



**SUPPLEMENTAL LETTER OF INSTRUCTION TO
ETHICS EXPERT GROUP**

17.2.2020

Professor Bobbie Farsides

Professor Emma Cave

Dear Professor Farsides and Professor Cave

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 20 December 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, along with those questions set out in the initial letter of instruction.

3. 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 it sees fit.
4. In paragraph 10 of the initial letter of instruction some of the allegations that had been made in the oral and written evidence were summarised. Some of the Core Participants have asked us to draw your attention to further allegations that have emerged from the evidence. These are set out in the following paragraph. We remind you that we are not asking you to comment on or express an opinion on the circumstances of any particular allegation or any particular individual. These examples are included here so that you can see the context within which some of the general ethical questions that we have posed to you arise.
5. Additional allegations that have emerged from the oral and written evidence (to be read with paragraph 10 of the initial letter of instruction) are:
 - a. People were not given sufficient information about continuing with existing treatment regimes (such as cryoprecipitate) and/or were not given the opportunity to continue with their existing treatment regimes.
 - b. People were not provided with the option of having no treatment in cases where their condition was mild and treatment was only needed on demand.
 - c. Sometimes the seriousness of HCV was downplayed, and people were not provided with information about its prognosis or potential complications. Some were told that it was less important or serious than other conditions (e.g. that they were more likely to die from smoking than HCV or were lucky they had not contracted HIV).
 - d. Sometimes people were told that HCV was extremely serious and would eventually cause liver disease and death, but were not given any information about timelines, treatment options, and how to manage the condition.
 - e. People were not given sufficient or any information about health complications arising from treatment for HCV, HBV or HIV, or about the effects of certain treatments on their existing health conditions.

- f. People were told of their infections in a way that suggested the clinician assumed they already knew about their infected status, when they did not.
- g. Please read paragraph 10(g) of the initial letter of instruction so that it includes the words 'and HCV' at the end.

Supplemental instructions

General

- 6. When answering questions in this letter of instruction and the initial letter of instruction please refer, to the extent that you consider appropriate, to any sources of international ethical principles set out in international codes and declarations that you consider relevant.
- 7. When answering question 19 of the initial letter of instruction (which asks you to identify the ethical principles and approaches that apply broadly to clinical decision-making and practice), please address what the ambit of medical ethics is and how medical ethics interact with the legal obligations of a clinician.
- 8. When answering question 20 of the initial letter of instruction (which asks about the principles of informed consent) please:
 - a. Consider in particular what information ought to be disclosed about the risks and benefits of existing, proposed and/or alternative treatments.
 - b. Set out the categories of information that a person would need to know and understand in order to give consent to treatment.

- c. Consider whether a clinician is required to determine if a person has understood the information and is in a position to give informed consent.
9. When answering question 21 of the initial letter of instruction (which asks whether consent should always be expressly obtained) please consider how the patient's consent should be obtained and recorded.
 10. When answering question 22 of the initial letter of instruction (which asks about the concept of implied consent) please also consider when, if ever, it is permissible for a clinician to rely on the concept of implied consent.
 11. When answering question 23 of the initial letter of instruction (which asks whether it is acceptable to treat a person with capacity without their express and informed consent), please also consider whether it is ever acceptable to treat a child without their or their parent's express and informed consent.
 12. When a patient is given treatment (such as a blood transfusion or the administration of blood products) in emergency circumstances, what ethical principles and obligations should guide the clinician's actions at the time of, and following, such treatment? Would this be different, and if so how, if a patient is unconscious or under general anaesthetic?

