



LETTER OF INSTRUCTION TO THE HEALTH ECONOMICS EXPERT GROUP
08.02.2021

Professor Paul McCrone and Dr Katharina Hauck

Dear Professor McCrone and Dr Hauck

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 by the group of Health Economists ('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 Timothy Hallett, Dr Shevanthi Nayagam, Professor Myfanwy Morgan and Dr Laura Downey. I have provided copies of this letter to them.
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.

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 vCJD.
6. The Inquiry's Terms of Reference require it to consider and report upon a wide range of issues. These include:

“To consider the impact of the infection from blood or blood products on people who were infected (“those infected”) and on partners, children, parents, families, carers and others close to them (“those affected”), including:

a. the mental, physical, social, work-related and financial effects of:

i. being infected with HIV and/or HCV and/or HBV in consequence of infected blood or infected blood products;

ii. the treatment received for those infections;

b. the extent to which treatment, medical and dental care for other conditions was compromised by perceived infective status;

c. the impact of these infections on partners, children, parents, families, carers and others close to those infected, including the impact on those who suffered bereavement; children who were taken into care; those who were advised to, or did, terminate pregnancies; and those who had to take difficult decisions about whether or not to have children;

d. the wider social impact on those infected and affected, including the stigma associated with a diagnosis of HIV and/or HCV and/or HBV.”

The report, which the group is being asked to produce at this stage, will assist the Chair in considering this part 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, many 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.

10. So as to inform his analysis and consideration of that evidence, the Chair would be assisted at this stage by receiving a report addressing the following topics, insofar as they are within your area of expertise and it is possible to address them on the evidence and data available to you:
 - a. A cost-of illness study from a societal perspective of the impact to the United Kingdom, to the extent that it can be estimated, of infection from blood or blood products and its consequences.
 - b. An historic cost-effectiveness analysis of the societal value of introducing surrogate testing of blood donations before HCV screening became available and also of introducing earlier HCV screening.
11. The Chair is conscious that as members of the group you have great expertise and experience in your respective fields. The topics are intended to provide a focus and structure to your work for the Inquiry. If you feel that the topics could helpfully be rephrased, or if there are matters that you consider should be added or omitted from those set out above, 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.
12. The topics are deliberately framed in broad terms. This is intentional, with the aim of allowing the group to approach the matters as you see fit.
13. You will of course be aware that many of the incidents contained within the evidence happened years ago. You are, however, being asked to express

your opinion on cost-of-illness and cost-effectiveness from today's perspective, irrespective of what may have been the practice or known about these matters in previous decades.

14. It is important to note that whilst you can be provided with extracts from both written and oral evidence given by individuals where requested to inform your work, you are not being asked to express an opinion either on the circumstances of any particular individual's experience or on the likelihood of any particular impact being suffered by an individual or indeed a group of individuals.

Further evidence

15. I understand that:

- a. The cost of illness study and the cost effective analysis will require epidemiological case estimates of primary and secondary infections. The Inquiry has instructed an expert group of statisticians to prepare report on this issue.
- b. The cost effectiveness analysis will require further information, including about testing. Where practicable, the Inquiry will seek to obtain such evidence as you require and provide it to you.
- c. It may also be the case that you require a selection of witness statements to inform your analyses or assistance as to the course an underlying medical condition such as haemophilia may take absent infection with a blood borne virus. If this is the case, please inform me what material or information you require and I will arrange the disclosure and/or put you in touch with members of the clinical expert group.

16. 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 (including qualifications on the confidence or uncertainty that accompany a particular issue or range of issues).
17. 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.
18. 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.
19. 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.
20. The Inquiry has instructed 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

21. 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.

22. 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

23. 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.

24. 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:

- 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.”*

25. 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.

26. 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.

27. I would be grateful if in general you, Dr Hauck and Professor McCrone, would undertake to be the point of contact for all correspondence between the group and the Inquiry.

Timetable

28. Once the members of the Group have had an opportunity to discuss this letter and to consider the extent to which any work can begin before receiving material from the statistics group, we will discuss with you a timetable for the next steps, including if necessary a further letter of instruction.

29. 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.

30. 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.

31. 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

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

Next Steps

33. To progress matters as quickly and efficiently as possible, I would be grateful if you and the other group members can return to me a signed confidentiality undertaking. Once that is received I will contact you to discuss how best to provide access to the evidence that the Inquiry has obtained. I hope you can then begin work on reviewing that material and preparing your report.

34. 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.

35. 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 black ink, appearing to read 'M Secker', with a small flourish at the end.

Michelle Secker

Infected Blood Inquiry, Secretariat