The Scottish Government
Population Health Directorate, Health Protection Division

Scottish Government
Riaghaltas na h-Alba
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17 July 2018

Dear Colleague

UK INFECTED BLOOD INQUIRY – RETENTION OF RECORDS

Summary
This Director's letter asks you to ensure any patient or other records you hold which may be relevant to the UK Infected Blood Inquiry are not destroyed. It also asks you to ensure that patients or, in the case of patients who have died, their relatives are not charged for copies of their medical records.

Background
The Infected Blood Inquiry will consider the events which led to NHS patients across the UK becoming infected with hepatitis c and/or HIV (and in some cases also hepatitis b) as result of treatment with blood products or via blood transfusions or tissue transplants up to 1991. It will also consider more broadly how those patients were diagnosed and advised of their diagnoses and the treatment and support they have received since diagnosis.

I have attached a copy of a letter from the chair of the UK Infected Blood Inquiry to Paul Gray, which includes a copy of the Inquiry's terms of reference. I should be grateful if you would review the letter and terms of reference to consider what records you have which may be relevant to the inquiry.

Whilst it has provisionally been agreed that the inquiry will not duplicate areas already considered by the Penrose Inquiry in relation to Scotland, it is still possible that the inquiry team will want to access copies of records which Lord Penrose previously considered. In addition, the UK Inquiry's scope is broader than that of the Penrose Inquiry, both in terms of subject matter and the time periods considered, so you may still have records which were not relevant to the Penrose Inquiry terms of

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Addresses

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reference, but which will be relevant to the UK Inquiry. Therefore, if there is any possibility that records may be relevant I would ask that they are retained, at least for the next two years. As well as the records held by the Scottish National Blood Transfusion Service and the Scottish haemophilia centres, records which could be relevant may also include anything related to: policies and decision making regarding provision of blood transfusions or tissue transplants, records regarding diagnosis and treatment of patients with hepatitis c, HIV, hepatitis b and patients suspected to be at risk of variant CJD.

I understand that there is already a hold on destroying GP patient records due to the Scottish Child Abuse Inquiry. I would ask that you also ensure hospital patient records are not destroyed for the time being – at least for the coming year – where they might be requested by the Inquiry or patients or their families. That will particularly apply to any records about whether or not a patient had a blood transfusion up to September 1991, any records relating to patients with inherited bleeding disorders and any other records relating to patients diagnosed with either hepatitis C or HIV, or both, who may have acquired their infection via NHS blood, tissue or blood products.

Sir Brian Langstaff's letter also asks that any fees for patients and their families to access patient records are waived. I would hope that this is not problematic. Under the General Data Protection Regulation (GDPR), it is no longer permissible to charge patients for access to their own medical records, although there are a few exceptions, such as for second or further copies which are requested within a short period of time. Whilst GDPR does not apply in the case of patients who have died, I would also ask that you do not charge fees in the case of family members seeking medical records of a deceased relative.

Action

I would therefore ask that you review the attached letter from Sir Brian Langstaff and arrange for staff in relevant areas to:

- Seek to identify records which may be relevant to the Inquiry and ensure that those records are not destroyed;
- Ensure that fees are not charged for access to patient medical records, including in the case of patients who have died.

Yours sincerely,

Gareth Brown
Deputy Director and Head of Health Protection Division

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Mr Paul Gray
Chief Executive of NHS Scotland
By email

05 July 2018

Dear Mr Gray,

Notice of retention/non-destruction of documents relating to the Independent Public Inquiry into Infected Blood and Blood Products (the Infected Blood Inquiry)

On 2 July the Minister of the Cabinet Office and Chancellor of the Duchy of Lancaster, David Lidington, announced the formal set up of an independent public inquiry, the Infected Blood Inquiry, of which I was appointed Chair on 8 February.

I write in my position as Chair of the Inquiry with regard to the large amount of information and records with potential relevance to the work of the Inquiry held by your organisation and by those for whom you are responsible.