Treatment

13. When answering questions 24(a) and (b) of the initial letter of instruction (which ask about the factors that a clinician should consider when considering whether to offer treatment and how those factors should be weighed), please consider whether there is an ethical obligation or responsibility on the clinician to explain to the patient the factors that he/she has weighed and/or an obligation or responsibility to explain to the patient how he/she has weighed those factors.
14. When answering question 24(f) of the initial letter of instruction (which asks about the provision of information about the risks of a particular treatment):

- a. Please consider not only well-known and widely-accepted risks, but also risks that are beginning to be suspected or known as a result of developing medical and scientific understanding.
 - b. Please consider whether, in circumstances where there is no reliable data to indicate that a product or treatment is safe, there is an ethical obligation to inform the patient of this.
15. When answering question 24(h) of the initial letter of instruction (which asks about the clinician's obligation to inform a patient of possible side-effects or complications of treatment), please also consider what obligation or responsibility a clinician has to offer other treatment or medication to mitigate such side-effects or complications.
16. Is there an ethical obligation or responsibility on clinicians to share information they have about the risks and benefits of products or treatments, with professional colleagues?
17. Is there an ethical obligation or responsibility on clinicians to keep themselves informed and up-to-date with current knowledge relating to the risks and benefits of products or treatments they are prescribing?

Testing for infection

18. When answering question 25 of the initial letter of instruction (which asks about the ethical principles informing the approach to testing a patient for infection), please also consider the following:
- a. In what circumstances should the clinician give advice about the testing of spouses, partners and others?

- b. Are there any circumstances in which it is ethical for a clinician to take blood from a patient (with capacity) without the patient (or, in the case of a child, the parent) being informed about what it is being taken for?
 - c. Are there any circumstances in which it is ethical for a patient's test results to be shared with any third party without the consent of the patient (or, in the case of a child, the parent)?
 - d. Is there an ethical obligation on clinicians to offer pre-test counselling to patients and if so in what broad circumstances?
19. When answering question 25(j) of the initial letter of instruction, please also consider whether (and if so why) it makes a difference if the patient is an adult or a child, and whether (and if so why) the patient's existing state of health makes a difference.

Informing people of infections

20. When answering questions 26 and 27 of the initial letter of instruction (which ask about ethical principles informing the approach to telling patients that they have been infected with a serious disease), please read 'serious disease' as incorporating potentially serious diseases or infections.
21. Does it make a difference, and if so what, to your answers to question 26 if the disease or infection is understood by the clinician to be less serious or relatively minor?
22. When answering question 26(a) of the initial letter of instruction (which asks what obligation or responsibility the clinician has to inform the patient of their diagnosis) please also address with what speed or urgency the clinician should inform the patient of the diagnosis.

23. When answering question 27 of the initial letter of instruction please consider whether it makes a difference if the disease is an infectious one.
24. If a patient is told that they have been or may have been exposed to the risk of a serious disease for which there is no diagnostic test, what categories of information, in broad terms, should be provided to them?
25. Is there an ethical obligation or responsibility on a clinician to advise a person who has contracted an infectious disease, of the risks of infecting others such as family and friends?
26. What ethical principles should inform the approach a clinician should take to answering reasonable questions from a patient about how they became infected and about their previous treatment? Please set out in broad terms the kind of information a clinician should provide to a patient in such circumstances.

Research

27. When answering question 30(d) in the initial letter of instruction (which asks whether there is an obligation to tell a patient that information is being provided to others for research or other purposes), please also consider whether there is a duty to seek the person's consent for information about them to be shared for research, monitoring or public health purposes.

Other

28. When answering question 31 in the initial letter of instruction (which asks about the obligation or responsibility to intervene or take action when a clinician becomes aware of conduct such as that described in paragraph 10 of the initial letter):

- a. Please consider what obligation or responsibility the clinician has from an ethical perspective to report such conduct to others.
 - b. In the event that there is a duty to intervene, act or report to others, please set out in broad terms the steps that should be taken, who should be notified and whether there is an obligation or responsibility from an ethical perspective to inform the patient and/or the patient's family of the steps taken.
29. When answering question 32 in the initial letter of instruction (which asks about the role of openness and candour in clinical decision-making and practice), please consider what obligation or responsibility a clinician has from an ethical perspective to notify patients of any errors, adverse events and/or wrongdoing that have occurred during the course of the patient's care.
30. What ethical principles should inform the approach to the recording of information on a person's medical record? In particular:
- a. In broad terms what kind of information should be recorded?
 - b. Are there any circumstances (and if so, what) in which it is ethical to record information about a person's infective status, diagnosis, or exposure to testing, research or treatment, that has not been shared with the patient?
 - c. Is it appropriate that visible signs/labels/stickers (e.g. stating "Biohazard") are placed on an infected person's medical record signposting their infective status? How should a clinician balance the need to maintain patient confidentiality with the need to ensure proper safety precautions are taken?
 - d. Is it ever permissible (and if so in what circumstances) for a medical professional to keep notes or records in respect of a patient which are not included in the patient's health record?

