INFECTED BLOOD INQUIRY

SUBMISSIONS ON BEHALF OF BELFAST HEALTH & SOCIAL CARE TRUST TO ASSIST THE CHAIR TO DECIDE WHETHER ADDITIONAL EVIDENCE NEEDS TO BE GATHERED RELEVANT TO THE MAKING OF RECOMMENDATIONS (NOT RELATED TO COMPENSATION)

Introduction

1. Some general observations about the scope of these submissions. The Inquiry will appreciate that the Belfast Health and Social Care Trust ("BHSCT") has not yet seen submissions on recommendations made on behalf of other Core Participants, including the Infected and Affected. It is likely that submissions on behalf of other Core Participants will raise issues not addressed in these submissions. The Inquiry may wish to seek a response from BHSCT and from other Core Participants outside the broad Infected and Affected grouping. If necessary, BHSCT will address issues that fall into that category in subsequent submissions.

2. In line with the guidance contained in the updated Statement of Approach from the Inquiry, these submissions are limited to the need for additional evidence on recommendations. They do not address factual findings or substantive recommendations that the Inquiry may make at a later stage. BHSCT will address factual findings and substantive recommendations as part of its more detailed submissions scheduled for October 2022.

3. BHSCT recognises that the Inquiry is likely to receive submissions from Core Participants covering generic themes and issues which are relevant to all the UK jurisdictions. To avoid potential duplication, the submissions on behalf of BHSCT focus on a selection of issues from a Northern Ireland perspective. It is hoped this approach may be more useful to the Inquiry albeit not all the issues addressed are likely to be exclusive to Northern Ireland.

4. Much of the evidence received by the Inquiry relates to circumstances and events 30 or 40 years ago. While the Inquiry's Terms of Reference extend beyond such events and circumstances, it is anticipated factual findings made by the Inquiry will provide a historical narrative. Without seeking to diminish the importance of that aspect of the Inquiry's work, BHSCT considers that recommendations should essentially be forward-looking rather than retrospective. The Inquiry will wish to make recommendations directed towards measures which promote improvement and public confidence in healthcare and which ensure that, so far as possible, mistakes of the past are not repeated.

5. In Northern Ireland, care and treatment of those suffering from inherited bleeding disorders has undergone major change particularly in the last 10 years. Many of the issues that loomed large in the 1980s and 1990s and which have been considered in detail by the Inquiry have been the subject of positive developments in the intervening years.

6. It is important to stress that the preceding paragraph is emphatically not indicative of complacency on the part of BHSCT which is responsible for the Northern Ireland Adult and Paediatric Haemophilia Comprehensive Care Centres. BHSCT remains totally committed to continuous improvement in patient care and outcomes. The Inquiry's recommendations will be of fundamental importance in that regard. However, for those recommendations to be of maximum benefit, the Inquiry will take account of the extent to which issues have been addressed and will focus on aspects in respect of which it concludes change is required.

7. Against that background, these submissions concentrate on five broad themes that have emerged from the evidence received by the Inquiry, particularly that from Northern Ireland. They provide no more than a brief overview of the current position at the Adult Belfast Comprehensive Care Centre ("the Belfast Centre"). Much of what is stated also applies to the Paediatric Centre.

8. BHSCT is mindful of the guidance from the Inquiry that rehearsing evidence is unlikely to be of assistance. Nevertheless, notwithstanding some transgression of that guidance, it is hoped the approach taken may assist the Inquiry in two ways. Firstly, by highlighting issues in respect of which progress has already been made and therefore recommendations are either not required or should be tailored appropriately to reflect the current position. Secondly, by highlighting local initiatives taken by BHSCT that may have wider application and be of interest to the Inquiry for that reason.

