SMALLER HAEMOPHILIA CENTRES PRESENTATION
NORFOLK & NORWICH

Directors, staffing and structure of the centre

1. The directors of the Haemophilia Centre at Norfolk & Norwich Hospital in the 1970s and 1980s were Dr John Leslie and Dr A J Black.

2. Dr John Leslie was director of the Norfolk & Norwich centre from at least 1976 (HCDO0000020_005). Prior to this, Dr Leslie was director of Southampton Haemophilia Centre. He was welcomed to that role in a meeting on 27 October 1972 (HCDO0001015) and continued in the role until at least 31 January 1974 (CBLA0000187).

3. From 1979, Dr A J Black is listed alongside Dr Leslie as director of the centre (HCDO0001358).

4. It appears that Dr Leslie was in favour of the formation of a kind of "supra-organisation" to govern the Haemophilia Centres, though it is noted that he was in a minority in holding that view (CBLA0000657).

5. Other (later) members of staff include: Dr Wendy Clark, staff grade in haematology in 1996 (HSOC0017477) and Dr J Wimperis, consultant haematologist in 1996.

6. The available documents do not detail the formal links between the haemophilia centre and specific regional transfusion centres. However, it is clear that Norfolk & Norwich hospital was itself taking blood donations and that the centre itself had taken blood that was used for cell separation (DHSC0002293_040).

7. The Royal Free Hospital haemophilia centre lists the Norfolk & Norwich centre as a proposed associate centre in a document dated 15 November 1976

(CBLA0002956_005).

8. It is noted in 1989 that there was no regional haemophilia centre in East Anglia. Dr Leslie states that the Norwich centre could provide most of the functions of a regional centre (HCDO0000436).

Numbers of patients registered and treated

9. From at least 1976, the Centre produced annual returns that were sent to the Oxford Regional Transfusion Centre. The returns recorded the number of patients that were registered with the Centre, at times distinguishing between those who were regular patients and those who were treated on a one-off basis. There is also a record of how many patients had developed F VIII or F IX antibodies and whether patients had developed jaundice that year. Generally, there is some record of which patients received blood products from the different NHS and commercial sources.

10. In 1976, there were 19 patients with haemophilia A, one of whom had developed antibodies. Four of these patients were receiving regular home treatment. There were also 13 patients with haemophilia B registered. None of these were recorded as receiving regular home treatment. There were two patients registered with von Willebrand's. No patient deaths were recorded, nor were any recorded as developing jaundice (HCDO0000020_005).

11. Fewer patients were treated in 1977. There were 13 patients with haemophilia A and, again, one of these had antibodies and four were receiving regular home therapy. There were nine patients with haemophilia B and by that year two of them were receiving regular home treatment. One patient with von Willebrand's was treated. No patients were recorded as developing jaundice (HCDO0001190).

12. 18 or 19 patients with haemophilia A were treated in 1978, none of whom had inhibitor antibodies. Again, four of these patients were listed as receiving regular home treatment. There were six haemophilia B patients, three of whom had received regular

home therapy. One patient with von Willebrand's was treated. No patients were recorded as developing jaundice (HCDO0001288).

13. 1979 is the first year in which the annual returns were signed off jointly by both Dr Leslie and Dr Black. 14 haemophilia A patients were treated, one of whom had factor inhibitors and four of whom received regular home treatment. Six patients with haemophilia B were treated, all with Oxford F IX product. Three of these patients received regular home treatment. Three patients with von Willebrand's were registered that year, as well as one carrier of haemophilia who was treated with a mix of NHS and commercial F VIII concentrate. No patients were recorded as developing jaundice (HCDO0001358).

14. The annual return for 1980 is nearly illegible, but the following appears to be correct. 15 patients with haemophilia A, six patients with haemophilia B and one patient with von Willebrand's were treated. This is the first year in which an electronically generated record of the products given to each patient is included with the return. Prior to this, a hand-filled form had been completed, which may demonstrate a change in the way the data was collected and managed by the centre. From this year onwards, the annual returns do not record the numbers of patients (if any) developing jaundice (HCDO0001456).

