



LETTER OF INSTRUCTION TO THE CLINICAL GROUP: HIV
25.09.2019

Professor Jane Anderson

Dear Professor Anderson,

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 HIV by members of the group of clinical experts. You have kindly agreed to convene this 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: **Professor Graham Cooke, Professor David Goldberg, Professor Jurgen Rockstroh, Dr Sara Marshall, Professor Philippa Easterbrook, Dr Mallika Sekhar, Sian Edwards, Dr Jonathan Wallis, Dr Katie Hands, Dr Katie Jeffery, Dr Scott Jamieson, and Dr David Johnston**. 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 late 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 for 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 who have been infected (or whose partners or family members were infected) with HIV as a result of receiving infected blood or infected blood products. The Inquiry has also heard a substantial amount of oral evidence from such individuals. 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 HIV, the treatments which have been, and those which are now, offered to those with HIV, and the potential symptoms, side effects and consequences of infection and/or treatment. You will note that some of the questions ask for information about developments and treatment during previous decades. Please answer these questions by reference to what is now known and understood about these matters.
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 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.

14. As far as possible, your report should cover the following topics and questions insofar as they are within your areas of expertise and it is possible to address them on the evidence and data available to you.
 - 14.1. An explanation as to what (a) HIV and (b) AIDS are.

 - 14.2. A history of the emergence of HIV in the UK and what has been understood about HIV and AIDS over the years from its emergence to the present day.

 - 14.3. Whether the HIV virus has changed or mutated since its emergence, and if so, how and with what consequences to resultant disease.

 - 14.4. An explanation as to how HIV is transmitted.

 - 14.5. How HIV and AIDS are diagnosed, and how this has changed over the years. Please include descriptions of the tests and procedures used to effect diagnoses and provide an analysis of how reliable the various diagnostic tests have been over the years.

 - 14.6. A description of the signs and symptoms a person may experience when first infected with HIV.

 - 14.7. A description of the period that may elapse between first being infected with HIV and symptoms of AIDS first emerging (a “latency period”) and what is known about any factors which may affect the length of this latency period either by shortening or prolonging it.

- 14.8. A description of the symptoms – physical, mental, and cognitive – a person may experience as HIV progresses. Please note that the Inquiry has received both written and oral evidence from those who have been diagnosed with HIV and/or AIDS, many of whom have reported a range of different chronic symptoms arising from the disease. Some of the key symptoms that have been described in the statements are listed in Annex 1 to this letter. Please consider this list when addressing this topic.
- 14.9. An explanation as to the complications of HIV, the different stages of the infection and the development of AIDS.
- 14.10. A description of the different treatments that have been provided to people infected with HIV and/or AIDS over the years up to the present day. Please set out the requirements of each treatment regime, any contra-indications to the treatments and the known side effects.
- 14.11. An analysis of:
- (a) The predictive factors in establishing the likelihood of treatment being successful; and
 - (b) How effective the various treatments have been over the years for people infected with HIV and/or AIDS.
- 14.12. A description as to what is known about the short and long term impact of those treatments. Please note that the Inquiry has received a substantial amount of both written and oral evidence from those who have been treated for HIV and/or AIDS over the years who have reported a range of significant side-effects and symptoms arising from that treatment (especially AZT), many of which have been listed in Annex 2 to this letter. Please consider this list when giving your opinion on this issue, stating whether it is your view that such symptoms or side-effects

are likely to be, or may be, attributable to the HIV/AIDS treatment and the likely longevity and severity of any such symptoms or side-effects.

14.13. A review of the associated illnesses that HIV and/or AIDS (or treatment for HIV and/or AIDS) can cause to those infected. Please explain how these illnesses are caused by or linked with the HIV infection (or treatment for the infection). Please note that the Inquiry has received evidence from those infected with HIV who have suffered from other health conditions or complications which they consider were or may have been caused by the HIV infection, alternatively by the treatment they received, or at least causally related to the infection or treatment to some extent. These are listed in Annex 3 to this letter. Please consider this list when giving your opinion on this issue and state whether you consider that there is or may be a causal link between such conditions and HIV/AIDS and/or the treatment for HIV/AIDS.

14.14. Please consider and address the prognosis and life expectancy of people infected with HIV and how this has changed over the years. Please also identify any predictive factors as to life expectancy and prognosis. When considering this issue please consider in particular:

(a) Whether early diagnosis and/or treatment makes a difference to prognosis and/or life expectancy? If so, is there is an optimum period of time within which a person should receive treatment? Has this differed over time?

(b) Whether the prognosis or life expectancy is different for a person who is co-infected with HCV and/or HBV compared to a person infected solely with HIV?