The Terms of Reference for the Inquiry (attached) are broad and cover a lengthy period and there is potential for material from around the time of the inception of the NHS to be considered in evidence.

Specific requests for information will be made by my team following some initial scoping work, and in order to preserve all potentially relevant material and to ensure that no line of investigation is prejudiced by the destruction of files or records I would be grateful if you would please circulate this letter and the attached Terms of Reference to all parts of your organisation.

To assist as a guide, the information that I request is retained includes, but is not limited to, the following types of material: reports, reviews, briefings, minutes; notes and correspondence however held (paper, electronic, microfiche, audio, video and any other means), which is potentially relevant to the issues set out in the attached Terms of Reference.

May I separately raise with you two issues concerning the medical records of people who were infected and affected (which includes the families of people who sadly died as a result of infection from infected blood and blood products). First, to stress that such medical records are likely to be highly relevant to the work of the Inquiry and to request that all necessary steps are taken to ensure that they are preserved. Second, to request that any fees normally charged to access and obtain copies of medical records, including the records of a deceased family member, are waived in the case of infected and affected people who request access and copies for the purpose of providing evidence to the Inquiry. The Inquiry anticipates that many hundreds and possibly thousands of infected and affected people will seek to provide witness evidence to the Inquiry and will need to access and make reference to their or their family member's medical records for this purpose. The Minister for the Cabinet Office has already announced through a Notice of Determination pursuant to section 40 of the Inquiries Act 2005 (a copy of which can be found on the Inquiry's website www.infectedbloodinquiry.org.uk) that, because of the exceptional nature and gravity of the infected blood tragedy, means testing for publicly funded legal expenses will be waived. I would be grateful if you could indicate that similar arrangements, by way of a waiver of fees normally charged to access and obtain copies of medical records, might be put in place for witnesses to the Inquiry.

In line with the approach I set out to the Minister and the people infected and affected, for an open and transparent Inquiry, a copy of this letter will be published on the Inquiry's website.

Thank you in anticipation of your assistance.

Yours sincerely

Sir Brian Langstaff

INFECTED BLOOD INQUIRY

TERMS OF REFERENCE

What happened and why?

1. To examine the circumstances in which men, women and children[1] treated by national Health Services in the United Kingdom (collectively, the "NHS")[2] were given infected blood and infected blood products, in particular since 1970, including:

    a. the treatment of men, women and children who were given infected blood or infected blood products through transfusion or other means;

    b. the treatment of men, women and children with haemophilia or other bleeding disorders who were given infected blood products (recognising that the position of those with mild, moderate and severe bleeding disorders may require separate consideration during the Inquiry);

    c. what was, or ought to have been, known at any relevant time about the risks of infection associated with blood donations and blood products, by Government (in particular the Department of Health[3]), pharmaceutical companies, any relevant licensing authorities, NHS bodies, the medical profession, and other organisations or individuals involved in decision-making in relation to the use of blood and blood products;

    d. to what extent people given infected blood or infected blood products were warned beforehand of the risk that they might thereby be exposed to infection, and if so whether such warnings as were given were sufficient and appropriate;

[1] Including all gender identities.
[2] References to NHS used throughout is intended to encompass the National Health Service in England, Health and Social Care in Northern Ireland, NHS Scotland, NHS Wales and their predecessors.
[3] References to Department of Health used throughout is intended to encompass the Department of Health and Social Care, the Department of Health in Northern Ireland, Health and Social Care Directorates of the Scottish Government, the Department for Health and Social Services in Wales and their predecessors.

e. the adequacy of the systems adopted for the screening of donors, and the collection, testing, licensing and supply of blood and blood products for use by the NHS;

f. the United Kingdom's failure to become self-sufficient in the production of blood products (and consideration of any relevant differences in terms of self-sufficiency between England, Wales, Scotland and Northern Ireland);

g. the actions of Government (in particular the Department of Health), pharmaceutical companies, licensing authorities, NHS bodies, the medical profession, and other organisations or individuals involved in decision-making in relation to the use of blood and blood products;

h. why people were given infected blood or infected blood products, including the nature and extent of any commercial or other interests which may have affected decision-making;

i. the extent to which the supply of infected blood or infected blood products could, and if so, should, have been avoided or been stopped earlier, and if so how best this might have been achieved.

