



**SUPPLEMENTAL LETTER OF INSTRUCTION TO BLEEDING DISORDERS
AND BLOOD DISORDERS EXPERT GROUP**

20.12.2019

Doctor 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 supplemental instructions in relation to the report which is being prepared by the group. This letter should be read together with the initial letter of instruction dated 25 September 2019. The basis upon which you are instructed remains as set out in that letter.
2. The Inquiry has received suggestions from Core Participants to the Inquiry for additional matters to be included in your report and for some of the questions in the initial letter of instruction to be expanded. The purpose of this supplemental letter is to ask you to address the matters set out below, which have been raised by Core

Participants and are appropriate to address at this stage of the Inquiry, along with those questions set out in the initial letter of instruction. The additional questions have been divided into two parts. The first part comprises the questions posed in paragraphs 5 to 11 below - you have indicated that the group will be able to address these in the report which is already being prepared in accordance with the initial letter of instruction. The second part comprises the questions posed in paragraphs 12 to 14 below - you have indicated that these matters will require further work to be undertaken and may have to be addressed in a supplemental report. Please let me know when you think the group will be able to complete the second part of the work.

3. We remind you that we are not asking you to consider or comment on the experiences of any particular individual.
4. As before, the topics and questions set out below are for the most part framed in broad terms, with the aim of allowing the group to approach them as you see fit.

Supplemental instructions (part one)

5. When answering question 15.1 in the initial letter of instruction:
 - 5.1. Please include a description of the different phenotypes of each bleeding disorder and how these impact on the symptoms and effects of the bleeding disorder.
 - 5.2. Other than the fact that haemophilia in females is significantly rarer than in males, please indicate whether the gender of a person with a bleeding disorder has any bearing on how the condition is likely to affect them.
6. When answering question 15.2 please include an explanation of spontaneous genetic mutation.
7. In the part of your report which considers bleeding disorders, please add a section on inhibitors including the following:
 - 7.1. a description of low level and high level inhibitors and an overview of the body's immune response;
 - 7.2. an explanation as to what triggers inhibitors and how the occurrence rates differ between bleeding disorders;

- 7.3. a description of the standard treatments available for people with inhibitors and how this has developed over time;
- 7.4. an explanation as to the risks, effects and likelihood of the success of these treatments.
8. When answering questions 15.6 and 15.7 please include consideration of treatment with whole blood, fresh frozen plasma, avoiding activity and bed rest.
9. When answering question 15.7 please include tranexamic acid (a treatment often given concurrently with DDAVP).
10. When answering questions 15.6, 15.7 and 15.8, please explain whether an increase in the severity of a person's haemophilia means that there is likely to be a corresponding increase in the frequency of factor treatment, or that a higher dose of factor treatment is likely to be prescribed? If not, what factors dictate the frequency or dose of factor treatment?
11. When answering question 15.10, please include the following matters:
 - 11.1. The particular impact of infection with hepatitis or HIV on a person's bleeding disorder and their treatment for their bleeding disorder.
 - 11.2. The particular impact of co-infection with hepatitis and HIV on a person's bleeding disorder and their treatment for their bleeding disorder.
 - 11.3. The particular impact of treatment for hepatitis and/or HIV on a person's bleeding disorder and their treatment for their bleeding disorder.
 - 11.4. Whether people with bleeding disorders who are infected with HIV and/or hepatitis may experience difficulties receiving appropriate treatment for those infections.
 - 11.5. Whether treatment for a bleeding disorder is affected by a person's viral load for hepatitis and/or HIV, and if so, why and how.
 - 11.6. Whether the treatment for hepatitis has any impact on either a person's blood or bleeding disorder, including whether it may trigger an inhibitor, or on the treatment they receive for the blood or bleeding disorder.
 - 11.7. Whether having hepatitis and/or HIV has an impact on the ability to clear an inhibitor.
 - 11.8. Whether having an inhibitor may impact on a person's HIV/hepatitis infection and/or treatment for the HIV/hepatitis infection.

Supplemental instructions (part two)

12. When answering question 15.1 in the initial letter of instruction please add a new sub-paragraph 15.1(e) 'rare factor deficiencies' (such as Factor VII deficiency, Factor X deficiency, Factor XIII deficiency and Glanzmann's disease). These can be covered in less detail than sub-paragraphs (a) – (d) but please take them into account where they are relevant to the questions in the initial letter of instruction.
13. When answering question 15.8 please explain what if any viruses could potentially be transmitted with modern day treatments.
14. When answering question 16.1 please:
 - 14.1. Include acquired haemophilia at paragraph 16.1(e).
 - 14.2. Include haemolytic disease of the foetus and newborn at paragraph 16.1(f).
 - 14.3. Include neonatal alloimmune thrombocytopenia at paragraph 16.1(g).
15. As I have indicated in the previous letter of instruction, if you feel that it is appropriate, please write to me if you consider that the questions or topics should be amended or changed.
16. May I thank you and the other group members once again for agreeing to assist the Inquiry. I am pleased that Michelle Sholzberg has accepted the nomination to join the group. 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,



Moore Flannery
Infected Blood Inquiry, Secretariat.