15. In 1981, 20 patients with haemophilia A, 7 patients with haemophilia B and one patient with von Willebrand's were treated (HCDO0001555).

16. In 1982, 21 patients with haemophilia A, six with haemophilia B, two with von Willebrand's and one carrier of haemophilia A were treated (HCDO0001655).

17. In 1983, 18 patients with haemophilia A (two of whom had antibodies), three with haemophilia B and one carrier of haemophilia A were treated (HCDO0001751).

18. The number of patients registered in 1984 is notably higher, with 27 patients with haemophilia A registered, two of whom had antibodies. There were also nine patients with haemophilia B and two with von Willebrand's (HCDO0001845).

19. In 1985, 23 patients with haemophilia A, five with haemophilia B, four with von Willebrand's and one carrier of haemophilia A were treated (HCDO0001940). A handwritten list, sent to Dr Snape at the Blood Products Laboratory, states that the Centre had a total of 34 patients. Seven of those are noted as being treated regularly with home treatment, while the others are seen either occasionally or rarely and are generally treated in the hospital (BPLL0010584).

20. In 1986, 25 haemophilia A patients (two of whom had antibodies), eight with haemophilia B, three with von Willebrand's and one carrier of haemophilia A were treated (HCDO0002035), (HCDO0000305_010).

Treatment policies and blood product usage

Annual returns, 1976-1986

21. The annual returns from 1980 onwards clearly distinguish between quantities of product administered in hospital and that administered as home treatment. However, the returns prior to this are not always as clear on this point. Some of the data for 1977 are accompanied by the caveat that they do not include figures for products administered in hospital. Whether that applies to the data for other years is not entirely clear (HCDO0001190).

22. In 1976, haemophilia A patients were treated with 28,840 units of cryoprecipitate, as well as a variety of commercial products:
    a. 27,025 units of Armour F VIII concentrate (Factorate);
    b. 3,000 units of Cutters F VIII concentrate (Koate);
    c. 3,000 units of Hyland F VIII concentrate (Hemofil); and
    d. 15,000 units of Immuno F VIII concentrate (Kryobulin).

    Haemophilia B patients were treated exclusively with NHS F IX concentrate, totalling 88,800 units. The two patients with von Willebrand's were treated with a small amount of cryoprecipitate (980 units) and 4,476 units of the Immuno concentrate

(HCDO0000020_005).

23. As mentioned, some of the 1977 data do not include products administered in hospital. However, the returns do provide total figures for the year which do seem to include hospital treatment. So, the total amounts administered to haemophilia patients are:
    a. 46,270 units of cryoprecipitate;
    b. 62,015 units of NHS F VIII concentrate;
    c. 260 units of Cutters F VIII concentrate (Koate);
    d. 23,300 units of Hyland F VIII concentrate (Hemofil);
    e. 453 units of Immuno F VIII concentrate (Kryobulin); and
    f. 137,049 units of NHS F IX concentrate.

    Additionally, one von Willebrand's patient was treated with 840 units of cryoprecipitate (HCDO0001190).

24. In 1978, relatively little cryoprecipitate was administered, falling to 7,200 units. This was around a quarter the total of the previous year despite a small increase in the number of patients treated. Patients were also treated with 84,890 units of NHS F VIII concentrate, 9,030 units of Hyland (Hemofil) concentrate and 113,890 units of NHS F IX concentrate. One patient with von Willebrand's was administered 885 units of cryoprecipitate (HCDO0001288).

25. In 1979, very little cryoprecipitate was administered, at just 1,960 units. The levels of cryoprecipitate given to patients remained at this low level from this year onward, while the quantities of concentrate used continued to rise. 104,570 units of NHS F VIII concentrate was used, as well as smaller amounts of commercial F VIII. 12,121 units of Armour (Factorate) and 14,037 units of Hyland (Hemofil). Haemophilia B patients were given 128,380 units of NHS F IX treatment. One carrier of haemophilia was treated with a mix of NHS and commercial products: 245 units of NHS F VIII and 472 units of Armour (Factorate). Three patients with von Willebrand's were also treated, receiving 420 units of cryoprecipitate and 510 units of NHS F VIII (HCDO0001358).