9. The five themes considered in the following discussion are:

(i) Facilities and services for patients and families
(ii) Information for patients
(iii) Consent
(iv) Treatment and patient safety
(v) Ensuring high standards of patient care

Facilities and services for patients and families

10. A useful starting point is the most recent QRS (Audit) Report for the Belfast Centre which followed an inspection in October 2019[1]. Findings included –

- Centre facilities were spacious and pleasant with plenty of patient information on display
- Staff at the Centre offered a very good clinical service and exemplary multi-disciplinary team (MDT) working
- The MDT had made efforts to give patients and families easy access for advice and assessment
- Transition practice for young people moving over to the adult service was good

---

[1] WITN3082028-0009

- Patients' feedback about the care they received was very positive

11. These findings reflect ongoing development of services at the Belfast Centre. For the first time there are now three dedicated consultants[2]. Additional laboratory scientific staff have been appointed[3]. A data manager has been appointed[4]. Previously psychological support was provided by open access to the Adult Psychology Service together with counselling provided by a dedicated social worker. A dedicated clinical psychologist was appointed for the duration of the Inquiry. That post has been made permanent[5]. There is a dedicated Occupational Therapist service[6] and physiotherapy service[7] at the Centre. These dedicated support services are augmented by informal input from the medical and nursing staff.[8] Home delivery of factor concentrate was introduced in autumn 2020. Patients on home treatment no longer have to collect concentrate from their local hospital blood bank[9].

12. The Belfast Centre has incorporated a range of specialist clinics into its services with a "one stop" ethos. For example, the combined clinic for patients infected with HIV[10] and the obstetric haematology clinic established in 2008[11].

13. The Belfast Centre has undertaken several initiatives to "reach out" to patients who tend not to attend routine clinics. The largest group of such patients are those with mild haemophilia. Initiatives such as use of telephone virtual review and invitations to patients to discuss how the Centre could assist them have been introduced[12].

---

[2] Transcript of Dr Benson's evidence 24/2
[3] Ibid 25/1 -6
[4] Ibid 23/7
[5] Ibid 27/7-11
[6] Ibid 24/24-25
[7] Ibid 24/21 -22
[8] Ibid23/4 – 29/9
[9] Ibid 18/21 – 19/2
[10] WITN3082015 §122
[11] WITN3082015 §§23, 24
[12] Transcript of Dr Benson's evidence 39/23 -40/6

14. A further initiative is a satellite clinic at Altnagelvin Hospital. Every two months the whole team – medical, nursing, physiotherapy, social work, and occupational therapy travel to the Northwest to offer full multi-disciplinary clinical consultations for patients living in that area[13].

15. Although considerable progress has been made in the provision of patient facilities and services, there is always room for improvement. This is readily acknowledged by the BHSCT and by the medical and nursing staff at the Belfast Centre. The 2019 QRS Audit Report identified a number of issues. These included –

    - Reliance on "paper returns" for home treatment with poor records of actual factor used (as opposed to factor issued)
    - Updated treatment plans not routinely sent to patients
    - Electronic patient records not including an "alert" indicating the patient had a bleeding disorder

    Since the Report was published Haemtrack has been introduced for patients with bleeding disorders in Northern Ireland. This has helped to address the problem of poor records of actual factor use[14]. Patients now receive copies of updated treatment plans sent to GPs following review clinic attendance by the patient. Work on how "alerts" that a patient has a bleeding disorder could be incorporated in electronic patient records is ongoing.

16. Facilities and services at the Paediatric Centre (located separately) on the Royal Victoria Hospital site are comparable to those at the Adult Centre. Transition from the Paediatric Centre to the Adult Centre is managed appropriately with emphasis on full involvement of patients. The Inherited and Acquired Haemophilia and Bleeding Disorders QRS Overview Report May 2020[15] (discussed below) highlighted the transition arrangements as examples of "good practice"

---

[13] Transcript of Dr Benson's evidence 32/13-20
[14] Ibid 48/21
[15] Copy appended as Annex 1 hereto

Information for patients

General approach

17. The Belfast Centre promotes a holistic approach to patient care and strives to be patient-centred[16]. Staff recognise the importance of providing relevant information communicated to patients in a comprehensible manner. They also recognise the importance of *how* information is provided. Thought is given to the nature of the information being provided and to ensuring the circumstances are appropriate. Information, especially if it has the potential to cause anxiety or distress, is conveyed with empathy and in a way that takes account of individual needs and circumstances.[17] Results of diagnostic tests would be an example[18].

18. Information is updated to reflect developments in treatment and management of bleeding disorders[19]. Furthermore, the Belfast Centre is open to expanding the provision of information to reflect developments in treatment and patient support or where a specific need is identified.

