge, or without their informed consent.

11. The Inquiry has also seen evidence to suggest that it was proposed in January 1982 (and, it may be, at other times) that claims made by the manufacturers of commercial blood products as to the efficacy of heat treatment of those products in inactivating the as yet unidentified virus or viruses which caused Hepatitis Non-A

Non-B to develop, should be tested by administering such products to those who had not as yet received any such product.

12. So as to inform his analysis and consideration of this evidence, together with the evidence that the Chair will be hearing from clinicians and other health professionals, the Chair would be assisted at this stage by receiving a report discussing the ethical principles that should govern and inform clinical decision-making and practice.

13. It is important to note that you are not being asked, in any of the questions below, to express an opinion on the circumstances of any particular individual's experience or on the decisions or actions of any particular clinician, individual or organisation.

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

15. You will of course be aware that many of the incidents described within the evidence happened years ago. You are being asked to express your opinion on the matters set out below from today's perspective. If, however, the ethical principles or approaches which you identify have changed or developed significantly over time, please also explain and describe those changes or developments within your report.

16. The topics and questions set out below are deliberately framed in broad terms. This is intentional, with the aim of allowing the group to approach the matters as you see fit.

17. Please note that you are not being asked to consider the particular legal or ethical considerations that might arise where an adult lacks the mental capacity to take decisions as to testing and treatment.

18. As far as possible, your report should cover the questions and topics set out below insofar as they are within your areas of expertise and it is possible to address them.

General

19. What are the ethical principles and approaches that apply, broadly, to clinical decision-making and practice? Please include a consideration of the ethical principles and approaches that apply when patients are wronged or harmed.
20. What are the principles of informed consent? In particular:
 - a. What information about risks and benefits ought to be disclosed?
 - b. What are the principles which ought to govern gathering more information prior to disclosure to the patient?
21. Should consent always be expressly obtained (assuming that the patient has capacity)?
22. What do you understand by the concept of implied consent?
23. Is it ever acceptable, from an ethical perspective, to treat a person with capacity without their express and informed consent?

Treatment

24. What ethical principles should inform decision-making about the treatments to offer a patient? In particular, and from a medical ethics perspective:
 - a. What factors should a clinician consider when determining whether a treatment is clinically indicated and so can be offered to a patient?
 - b. How should a clinician weigh those factors?
 - c. What obligation or responsibility does the clinician have to identify and offer the best treatment for a patient?
 - d. What obligation or responsibility does the clinician have to identify and offer alternative treatments for a patient?
 - e. In broad terms what kind of information should a clinician provide to a patient about possible treatments?

- f. What obligation or responsibility does the clinician have to inform the patient of the risks of a particular treatment that is being recommended or considered?
- g. Where there is a risk (even a small one) of exposure to a serious infection, is it always incumbent upon the clinician to inform the patient of that risk so that the patient can take an informed decision for themselves?
- h. What obligation or responsibility does the clinician have to inform the patient of the possible side-effects, or possible health complications, of a particular treatment that is being recommended or considered?
- i. Does it make a difference if the patient is a child? If so, how and why?

Testing for infection

25. What ethical principles should inform the approach to testing a patient to determine whether they have been infected with a disease? In particular and from a medical ethics perspective:

- a. When should a clinician or health body inform a person they may have been exposed to an infectious risk?
- b. What factors should a clinician consider when deciding whether or not to offer a patient a test?
- c. How should a clinician weigh those factors?
- d. In broad terms what information should a clinician provide to a patient prior to the patient deciding whether or not to be tested?
- e. Are there any circumstances in which it would be ethical for a clinician to test a person with capacity without their knowledge or consent? If so, what are they?

- f. What obligation or responsibility does the clinician have to inform the patient of the result of the test?
- g. Are there any circumstances in which it would be ethical for a clinician to withhold a test result from a person with capacity? If so, what are they?
- h. Is it ethical for a clinician or hospital to store samples (e.g. of a patient's blood), for later testing and/or for research, without their knowledge or consent?
- i. Does it make a difference if the patient is a child? If so, how and why?
- j. To what extent if at all is it legitimate to test the likelihood that a particular therapy may give rise to infection by administering it to a patient?

