Response to the Infected Blood Inquiry Consultation on Terms of Reference - Online Questions

Question 1: On what time period or periods should the Inquiry focus?

The investigation process should focus from the commencement of the utilisation of blood and blood products within the United Kingdom. The history as to how blood product treatment evolved is very relevant in the context of the understanding of the risks of pooled blood products. Also, all issues in terms of the pooling of blood products in the context of viral transmission that were present from the earliest introduction of blood and blood products in the United Kingdom, most particularly relating to Hepatitis B infection, are required to be considered.

There are different time periods or periods applicable in respect of each viral infection risk. Also, different time periods apply in respect of the response of government, government agencies, trusts and treating physicians in respect of various viral infections. Those issues require discussion in the context of the documentation that exists.

Question 2: Blood and Blood Products

Although the synopsis under the title blood and blood products is relevant to an appropriate investigation process, we feel that this needs to be more comprehensive.

We have provided a more comprehensive list of subject matters however The Haemophilia Society would welcome an opportunity to prepare a position paper and deliver submissions at the request of the Inquiry in relation to the extent and nature of the investigation process.

Pathogen Identification and Testing

- Which blood borne agents, including bacteria, viruses, and prions were people treated with blood products exposed to? When were those agents identified and what was the state of knowledge throughout the relevant period? This should include but not be limited to, Hepatitis viruses, HIV and CJD causing prions.
- What were the rates and numbers of people infected, what was the variation by location – regionally and by centres?
- What tests were available, including surrogate testing and when were these adopted, internationally and regionally what influenced these decisions? How widely available were they, what was the accuracy and reliability of the tests?

Self-sufficiency

- How was the issue of self-sufficiency in blood products approached by the Department of Health and Social Security? What were the levels of funding and commitment to the project and who was responsible for delivery? What was the impact on infection rates caused by the delay in achieving self-sufficiency?
- What impact did the infrastructure and capacity to collect blood from the UK population have on the ability to achieve self- sufficiency?
- What was the level of cross border cooperation and knowledge sharing, and how did this impact the ability to achieve self-sufficiency in the UK?
- How did the internal management of projects to increase production at BPL affect the ability to become self-sufficient?

Donor Selection and Products

- What was the impact of "donor" selection criteria on the rates of infection, how was this monitored, what steps were made to reduce contamination rates and who was responsible for this?
- What procedures were in place to monitor manufacturing standards, licence, regulate and procure blood products both produced in the UK and imported? How did this compare to global and regional standards? What consideration was given to the relative safety risks of UK produced vs. imported products?
- What knowledge did blood product manufacturers have of the risks attached to their products? What standards and procedures did they put in place to address the risks and who had responsibility for ensuring they were adhered to in manufacture? To what extent did the producers achieve compliance with their own and international standards?
- Were the commercial interests of pharmaceutical and blood product companies used to influence decision making on the availability of products and if so how was this affected?
- What steps were taken to reduce contamination via product screening, how was this monitored and what were the timings to recall products? How effectively was this communicated and implemented?
- Why were the potential risks of using blood products not communicated effectively, or not at all, to patients and families prior to treatment and alternative options discussed?
- The use and development of heat treatment in viral deactivation. How long did it take for this to become the standard and how did this compare to international standards? How were the cost implications of this considered?

Product trials and testing of products

- What level of informed consent was gained from individuals and guardians about testing individuals with new products, including heated treated products, and being involved in clinical trials?
- Have observational studies been carried out and testing of individuals without informed consent or parental consent?

Transparency of events and documentation

- If instruction was given to destroy documentation pertaining to any aspects of the use, purchase, distribution, manufacture of contaminated blood products was ordered and by who? To understand whether this documentation was destroyed outside of the normal standards for data preservation and destruction?
- Examination of the gaps in individual's medical records and whether there was a systematic process to cover up actions related to contaminated blood products. To understand whether this documentation was destroyed outside of the normal standards for data preservation and destruction.

Question 3: Is there any type of evidence, such as documents, communications or expert reports that you think is essential for the Inquiry to obtain?

The issue of documentation, communications, sources of documents both within the United Kingdom and abroad ought similarly to be addressed by way of a Position Paper and subsequent submission/discussion if so requested by the Inquiry.

Question 4: The care and support provided after infection

The adequacy and timeliness of the response of not only government but various governmental agencies, trusts, treating physicians etc. requires to be investigated in detail most especially in the context of the provision of healthcare entitlements, support services and recompense.
We have highlighted below an outline of some of the key issues:

Impact on people

- What was the initial short term and long-term impact on individuals infected their families and carers?
- What has been the emotional, psychological and financial effect such as loss of income; loss of opportunity in education, employment and social life; of contracting a virus gained through contaminated blood products?
- What level of support, financially, practically and emotionally has been provided to affected individuals and their families and how has access to

support been achieved and managed? Did this truly reflect the real loss incurred by individuals and their families after contracting a viral condition?
- What have been the impacts of subsequent treatments to manage the conditions contracted and has access to treatment been equitable and fair?
- How did the way the support was administrated impact people and their families?
- How did the length of time and continued fight to get a Statutory Public Inquiry affect the community and families psychologically and financially?