19. Fundamental to achieving the goals of a holistic approach and being patient-centred is information flowing in both directions – staff to patients and patients to staff. Dr Benson's written and oral evidence gave the Inquiry insight into current practice[20].

20. More detail is given in the following paragraphs.

Information about treatment.

21. Dr Benson outlined the information provided to individual patients in relation to their treatment. For those on recombinant products (the vast majority), change of product tends to be an issue especially if previously treated with plasma-derived

---

[16] Transcript of Dr Benson's evidence 25/18 – 26/20
[17] Ibid 83/25- 86/7
[18] Ibid 54/21 -55/1
[19] Ibid 47/2 -22
[20] Ibid 25/18 – 26/16. WITN3082015 §248

product. Patients are informed of why it is necessary to change products and re-assured that they are not reverting to plasma-derived products[21]. Availability of alternative products with relevant advantages and disadvantages is discussed[22]. Updated information about the risk of inhibitor development associated with the product is provided[23]. Information about vial dosage is also given. This can be a significant issue for some patients as it affects administration of the product[24].

22. For patients whose treatment involves use of plasma derived products, it is explained that such products are prepared from donations of multiple blood donors. It is explained that the blood has been screened and tested for known viruses and that the product has undergone viral inactivation. It is explained that notwithstanding these measures there remains a small risk of transmission of known viruses as well as the possibility of transmission of a yet unknown pathogen. It is also explained that in making treatment decisions these risks are balanced against clinical need for clotting factor and whether alternatives are available.[25]

Information about the risk of infection

23. It may be helpful to preface discussion of this aspect by outlining the context. No new cases of hepatitis or HIV have been diagnosed while Dr Benson has been Director of the Belfast Centre[26]. No current patients are known to have active Hepatitis B. Of patients previously infected with Hepatitis C, all have been treated with non-interferon therapies and have achieved sustained viral remission[27]. Three patients are infected with HIV and are treated at a combined clinic with HIV specialist.[28]

---

[21] Transcript of Dr Benson's evidence 46/20 – 47/6
[22] Ibid 47/7 – 16
[23] Ibid 47/17 -22
[24] Ibid 47/23 – 48/17
[25] WITN3082015 §52; Transcript of Dr Benson's evidence 49/6 – 50/23
[26] WITN3082015 §69
[27] WITN3082015 §72. One patient who at the time Dr Benson gave evidence to the Inquiry had opted not to pursue treatment has now received non-interferon treatment and has achieved sustained virological remission.
[28] Transcript of Dr Benson's evidence 58/25. 59/22

24. Information relating to the risk of infection is tailored accordingly and includes information on –

- Sexual health[29]
- Risk of transmission to others[30]
- Measures to reduce the risk of transmission to others[31].

Other information

25. The Belfast Centre also provides information of a more general nature which might assist patients and their families. Examples include –

- Signposting to specialist and support services[32]
- Lifestyle advice[33]
- Advice on the challenges of living with chronic hepatitis[34]
- Teratogenic effect of conceiving while on therapy for Hep C[35]

Information from patients

26. As stated, information is not "one way". Medical and nursing staff encourage and receive regular feedback from patients. It is recognised that patients are experts in their own condition. At reviews, staff endeavour to engage with patients to gain as full a picture of their personal circumstances and current issues as possible[36].

Consent

27. BHSCT operates in line with guidance contained in Department of Health Northern Ireland (DHNI) "Reference Guide to Consent for Examination, Treatment or Care" issued in March 2003.[37] This is a detailed document setting both principles and

---

[29] WITN3082015§71
[30] WITN3082015 §70
[31] WITN3082015 §72
[32] Transcript of Dr Benson's evidence 30/1 -38/8
[33] Ibid 74/11-14
[34] WITN3082015 §136
[35] WITN3082015 §70
[36] Transcript of Dr Benson's evidence 25/18 -26/20
[37] WITN3449030

practical guidance in relation to consent. It provides the foundation on which the approach to patient consent in Northern Ireland is based.