2. To ascertain, as far as practicable, the likely numbers of people who have been infected (directly or indirectly) in consequence of:

a. the use of infected blood; and

b. the use of infected blood products.

3. To examine whether, in addition to the HIV, Hepatitis C and Hepatitis B ("HCV" and "HBV") viruses with which it is known that people were infected, people may have been exposed to the risk of other diseases (such as vCJD) in consequence of the use of infected blood or infected blood products.

Impact

4. 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 these infections;

    b. the extent to which treatment, medical and dental care for other conditions was compromised by perceived infective status;

    c. the impact of these infections on partners, children, parents, families, carers and others close to those infected, including the impact on those who suffered bereavement; children who were taken into care; those who were advised to, or did, terminate pregnancies; and those who had to take difficult decisions about whether or not to have children;

    d. the wider social impact on those infected and affected, including the stigma associated with a diagnosis of HIV and/or HCV and/or HBV.

The response of Government and others

5. To examine:

    a. the nature, adequacy and timeliness of the response of Government (in particular the Department of Health), NHS bodies, other public bodies and officials, the medical profession, the UK Haemophilia Centre Doctors Organisation, the pharmaceutical industry and other organisations (including the Haemophilia Society), to the use of infected blood or infected blood products to treat NHS patients;

b. the nature and extent of any attempt to identify those who may have been infected and might benefit from treatment, to include the adequacy of any "look back" exercise;

c. whether Government or the NHS could or should have done more to counter any stigma associated with these infections.

Consent

6. To examine:

   a. whether and to what extent people were treated or tested or their infection status was recorded without knowledge or consent;

   b. the testing or treatment of a category of patients referred to as Previously Untreated Patients ("PUPS").

Communication and information-sharing

7. To examine the adequacy of the information provided to people who were infected or affected, including:

   a. the nature, adequacy and timeliness of the information provided to those infected about their condition(s);

   b. how the results of tests or information about their condition(s) were communicated to those infected;

   c. whether, and if so what, information should have been provided to those most closely affected by the infection of a patient about that infection and any consequent risk to them.

Treatment, care and support

8. To consider the nature and the adequacy of the treatment, care and support (including financial assistance) provided to people who were infected and affected (including the bereaved), including:

    a. whether and to what extent they faced difficulties or obstacles in obtaining adequate treatment, care and support;

    b. the availability and adequacy of any counselling or psychological support for those infected or affected;

    c. the actions of the various Trusts and Funds set up to distribute payments;

    d. the differing criteria for eligibility for financial assistance applied by the various Trusts and Funds, the justification (if any) for such differences and whether such differences were or are equitable;

    e. the appropriateness of preconditions (including the waiver in the HIV Haemophilia Litigation) imposed on the grant of support from the Trusts and Funds;

    f. the extent of any differences in the arrangements made for financial assistance between England, Wales, Scotland and Northern Ireland;

    g. a broad consideration of the extent to which support is and has been comparable with support for those similarly infected and affected in other countries, for example, Canada and EU nations, such as France and Ireland.

Candour, openness and cover-up?

9. To examine whether:

    a. there have been attempts to conceal details of what happened (whether by destroying documents or withholding information or failing to include

accurate information in medical records or otherwise), and if so the extent to which those attempts were deliberate;

b. there has been a lack of openness or candour in the response of Government, NHS bodies and/or other bodies and officials to those infected or affected.

Responsibilities

10. To identify, in relation to the matters set out above, any individual responsibilities as well as organisational and systemic failures.

Recommendations

11. If the Inquiry considers it appropriate, to make interim recommendations.

12. To report its findings to the Minister for the Cabinet Office, and to make recommendations, as soon as practicable.