Diagnosis and communication

- How was information about infection and subsequent symptoms recorded in medical notes?
- How and when were infected individuals and their families told about their diagnosis and what level of support was offered? What the impact of delayed diagnosis and individuals and family members? What was the impact of delayed communication of diagnosis to individuals and their families?
- What was the level of communication to non-specialist treatment centres about risks of contamination?

Response of government

- What was the response of government to the disaster, what did they put in place to support infected individuals and their families?
- How transparent have government been in making sure all documentation has been made available and nothing has been hidden or destroyed to cover the truth?
- Has the government been receptive to the voices of the infected community and been open to hear their testimony?

Question 5: Do you agree that the Inquiry should seek these individual responsibilities and make recommendations?

We strongly agree that the Inquiry should seek individual responsibilities and make recommendations.

If the remit of the investigation is sufficiently wide to the extent that the patterns of repeated exposure of people with inherited bleeding disorders to blood borne pathogens is understood, then a situation will occur where focused, comprehensive and effective recommendations can then occur.

The terms of reference must be sufficiently specific in its investigation requirements so that each particular topic is examined in detail and recommendations are made in relation to that topic.

For example, the Inquiry could comment on where lessons can be learned to improve public safety arising from the circumstances of the infected and affected, also the Inquiry should consider reaching conclusions which are of practical application to both the Haemophilia community and the wider U.K. population who depend upon the provision of safe healthcare services.

Some specific questions

- Who had ultimate responsibility at the Department of Health to make decisions based on available evidence to ensure the safety of patients requiring blood products?
- Who were the leading voices of authority, how were their views communicated and who was in receipt of this information, how was this disseminated?
- What were the standards and procedures applied by the Department of Health at the time to protect and mitigate the risk of exposure to pathogens viral infection. Were they adequate and how widely were they applied?
- What were the Clinical Standards to prevent infection when the risks were first identified and who had responsibility for ensuring these were followed on a national and local basis? How closely were they followed nationally and locally?
- What were the International standards and procedures at the time and what was the timeline of incorporating updated information?
- Look at recommendations on procedures to protect against the potential for future blood transmissible infections.
- Examine and make recommendations for safeguarding future healthcare for people living with bleeding disorders and those living with infection from contaminated blood.
- Examine recommendations to ensure access to up to date treatments and comprehensive care.

THE HAEMOPHILIA SOCIETY

Additional Comments

We have contributed to this consultation process and the specific questions that have been raised, resulting in the specific answers. It is the view of The Haemophilia Society that the Inquiry would gain additional valuable information if participants were invited to prepare a position paper.

The position paper that The Haemophilia Society would prepare will include and address the following:

- Powers and procedural terms for the Inquiry process.
- The structure of the Inquiry investigation process in terms of its modular approach to such an investigation.
- The entities and individuals who ought to be the subject of consideration by the Inquiry in the context of the proposed Terms of Reference or issues to be contained in the Terms of Reference.
- The sources of information including both documentation and evidence to be adduced, to include addressing evidential lacunae that exist arising from the passage of time.
- In addition to investigation of what occurred the inquiry will also be required to come to conclusions on the topics below:
    - Alternative treatments and treatment regimens.
    - The balance of risk versus safety.
    - The appropriate standards applicable in relation to past actions.
    - Risk benefit analysis.
    - The appropriateness of crown-immunity in the context of licensing.
    - The effectiveness of targeted look-backs.
    - Ultimate responsibility issues.

These are additional matters that require to be considered in the context of the Terms of Reference and the balance that needs to be struck between a comprehensive, effective investigation process versus the requirement to achieve appropriate expedition.

There are additional issues and concerns which have arisen from our consultation with our members and we would wish to discuss with the inquiry, these include:

- A need for initial emphasis on the people impacted by the events of the contaminated blood scandal with adequate opportunities to tell their stories as part of a truth and reconciliation process. People need to feel involved from the start of the process.

- The setting of adequate methods to allow people to give evidence and testimony whilst maintaining anonymity.
- Ensuring a wide range of testimonies is examined to ensure a comprehensive understanding of the full impact of the use of contaminated blood products. It must be inclusive of all voices.
- Maintain accurate and easily accessible levels of communication with the affected community throughout the process, with clear rationale for decisions, including times when the process is internally facing.
- It must be clear the process is seen to independent of government influence.
- A transparent communication of the relationship and agreement between the Cabinet Office and the Inquiry when it comes to setting the Terms of Reference.
- Psychological support for the community, not just those giving evidence but those who seek to remain in the background but are equally affected, and the provision of effective support either via the inquiry directly or by allocated resources to enable support to be delivered by charity and support organisations.
- Potential areas where the Inquiry could examine to make recommendations to benefit the community living with infection and bleeding disorders.

The Society would welcome a further opportunity to engage in a dialogue process both by way of a Position Paper or a formal meeting process to address issues that require to be considered. It is our belief that we can contribute in a constructive, effective and proactive manner on behalf of the Society and its membership in terms of ensuring an all-encompassing Inquiry process.