14.15. What is the significance, in terms of symptoms, impact and treatment, of co-infection with (a) HBV and/or (b) HCV and/or (c) other viruses?

14.16. To what extent, and how, does HIV affect people with:

- (a) haemophilia,
- (b) von Willebrand disease,
- (c) thalassaemia,
- (d) sickle cell anaemia,

differently from those who do not have a bleeding or blood disorder?

14.17. What advice and information would you expect a person now to be given about HIV, including advice and information about the risks of transmission, prognosis and treatment options?

14.18. Please outline the work being undertaken to find a cure for HIV.

Further evidence

- 15. If there are issues on which you consider that you require further evidence before being able to reach a conclusion on 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.
- 16. 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.
- 17. 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.
- 18. 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.

19. 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.
20. 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.
21. The Inquiry will be instructing other expert groups during the course of its work. You may consult freely with the 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

22. 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.
23. 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

24. In preparing your report please make sure that:

- 24.1. It sets out details of the qualifications of all members of the group contributing to the report and their clinical and/or academic experience.
 - 24.2. It gives details of any literature or other material which you have relied on.
 - 24.3. It contains a statement setting out the substance of all facts and instructions which are material to the opinions expressed.
 - 24.4. It makes clear which of the facts stated are within your knowledge.
 - 24.5. 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.
 - 24.6. 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.
 - 24.7. It contains a summary of your conclusions.
 - 24.8. It sets out any qualification to an opinion or conclusion provided.
 - 24.9. It contains a statement that each of the contributing group members understands their duty to provide independent evidence and has complied with that duty.
25. The final report must be verified by statements from all group members who have contributed to the report, 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.”

26. 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.
27. 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 clear, please provide a brief explanation as to their meaning.
28. I would be grateful if, in general, Professor Anderson would undertake to be the point of contact for all correspondence between the group and the Inquiry.

Timetable

29. 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 the second half of February 2020.
30. 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.
31. 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.

32. One or more group members will be asked to attend the Inquiry to give oral evidence in late February 2020.
33. 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

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

Next Steps

35. 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.
36. 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.
37. 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,



Moore Flannery
Infected Blood Inquiry, Secretariat



ANNEX 1: EXAMPLES OF SYMPTOMS DESCRIBED IN WITNESS STATEMENTS¹

- Mental health and cognitive difficulties, including depression, anxiety, anger, mood swings, difficulties with concentration and delusions
- Night sweats
- Insomnia
- Chronic fatigue
- Stomach problems including diarrhoea, abdominal pains and nausea
- Weight loss
- Lipodystrophy
- Incontinence
- Skin infections including fungal infections, and skin rashes
- Aches and pains over the body
- Rheumatoid problems
- Gum infections, oral thrush, mouth ulcers and hairy leukoplacia
- Loss of teeth

¹ Please note that some witnesses describing these symptoms may be co-infected with HIV and HCV and/or HBV.

- Weakness
- Falling over and or passing out

- Loss of sight

ANNEX 2: EXAMPLES OF SIDE EFFECTS OF TREATMENT DESCRIBED IN WITNESS STATEMENTS

- Mood and or cognitive disorders including confusion, nightmares, anxiety, and insomnia
- Tiredness and fatigue
- Feeling of weakness
- Black outs and memory gaps
- Headaches
- Dizziness
- Peripheral neuropathy
- Burning sensations in the skin

- Skin conditions including painful rashes, dry skin
- Bilateral gynaecomastia

- Osteoporosis and fractured bones
- Loss of teeth and or severe tooth decay
- Muscle pain

- Vomiting and nausea
- Loss of appetite

- Anaemia

ANNEX 3: HEALTH COMPLICATIONS DESCRIBED IN WITNESS STATEMENTS

- Chest infections and bronchitis
- Pneumocystis pneumonia
- Bronchiectasis

- Septicaemia

- Cytomegalovirus
- Leukoencephalopathy
- Encephalitis
- Strokes and or cerebral haemorrhage
- Epilepsy
- Bell's Palsy

- Blindness

- Duodenal ulcer
- Pancreatitis
- Kidney stones
- Gallstones
- Bladder problems
- Ulcerative colitis
- Anorexia
- Irritable bowel syndrome
- Diverticulosis
- Chronic kidney disease
- Hernias

- Cancer including brain tumours, bowel cancer
- B-cell lymphoma including non-Hodgkins lymphoma

- Mental health conditions including depression, anxiety, OCD and drug and alcohol dependency
- Persistent generalised lymphadenopathy
- Poor circulation
- Frequent bouts of shingles