31. What ethical principles should inform the approach to the disclosure by clinicians of any commercial relationship with, or any remuneration, support or assistance received from, suppliers of products or treatments used by the clinician? In particular, is there an obligation to disclose this information, if so, to whom, when does this obligation arise, and what information in broad terms should be disclosed?
32. What ethical principles should inform or guide medical professionals involved in the collection of blood?

Further information

33. Paragraph 15 of the initial letter of instruction asks you to express your opinion from today's perspective while describing any changes or developments to the ethical principles or approaches which you identify over time. You are being asked to set out the ethical principles and standards that are relevant to the questions posed in the letters of instruction and it is understood that you will do so largely from a modern perspective. If you are able to provide an annotated timeline outlining how standards and principles have changed over time, please do so; if you have observations to make (based on your expertise) about the landscape in which clinicians were operating in earlier decades, please include them – but the Chair does not expect you to go beyond the limits of your collective expertise and you should offer a historic perspective only to the extent that you feel able to do so.
34. I append to this letter a list of the materials which you have requested and which the Inquiry has supplied to the group.

35. 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.

36. May I thank you and the other group members once again for agreeing to assist the Inquiry. I am pleased that Ian Kerridge is able 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.

APPENDIX

The following documents have been supplied to the Medical Ethics Expert Group:

- BMA, Medical Ethics (1970)
- GMC, Blue Books (1963-1969)
- GMC, Blue Books (1970-1993)
- BMA, Professional Standards: BMA Board of Science and Education (1972)
- BMA, Medical Ethics (1974)
- BMA, The Handbook of Medical Ethics (1980)
- BMA, The Handbook of Medical Ethics (1981)
- BMA, Statement on AIDS: BMA Board of Science and Education (1985)
- BMA, Statement on AIDS (1986)
- BMA, Third Statement on AIDS (1986)
- BMA, HIV Antibody Testing: Guidance from an opinion provided for the BMA by Michael Sherrard QC (1987)
- BMA, HIV Antibody Testing: Summary Guidance (1987)
- BMA, HIV Antibody Testing Opinion (1987)
- BMA, Report of a Working Group on the Monitoring and Surveillance of HIV Infection and AIDS (1988)
- BMA, Motion by the Chairman of the Working Party on AIDS (1988)
- BMA, Philosophy and Practice of Medical Ethics (1988)
- GMC, Statement on AIDS and HIV (1991)
- GMC, Transplantation of Organs from Live Donors (1992)
- BMA, Statement on HIV Testing and Related Issues, Joint Consultants Committee (1992)
- BMA, Medical Ethics Today (1993)
- BMA, Medical Ethics Today – Its Philosophy and Practice (1993)
- BMA, Procedural Guidance, Programme to Identify Recipients of Blood Infected with Hepatitis C Virus (HCV) (1995)
- BMA, Transfusion-Transmitted Hepatitis C: Guidelines for Counselling Patients (1995)
- BMA, A Guide to Hepatitis C: Board of Science and Education (1996)
- GMC, Serious Communicable Diseases (1997)
- GMC, Seeking Patients' Consent: The Ethical Considerations (1998)
- BMA, HMSC 13 Re HIV Testing Advice (1998)
- GMC, Children's Consent to Medical Treatment (2000)
- BMA, Report of the Consent Working Party Incorporating Consent Toolkit (2001)
- BMA, HIV Infection and AIDS: Guidance for the Medical Profession (Date unknown)
- BMA, BMA Response to the Report of the Working Group on the Surveillance of HIV Infection and AIDS (Date unknown)