



**LETTER OF INSTRUCTION TO THE CLINICAL GROUP: BLEEDING
DISORDERS AND BLOOD DISORDERS
25.09.2019**

Dr Oliver Tunstall

Dear Dr Tunstall,

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 on bleeding disorders and blood disorders by members of the group of clinical experts. You have kindly agreed to convene the group for the purpose of this report, and to act as a point of contact between the group and the Inquiry. The other members of the group are: **Dr David Edgar, Dr Marie Scully, Dr Mallika Sekhar, Professor Jurgen Rockstroh, Dr Sara Marshall and Dr Kate Ryan**. 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. The Chair will ask one or more contributors to the report to speak to its content at the Inquiry's public hearings in February 2020.

3. In due course, I will 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 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.
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 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 treatments received for those infections.”

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. Among the other matters that the Inquiry is required to consider are the following:
 - 7.1. What was, or ought to have been known at any relevant time about the risks of infection associated with blood donations and blood products.
 - 7.2. The actions of relevant individuals and bodies involved in decision-making in relation to the use of blood and blood-products.
 - 7.3. The nature, adequacy and timeliness of the response of relevant individuals and bodies to the use of infected blood or infected blood products to treat NHS patients.
 - 7.4. The nature and extent of any attempt to identify those who may have been infected and might benefit from treatment, including the adequacy of any ‘look back’ exercise.
 - 7.5. Whether and to what extent people may have been exposed to the risk of diseases other than HBV, HCV and HIV as a consequence of the use of infected blood and blood products.
 - 7.6. The identification of any individual responsibilities as well as organisational and systemic failures in relation to any of the matters falling within the Terms of Reference.

It is likely that you will be asked in due course to produce further reports relevant to these matters.

8. 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.

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

Instructions

10. The Inquiry has received and considered many written witness statements from people with haemophilia A, haemophilia B and von Willebrand disease who have been infected (or whose partners or family members were infected) with hepatitis and/or HIV as a result of receiving infected blood products or infected blood. The Inquiry has also heard a substantial amount of oral evidence from such individuals. Written and oral evidence has also been received from individuals with blood disorders who received infected blood or infected blood products. So as to inform his analysis and consideration of that evidence, the Chair would be assisted at this stage by receiving a report setting out the up-to-date clinical knowledge on the different types of bleeding disorders and blood disorders. You will note that some of the questions ask for information about treatments during previous decades. Please answer these questions by reference to what is now known and understood about such treatments. You are not currently being asked to consider what was or should have been known at the time, and whether different decisions or actions should have been undertaken.
11. The Chair is conscious that as members of the clinical group you have great expertise and experience in your respective fields. 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.
12. Please note that you are not being asked to express an opinion on the circumstances of any particular individual person.

13. The evidence considered and heard thus far is mostly concerned with those suffering from bleeding disorders (haemophilia A and B and von Willebrand disease) and beta-thalassemia major. The Inquiry anticipates that it may in due course receive further evidence from, or concerning, individuals with blood disorders who were infected through transfusion and/or individuals with primary immunodeficiency.
14. The Chair has found chapter two of the Krever Commission report (provided with these instructions) helpful in informing his understanding of the matters set out below. The Chair would therefore like to know the extent to which the matters set out there remain accurate so far as they fall within your particular field and to what extent the science has developed.

Bleeding disorders

15. As far as possible, your report should cover the following topics with regard to bleeding disorders insofar as they are within your areas of expertise and it is possible to address them on the evidence and data available to you.
 - 15.1. A description of each of the following bleeding disorders and their symptoms and effects:
 - (a) haemophilia A;
 - (b) haemophilia B;
 - (c) haemophilia C;
 - (d) von Willebrand disease.
 - 15.2. An explanation as to the mechanism by which each of these bleeding disorders occurs in a person, including how they may be passed on within family groups.
 - 15.3. An explanation as to how, and by what criteria, each of these bleeding disorders is classified as mild, moderate or severe.