Informing people of infections

26. What ethical principles should inform the approach to telling a patient that they have been infected with a serious disease? In particular and from a medical ethics perspective:

- a. What obligation or responsibility does the clinician have to inform the patient of their diagnosis?
- b. Are there any circumstances in which it would be ethical for a clinician to withhold a diagnosis from a person with capacity? If so, what are they?
- c. Are there any circumstances in which a clinician should inform a patient of their diagnosis (for example, on public health grounds) contrary to the patient's expressed wish? If so, what are they?
- d. What factors should a clinician consider when deciding when, how and in what setting to inform a patient that they have contracted a serious disease?

- e. What are your views on clinicians providing information to patients about the possibility (or fact) of infection with a serious disease in a group setting, with other patients present?
- f. What obligation or responsibility does the clinician have to inform the patient that they may have contracted, or did, contract the disease as a result of their medical treatment?
- g. In broad terms, what categories of information should a clinician provide to a patient when informing them that they have been infected with a serious disease?
- h. What kind of counselling or support should be offered to a patient by a clinician who is informing them that they have contracted a serious disease?
- i. Does it make a difference if the patient is a child? If so, how and why?
- j. Does it make any difference to the decision as to whether, when and if so how to inform the patient, if the disease is one for which there is no available and/or effective treatment? If so, how and why?

27. What ethical principles should inform the approach to telling a patient that they may have been, or have as a matter of fact been, exposed to the risk of a serious disease for which there is no diagnostic test?

28.

- a. What ethical principles should inform decision-making about whether, and if so in what circumstances, a clinician could or should disclose confidential information about a patient's health to a third party (e.g. a partner who might themselves be at risk of being infected or a public health authority)?

- b. What obligations does a clinician have in the public interest to protect others when a patient has been informed they may have contracted an infectious disease?
- c. How should a clinician weigh those factors when making a decision?

Research

- 29. What is the difference between audit of practice and research? What different ethical principles apply to each?
- 30. What ethical principles should inform decisions about participation in research? In particular and from a medical ethics perspective:
 - a. What factors should a clinician take into account when considering whether a patient might take part in a research project or otherwise be the subject of research or study?
 - b. What obligation or responsibility does the clinician have to inform the patient that they are participating in a research project or are the subject of research or study?
 - c. In broad terms, what kinds of information should a clinician provide to a patient to enable the patient to give informed consent to participating in a research project or being the subject of research or study?
 - d. What obligation or responsibility does the clinician have to tell the patient that information about them is being provided to others for research or monitoring or public health purposes?
 - e. Are there any circumstances in which it would be ethical for a clinician to enrol a patient in a research project, or make them an object of research or study, without the patient's knowledge or informed consent?

- f. Are there any circumstances in which it would be ethical for a clinician to provide information about a patient (on a named, de-identified or on an anonymous basis) to others for research or monitoring or public health purposes, without the patient's knowledge or informed consent?
- g. Does it make a difference if the patient is a child? If so, how and why?

Other

31. If a clinician becomes aware of (for example) conduct such as that summarised in paragraph 10 above, what obligation or responsibility does the clinician have, from an ethical perspective, to intervene or take action?

32. The Inquiry's Terms of Reference also require it to consider whether there has been a lack of openness or candour towards those who have been infected or affected. From an ethical perspective, what role does openness and candour have in clinical decision-making and practice? Are there different considerations depending on whether the errors identified are by individual clinicians, by organisations or as a result of defective systems?