28. Consistent with the DHNI reference guide, consent of patients at the Belfast Centre is seen as a process rather than a discrete event[38]. Central to the process is patients understanding the nature and purpose of the tests to be undertaken. A blood sample is taken from patients at each outpatient attendance and routinely tested for a range of clinical markers. Before taking a sample, medical staff discuss with patients trends evident from previous tests, explain what tests are to be undertaken, and the reason for them[39]. Nursing staff generally recap with each patient before proceeding to take the blood sample. When a test for a specific marker or pathogen (not part of the block of routine tests) is to be undertaken, it is discussed fully with the patient. No tests are undertaken without the patient being informed as to the nature and reason for the test. Whether a routine or specific test, patients are given the opportunity to raise any concerns[40]. Patients are not tested for HIV or hepatitis or for any other purpose without their express and informed consent.[41]

29. Blood samples are not stored following completion of testing. The only exception is genetic screening. For genetic screening retention of samples is discussed with the patient and signed consent obtained.[42]

30. No patients have been involved in research without their express consent during the time Dr Benson has been in post[43]. Likewise, patient data has not been used without express consent[44].

---

[38] Transcript of Dr Benson's evidence 52/22 -53/21
[39] WITN3082015 §§73,74; transcript of Dr Benson's evidence 53/15 -21
[40] Ibid 55/18-22
[41] WITN3082015§75
[42] WITN3082015§74
[43] WITN3082015§84
[44] WITN3082015§85

31. Dr Benson referred to evidence on patient records of consent given to provision of information to UKHCDO. This goes back to Dr Anderson's time as Director and includes an explanation of what patient data was shared and for what purpose it was used. Dr Benson undertakes a similar exercise for patients transferring from the Paediatric Clinic[45].

Treatment and patient safety

Product selection

32. Patient safety is paramount. Since 2008 all patients with Haemophilia A have been on recombinant factor VIII. All but one Haemophilia B patient have been on recombinant factor IX[46]. The patient who is on plasma-derived factor IX chose to revert to that product because he felt it was more effective in controlling his bleeding.

33. VWD patients are treated with DDAVP, virally inactivated plasma-derived concentrate, or recombinant factor[47].

34. All products used for the treatment of patients are tendered and procured through the national clotting factor tender process in common with the rest of the UK[48]. Change of products is maintained at the minimum level subject to any product being withdrawn from the tender process.[49] Where product change is necessary, this is discussed with the patient. Any product change is recorded in the patient notes and included in the review clinic letter sent to the patient's GP after each review.[50]

---

[45] Transcript of Dr Benson's evidence 99/10 -100/3
[46] WITN3082015 §39
[47] Ibid 45/4
[48] WITN3082015 §40
[49] WITN3082015§41
[50] Transcript of Dr Benson's evidence 51/1-9

35. Pharmaceutical companies have no influence on product selection[51]. In addition to the protection against such influence provided by central tendering, BHSCT has provided for declaration of conflict of interest and has a policy in relation to staff accepting gifts from patients and external bodies. It also has a specific policy regarding pharmaceutical company visits and interaction with staff[52].

Patients with HIV

36. As stated above, three patients with HIV currently attend the Belfast Centre. They attend a combined clinic run with HIV specialist Dr Qhah every 3-4 months.[53] The combined clinic aims to provide a "one stop shop" for patients and, so far as possible, avoid the need to attend multiple outpatient clinics.

Patients with HBV

37. No current patients of the Belfast Centre are known to have hepatitis B.[54]

Patients with HCV

38. With the introduction of the new generation of non-interferon-based treatment, all patients at the Belfast Centre were reviewed, assessed, and offered treatment. All have achieved sustained virus remission.[55]

39. Patients who are PCR negative and have not developed cirrhosis are monitored for any changes that might indicate progression of liver disease by liver function tests which are part routine blood tests undertaken at each haematology outpatient review clinic.[56] Patients who have concerns about HCV returning or who are seeking re-assurance are signposted to the Hepatology service for further management including FibroScan examination.[57]

---

[51] WITN3082015§43
[52] Transcript of Dr Benson's evidence 119/9 - 19
[53] Ibid §122
[54] Ibid §125
[55] WITN3082015 §66
[56] Transcript of Dr Benson's evidence 82/3 -6
[57] Ibid 84/23 – 85/3

40. Patients who have developed cirrhosis (which will have been confirmed by FibroScan) are managed by the Hepatology service. The Hepatology service operates a hepatoma surveillance service. This involves a 6 monthly ultrasound scan and serum alpha-fetoprotein testing[58]. This is in addition to the blood tests that are part of the routine haemophilia review clinics.