26. Starting in 1980, the quantities of product administered were broken into categories depending on whether the treatment was delivered in hospital or at home. It should be

noted that this document is nearly illegible in some parts. That being said, it appears that haemophilia patients received:

a. 23 packs of cryoprecipitate (there is no quantity in units as before) in hospital;
b. 8,635 units of NHS F VIII concentrate in hospital and 74,650 units at home;
c. 11,883 units of Armour F VIII (Factorate) in hospital and 42,624 units at home;
d. 3,346 units of Hyland F VIII (Hemofil) in hospital and 20,270 units at home; and
e. 6,865 units of NHS F IX in hospital and 74,650 units at home.

One patient with von Willebrand's disease was treated with 885 units of NHS F VIII and 1,644 units of Armour F VIII (Factorate) (HCDO0001456).

27. In 1981, just as in the previous two years, the levels of cryoprecipitate administered remained very low. The levels of both NHS and commercial products used both increased markedly. Generally, the quantities of products administered in hospital were much lower than that taken as home treatment. Starting in 1981 however, patients received far more Armour (Factorate) at hospital than they did at home. Haemophilia patients received:

a. 12 bags of cryoprecipitate in hospital;
b. 21,283 units of NHS F VIII at hospital and 164,537 units at home;
c. 71,805 units of Armour F VIII (Factorate) at hospital and 13,158 units at home;
d. 225 units of Hyland F VIII (Hemofil) at hospital and 2,550 units at home; and
e. 23,160 units of NHS F IX at hospital and 179,785 units at home.

In addition, one patient with von Willebrand's was treated with 12 bags of cryoprecipitate and 500 units of Armour F VIII (Factorate) at hospital (HCDO0001555).

28. In 1982, the total levels of product used at home and in hospital were largely similar to the year before, with levels of Armour F VIII (Factorate) used in hospital remaining relatively high. Haemophilia patients were treated with:

a. 21,325 units of NHS F VIII concentrate in hospital and 175,623 units at home;
b. 68,400 units of Armour F VIII (Factorate) in hospital and 38,235 units at home; and
c. 13,355 units of NHS F IX at hospital and 188,480 units at home.

One haemophilia A carrier was treated with 12 bags of cryoprecipitate at hospital and two patients with von Willebrand's disease were treated with the same (HCDO0001655).

29. In 1983, the level of NHS product use increased while commercial product use was stable. Haemophilia A patients received:
    a. 17,120 units of NHS F VIII concentrate at hospital and 239,733 units at home;
    b. 64,199 units of Armour F VIII (Factorate) at hospital and 33,250 units at home;

    Haemophilia B patients are recorded as receiving 199,085 units of NHS F IX at home and no treatment administered in hospital at all. One carrier of Haemophilia A was treated at hospital with 1,050 units of Armour F VIII concentrate (Factorate) (HCDO0001751).

30. In 1984, the quantities of NHS treatment administered rose significantly, while the quantities of commercial factor products used were substantially reduced. Haemophilia patients received:
    a. 68,185 units of NHS F VIII at hospital and 308,015 units at home;
    b. 1,010 units of Armour F VIII (Factorate) at hospital and 450 units at home;
    c. 2,600 units of Cutters F VIII (Koate) at hospital; and
    d. 100,110 units of NHS F IX at hospital and 211,780 units at home.

    Two patients with von Willebrand's were treated with 10 bags of cryoprecipitate and 10,620 units of NHS F VIII (HCDO0001845).

