



**SUPPLEMENTAL LETTER OF INSTRUCTION
TO THE CLINCIAL GROUP: HEPATITIS**

20.12.2019

Professor Graham Cooke

Dear Professor Cooke

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 and 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 of instruction is to ask you to address in your report the matters set out below, which have been raised by Core Participants, along with those questions set out in the initial letter of instruction.
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 the matters as you see fit.

Supplemental instructions

5. Please address Hepatitis G, whether this is still considered a hepatic virus and if not, why not, and what impact this may have on the latency and development of the HIV virus.

6. When answering question 15.2 and 15.6 please include:

6.1. An explanation of how the understanding of genotypes has developed over the years, and whether and if so how the genotype relates to the source of the infection and the geography of origin of the infection.

6.2. How a genotype is diagnosed.

6.3. How and why a person exposed to multiple genotypes of hepatitis will be diagnosed with a dominant genotype.

6.4. Whether the ALT liver enzyme test is currently considered to be of diagnostic value (you are not being asked to consider what the position was historically).

7. When answering question 15.5 please include an explanation as to how hepatitis is transmitted from mother to foetus in utero, and/or from mother to baby during birth. How likely is it that infections will occur by either of these two routes?

8. Please consider, to the extent that you are able, the impact on a person's fertility of infection with hepatitis and/or treatment for the virus and the impact on a person's ability to undergo fertility treatment such as IVF arising not only from the effect of the virus on the person but also from any contamination risk for storage of gametes or embryos.

9. When answering question 15.12 please consider whether the particular genotype is relevant to the person's prognosis and/or susceptibility to treatment.

10. When answering question 15.13:

10.1. Please explain whether the clinical guidelines and/or best practice for the treatment of hepatitis varies according to the genotype?

10.2. Please ensure that you include palliative care for people infected with hepatitis whose condition is terminal.

11. When answering question 15.15 please state whether there is any evidence that the PEG element of PEGylated interferon has an impact on the choroid plexus in the brain and what the risk is of associated neurological conditions developing as a result of this.

12. When answering question 15.16:

12.1. Please include prognosis in your answer.

12.2. At paragraph 15.16(a) explain what role hepatitis plays in the opportunistic infections which are characteristic of HIV and AIDS.

12.3. In paragraph 15.16 (c), please consider specifically co-infection with parvovirus and cytomegalovirus.

12.4. Please add a new paragraph (d) co-infection with more than one genotype of hepatitis.

13. When answering question 15.18 please identify the tests used to assess whether a person has cleared or has been cured of the virus.

14. Please provide details of any research or studies that you are aware of into the impact of infection with viral hepatitis on those with a blood and bleeding disorder.

15. When answering question 15.23 please address the following questions:

15.1. Would you expect a person to be given any advice or information (and if so, what) about starting a family?

15.2. Would you expect a person to be given any advice or information (and if so, what) about donating blood?

15.3. What support (in addition to advice and information) would you expect a person diagnosed with hepatitis to receive?

15.3.1. What advice, information and support you would expect to be given to the family of a person who has been diagnosed with hepatitis?

16. When answering question 15.24, please set out how this has changed over time.

17. When answering question 15.26:

- 17.1. Please set out the steps that have been taken and progress made to develop a vaccine for hepatitis.
- 17.2. Please set out the steps that England, Northern Ireland, Scotland and Wales have taken thus far.
18. Please add to Annexe 1 the following: autoimmune hepatitis; fatal foetal abnormalities; miscarriage.
19. Please add to Annexe 2 the following: suicidal ideation and on some occasions suicide attempts; avascular necrosis; auto-immune disorders; fatal foetal abnormalities; miscarriage; speech and language difficulties.
20. Please add to Annexe 3 the following: auto-immune disorders; fatal foetal abnormalities; miscarriage; speech and language difficulties; cancers, including neck and thyroid cancer; polyneuropathy
21. To what extent, and how, do hepatitis infections affect babies and children differently from adults?
22. What knowledge should a GP have today about hepatitis in order to correctly identify that a person should be tested for it?
23. Is there any detectable difference in signs or symptoms which would allow a clinician treating a person with raised LFTs/cirrhosis to distinguish between hepatitis and alcohol abuse as the cause?
24. Where a person is already infected with hepatitis, to what extent is their viral load affected by further exposure to infection? What effect will this have on them?
25. Why do some people self-clear hepatitis? How likely is it that a person will clear hepatitis? What are the factors which effect the likelihood of a person clearing hepatitis?
26. What advice would you expect people to be given today about the risks and likely side effects of treatment for hepatitis? To what extent would you expect people to be provided with information or advice about their mental health?
27. What are the current clinical guidelines for infection control when treating a person with hepatitis?

28. 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.

29. For ease of reference, I include in this letter the clarification I sent on 22 November:

We have been asked by some core participants to clarify one aspect of your letter of instruction. In para. 15.3 of the letter, you have been asked to provide "A short history of the emergency of blood borne viral hepatitis in the UK and what has been known and understood about the different types of blood borne viral hepatitis from their emergence to the present day". We wish to clarify that you are not being asked to give your views on what was or what ought to have been known by clinicians in the 1970s (or earlier), 1980s or 1990s about hepatitis or the risks of infection. You are being asked to provide, from a modern perspective, a history of the emergence of blood borne viral hepatitis and the major scientific milestones in understanding and treating hepatitis: you are not being asked to give an opinion on what a clinician at the time either knew or ought to have known about it.

30. May I thank you and the other group members once again for agreeing 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 "Joanne Flannery". The signature is written in a cursive style with a long, sweeping underline.

Moore Flannery
Infected Blood Inquiry, Secretariat.