41. The Hepatology service manages all patients who have undergone liver transplant.[59]

42. Patients are routinely counselled in relation to diet and alcohol intake[60].

Improving standards of patient care

43. In common with other Comprehensive Care Centres and Haemophilia Centres in the UK, the Belfast Centres are subject to periodic external audits. These audits are undertaken by the Quality Review Service (QRS) (formerly the West Midlands Review) to review compliance with Quality Standards developed by the UKHCDO Peer Review Working Group in conjunction with the QRS. Some of the main findings of the most recent review of the Belfast Centre in 2019 have already been referenced above (§9). It is submitted that, overall, the report demonstrates not only commitment to continuous improvement but also demonstrates that improvements in patient care have been achieved. During Dr Benson's evidence, the Inquiry considered audit reports from 2006, 2009 and 2013. At the time of 2019 review many of the issues identified in those earlier reports had been addressed. Others were being addressed. The picture emerging demonstrates the Centre's commitment to continuous improvements in patient care.

44. Further support for this conclusion is found in the QRS Overview Report prepared for the Inherited and Acquired Haemophilia and other Bleeding Disorders Peer

---

[58] Ibid 79/16 – 80/10
[59] WITN3082015 §127
[60] Transcript of Dr Benson's evidence 74/15 – 75/4

Review Programme (May 2020)[61]. This report presents findings in relation to 28 Comprehensive Care Centres and 11 Haemophilia Centres throughout the UK, including the Adult and Paediatric Centres in Belfast. The authors of the report stressed that it was not a "league table", but it does provide a useful indicator of how standards of patient care in the Belfast Centres compare with those in other UK centres. The Belfast Centres were included among Centres found to have demonstrated "good practice" in various aspects of patient care[62] -

- a *"Welcome to the adult service"* pack for young people transitioning from the Paediatric Centre
- a "*Playing it safe*" leaflet encouraging physical activities within safe limits
- a "single assessment tool" which patients completed while waiting for their consultations and in which they record aspects of their physical or mental health they wished to discuss during their consultation
- Excellent detailed guidance for each patient applying for Personal Independence Payments (PIP)
- Full information packs, individualised by condition and severity, for children and parents joining the service (Paediatric Centre)
- Extensive in-service training for the multi-disciplinary team which was subject to care annual evaluation
- Electronic patient record system accessible by healthcare professionals across Northern Ireland
- A clear colourful poster to guide ED staff in the initial management of patients presenting for acute conditions or issues
- Dedicated arrangements for conveying urgent samples and factor concentrates between sites (Paediatric and Adult Centres)

45. It bears repeating that while BHSCT and staff at the Belfast Centres have been greatly encouraged by the positive audit findings, there is no complacency.

---

[61] Annex 1

[62] Ibid p18,24,30,36,39

Continuous improvement in patient care is an integral part of the holistic care model practised at the Belfast Centres[63].

Conclusion

46. Insofar as it is possible to extract from the themes discussed above aspects that might potentially be the subject of recommendations of general application and that may benefit from further evidence, BHSCT invites the Inquiry to consider the following–

    - Mechanisms to promote and facilitate exchange of information between patients and healthcare professionals involved in their care
    - Measures to reach out to patients who have ceased to attend clinics or who are infrequent attenders at clinics including greater use of "remote" consultations
    - Structured collection and use of patient feedback
    - Promotion of a "holistic" model of clinical care for patients with Inherited and Acquired bleeding disorders across the UK

47. The Inquiry will, of course, identify from its own assessment of the evidence and from submissions from other Core Participants aspects of patient care that it feels should be the subject of recommendations. BHSCT looks forward to reading the submissions of other Core Participants and, in due course, the recommendations of the Inquiry to which it will give full and careful consideration.

---

[63] Transcript of Dr Benson's evidence 124/5 -10

PHILIP ALDWORTH QC

MARK ROBINSON QC

BRIAN DONNELLY Solicitor

NAOMI McVEIGH Solicitor

17 June 2022