31. In 1985, the quantities swung back the other way, with NHS F VIII products falling substantially in quantity and commercial products being relied on more. It is also the first time that the Alpha product is used in Norwich & Norfolk. Haemophilia patients received:
    a. 1,120 units of cryoprecipitate at hospital;
    b. 21,225 units of NHS F VIII at hospital and 149,300 units at home;
    c. 3,060 units of Alpha F VIII (Profilate) at hospital and 2,040 at home;
    d. 16,925 units of Armour (Factorate) at hospital and 70,490 at home;
    e. 5,385 units of Cutters F VIII (Koate) at hospital and 5,700 units at home; and
    f. 123,760 units of NHS F IX at hospital and 217,150 units at home.

One carrier of haemophilia A was treated with 990 units of NHS F VIII at home. Four patients with von Willebrand's disease were treated with a total of 1,260 units of cryoprecipitate, 1,470 units of NHS F VIII in hospital and 3,985 units at home, as well as 1,000 units of Armour F VIII (Factorate) in hospital (HCDO0001940).

32. 1986 is the first year which records porcine F VIII being administered. Haemophilia patients received:
    a. 101,660 units of NHS F VIII at hospital and 217,380 units at home;
    b. 15,810 units of Alpha F VIII (Profilate) at home;
    c. 56,650 units of Cutters F VIII (Koate) in hospital and 21,300 units at home;
    d. 23,504 units of Porcine F VIII in hospital and 5,620 units at home; and
    e. 14,380 units of NHS F IX in hospital and 154,965 units at home.

    One haemophilia carrier was treated with 3,970 units of NHS F VIII concentrate in hospital. Three patients with von Willebrand's were treated with three bags of cryoprecipitate and 2,340 units of NHS F VIII concentrate, both administered at hospital (HCDO0002035).

Other documents

33. Dr Leslie wrote to Dr Rizza, Oxford Haemophilia Centre, on 24 September 1975, stating that there was no satisfactory standard for F VIII related antigen immunoassay. He also asked Dr Rizza whether he had experience using Hyland, a commercial F VIII product (OXUH0001063_002). Dr Rizza replied on 29 September 1975, discussing the various standards that had been developed and directing Dr Leslie to Dr Barrowcliffe at the National Institute for Biological Standards (OXUH0001063_003). On 2 October 1975, Dr Leslie replied thanking Dr Rizza for providing some of his pool to be analysed and stating he will approach the institute for further information (OXUH0001063_001).

34. Dr Leslie informed a Haemophilia Centre Directors meeting on 23 September 1977 that the Norfolk & Norwich centre had exclusively used NHS concentrate for home treatment and had not at that time needed to buy any commercial concentrate

(CBLA0000657).

35. In a 12 February 1990 meeting of the UK Regional Haemophilia Centre Directors, Dr Leslie engaged in discussions about the choice between different types of blood products. The issue of the use of unlicenced products was raised. Dr Leslie expressed the view that production of third generation blood products should be carried out at Elstree. The general view was that the opinions of Haemophilia Centre Directors were not being taken into account by the Department of Health in decision making. It was agreed that they ought to have representation on the NHS Management Board to ensure their views were taken into account (HCDO0000437).

36. The issue of recombinant F VIII was raised as an issue at the Centre in 1996. Dr Wendy Clark, in the Department of Haematology at the hospital, wrote on 25 October 1996 that they did not currently offer recombinant F VIII due to cost constraints but that they were hoping the matter would be reconsidered soon (HSOC0017477).

Knowledge of risks of hepatitis and AIDS and response to risk

37. Dr Leslie appears to have attended his first UKHCDO meeting in October 1972; he is recorded as attending also in 1974, 1975, 1977 and 1978. It can reasonably be assumed, therefore, that he would have been aware of the discussions and information-sharing relating to hepatitis that took place at those meetings. He does not appear to have attended the 1979 meeting and the attendees at the 1980 meeting are unclear. He was in attendance at the 1981 annual meeting; Dr Black attended in 1982; and Dr Leslie again in 1983 at which the issue of reverting to cryoprecipitate in response to AIDS was discussed. Drs Leslie and/or Black would presumably also have received the March and June 1983 UKHCDO communications about AIDS.