33. The above questions focus on the decisions and actions of clinicians in relation to their individual patients. More broadly:

- a. If a clinician is involved in commissioning care, purchasing treatments, authoring guidelines or issuing advice to other clinicians, what do you see as the ethical principles that should guide such actions? What factors should a clinician consider, from an ethical perspective, and how should a clinician weigh those factors?
- b. There is evidence (yet to be fully explored) that a number of clinicians also played a role in relation to a cohort of patients (for example, those attending a particular haemophilia centre), by selecting the particular product or products of a particular genus (such as commercial Factor VIII, or NHS product) for use in treating clotting disorders, and purchasing that product rather than other products; or by administering tests for the presence of virus in local supplies of blood for transfusion although such tests were not in general national use at the time, and

that others were critical of this as “jumping the gun” or “breaking ranks”. What do you see as the ethical principles that should guide such behaviours?

34. What principles should guide the introduction of new interventions into clinical practice?

35. The Chair is likely to invite you to provide a further report in due course as to the ethical principles and factors that should, in your view, inform decision-making by central government, NHS bodies and other relevant organisations.

Further information

36. If there are issues on which you consider that you require 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 such information as you require and provide it to you. In the event that you wish to consider them, the written statements of the witnesses who have given oral evidence so far, and the transcripts of their oral evidence, are publicly available on the Inquiry’s website. Please bear in mind, however, that the Inquiry is still in the process of obtaining evidence from clinicians and that you are not being asked to express an opinion on the circumstances of any particular individual’s experience or any particular clinician’s decisions and actions.

37. Where appropriate, you 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.

38. The manner in which you address the topics set out is a matter for you, as is the way in which you express your conclusions and any qualifications that accompany them.

39. 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.

40. 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 you have reached the particular conclusion that you have.

41. If there is a disagreement among group members about any matter within the report, then this too should be made clear. The report should summarise the range of opinions, attribute them to the relevant group members, and provide the reasons explaining the views expressed.

42. The Inquiry will be instructing other expert groups during the course of its work. You may consult freely with members of these other expert groups, as may help you, but should acknowledge in your report what, if any, material assistance their input has given you.

Expertise and Duties of an Expert

43. If having read this letter you or other members of the group feel that you do not have the appropriate experience or expertise then please let me know immediately. You should also notify me if you have any queries or require any further information.

44. As an expert witness, you have a duty to exercise reasonable skill and care in carrying out your instructions and must comply with any relevant professional code of practice. Your overriding duty is to assist the Inquiry and to provide your unbiased opinion as an independent witness in relation to those matters which are within your expertise.

Format of the Report

45. In preparing your report please make sure that:
- a. It sets out details of the qualifications of all members of the group and their academic and/or professional experience.
 - b. It gives details of any literature or other material which you have relied on.

- 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 your knowledge.
- e. It identifies who carried out any other work used for the report. The report should give the qualifications for the individual and indicate whether their work was carried out under your supervision.
- 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 your conclusions.
- h. It sets out any qualification to an opinion or conclusion provided.
- i. It contains a statement that each of the group members understands their duty to provide independent evidence and has complied with that duty.

46. The final report must be verified by statements from all contributing group members saying:

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

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

47. You should let me know immediately if at any time after producing your report and before the conclusion of the Inquiry you change your views. It is also important that you notify me promptly if you feel it is necessary to update your report after it has been finalised, for example because new evidence has come to light.

48. 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.

49. I would be grateful if, in general, you, Professor Farsides and Professor Cave would undertake to be the point of contact for all correspondence between the group and the Inquiry.

Timetable

50. I would be grateful if you can provide a draft copy of your report by 20 March 2020.

51. 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.

52. 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 your report they will identify further issues that I may wish to raise with you.

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

Fees

54. I will correspond with you separately about arrangements for your fees.

Next Steps

55. As I have indicated in this letter, and if you feel that it is appropriate, please write to me if you consider that the questions or topics should be amended or changed.

56. May I thank you and the other group members once again 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 you would like to clarify then please do not hesitate to contact me.

Yours sincerely,

A handwritten signature in blue ink that reads "Moore Flannery". The signature is written in a cursive style with a prominent flourish at the end.

Moore Flannery

Infected Blood Inquiry, Secretariat.