- 15.4. An explanation as to how each of these bleeding disorders is typically diagnosed and any significant changes in methods of diagnosis over the years.
- 15.5. A description of the typical impacts of each of these bleeding disorders (including the disorder's impact on susceptibility to infection). Please differentiate as appropriate between different severities of the same bleeding disorder and the different impacts at different ages.
- 15.6. A description of the treatments that were available for each of these bleeding disorders pre-1970, how they were delivered, how effective they were and their risks, side effects, impacts and/or consequences.
- 15.7. A description of the treatments that were available for each of these bleeding disorders from 1970 onwards (including cryoprecipitate, DDAVP, factor products, and recombinant products), how they were delivered, how effective they were and their risks, side effects, impacts and/or consequences.
- 15.8. A description of the treatments that are currently available for each of these bleeding disorders, how they are delivered, how effective they are and their risks, side effects, impacts and/or consequences.
- 15.9. The co-morbidities, prognosis and life expectancy of those with bleeding disorders and how that has changed over the years.
- 15.10. The particular difficulties of infection with HIV or hepatitis for people with a bleeding disorder.

Blood disorders

16. As far as possible, your report should cover the following topics with regard to blood disorders insofar as they are within your areas of expertise and it is

possible to address them on the evidence and data available to you.

16.1. A description of each of the following, their symptoms and effects:

- (a) thalassaemia (please describe each type of thalassaemia);
- (b) sickle cell disease (please describe each type of sickle cell disease);
- (c) other blood disorders that require regular treatment with blood or blood products;
- (d) primary immunodeficiency disorder (please describe the particular disorders that may require regular treatment with blood or blood products).

16.2. An explanation as to the mechanism by which each of these disorders or types of disorder occurs in a person, including how they may be passed on within family groups.

16.3. An explanation as to how each of these disorders or types of disorder is typically diagnosed and any changes in methods of diagnosis over the years.

16.4. A description of the typical impacts of each of these disorders or types of disorder (including the disorder's impact on susceptibility to infection). Please differentiate as appropriate between different severities of the same disorder and the different impacts at different ages.

16.5. A description of the treatments that have been available for each of these disorders or types of disorder over the years, how they were delivered, how effective they were and their risks, side effects, impacts and/or consequences.

16.6. A description of the treatments that are currently available for each of these disorders or types of disorder, how they are delivered, how effective they are and their risks, side effects, impacts and/or consequences.

16.7. The co-morbidities, prognosis and life expectancy of those with these disorders or types of disorder and how that has changed over the years.

Further evidence

17. If there are issues on which you consider that you require further evidence before being able to reach a conclusion on any 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 evidence as you require and provide it to you.
18. Where appropriate, you should provide provisional answers to the questions set out above, qualifying them as necessary with reference to further evidence that may be required to provide a more complete answer.
19. 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.
20. 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.
21. 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.
22. 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.
23. 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

24. 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.

25. 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

26. In preparing your report please make sure that:
 - 26.1. It sets out details of the qualifications of all members of the group who have contributed to the report and their clinical and/or academic experience.

 - 26.2. It gives details of any literature or other material which you have relied on.

 - 26.3. It contains a statement setting out the substance of all facts and instructions which are material to the opinions expressed.

 - 26.4. It makes clear which of the facts stated are within your knowledge.

 - 26.5. 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.

- 26.6. 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.
- 26.7. It contains a summary of your conclusions.
- 26.8. It sets out any qualification to an opinion or conclusion provided.
- 26.9. It contains a statement that each of the group members who have contributed to the report understands their duty to provide independent evidence and has complied with that duty.
27. The final report must be verified by statements from all contributing group members, saying:
- “I confirm that in respect of those parts of this 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.”*
28. 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.
29. 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.
30. I would be grateful if, in general, Dr Tunstall would undertake to be the point of

contact for all correspondence between the group and the Inquiry for the purposes of this report.

Timetable

31. I would be grateful if you can provide a draft copy of your report by 31 December 2019. The Inquiry's oral hearings are under way and the Inquiry wishes to hear evidence arising from the report in oral hearings in late February 2020.
32. 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.
33. 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.
34. One or more group members will be asked to attend the Inquiry to give oral evidence in late February 2020.
35. I may also provide you with further instructions at a later date in respect of other matters on which we seek evidence from you or the group.

Fees

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

Next Steps

37. 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.

38. 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.
39. 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 large initial 'M' and a long horizontal flourish at the end.

Moore Flannery

Infected Blood Inquiry, Secretariat