38. On 29 August 1980, Dr AJ Black signed off a "hepatitis survey", which was a notification document to be completed and sent to the Oxford Haemophilia Centre immediately upon a patient being suspected of having contracted hepatitis (HCDO0000257_006). The document notes that the patient had received a number of

different commercial concentrate products in the previous six months and lists the batch numbers.

39. Dr Black attended the 15th meeting of the UK Haemophilia Centre Directors on 27 September 1984. Dr J. Leslie sent his apologies but, it is assumed, is likely to have seen the minutes. The minutes clearly acknowledge the risk of HIV/AIDS. The need to maintain comprehensive records on patients treated was reinforced (PRSE0003659).

40. On 11 March 1985, Dr Leslie wrote to Dr Snape, Blood Products Laboratory, sharing a list of patient names and offering to take part in trials of heat-treated products (BPLL0002368_004).

41. Correspondence between Dr Black, Dr Lane of the Blood Products Laboratory and a surgeon at Norwich & Norfolk Hospital, shows the planning involved in ensuring that a haemophilia patient would have sufficient factor product available to them ahead of planned surgery (BPLL0005848). Dr Black wrote on 22 July 1985, stating his preference that the operation be delayed until heat treated factor product was available, in light of the risk of HIV (CBLA0002221).

42. The Inquiry has received witness evidence in relation to treatment at the Centre to the effect that advice was not given about the risks of being exposed to infection through the use of blood products.

43. A 6 February 1986 letter from TW Davies (Specialist in Community Medicine) to A Harris (Assistant Secretary at the Department of Health) states that the Norfolk and Norwich Centre had in the past taken blood for cell separation and that the directors (Dr Leslie and Dr Black) had been asked to ensure that donors were tested for HTLV III/LAV antibodies (DHSC0002293_040).

44. Following the death of a patient treated by the Centre in around 1995, it was noted in the course of an application for compensation from the Macfarlane Trust, that the patient had been informed of their HIV infection status by Dr Leslie. However, it was

suggested that the way in which the letter had been worded might not have been clear to the patient, as it had referred to HTLV-III infection rather than HIV. It was suggested that this term was not commonly in use and might not have been well understood (DHSC0002532_012). Unfortunately, the original letter has not as yet been located. A consultant physician at the hospital, Dr Simon Watkin, wrote that in his view the patient had not understood the original letter to mean that he had been infected with HIV and had been shocked to learn, eight years later, that this was the case (DHSC0002532_014), a view which is reinforced by another clinician in a separate letter (DHSC0002532_015).

45. In relation to that patient, Dr Leslie wrote to Mr T Williams (social worker with the Macfarlane Trust) (DHSC0002532_013). He stated that the patient had been treated with blood products prior to the introduction of viral inactivation and that he had been tested positive for HIV in 1985. He states that the patient was "given the literature and counselled about the result" verbally. However, he states that the patient did not attend any of the follow-up appointments and that therefore further counselling was not possible.

46. In 1995, Dr Black appears to have told a lawyer acting for the hospital that HCV testing began in 1989 (NHBT0103821_005). In response to follow up questions from the lawyer, Dr Black clarified that tests were available in 1989 but were not introduced until "August 1991" as the transfusion centres had waited to introduce second generation tests (NHBT0103821_006).

47. A letter sent by Dr Elizabeth Caffrey, Consultant in Transfusion Medicine at Norfolk and Norwich Hospital, suggests that the hospital did not always inform patients that they may have been infected with HCV. The letter is addressed to a surgeon on 29 November 1996 following an HCV lookback exercise. The choice as to whether the patient was informed of their infection status was left to the surgeon, with Dr Caffrey noting that, if the surgeon thought it would be "inappropriate and unkind", the patient need not be informed (NHBT0020389). Whether this approach was confined to the transfusion department or whether it was also adopted at any point in the Haemophilia Centre is unclear.

Numbers of patients infected with HIV

48. Provisional UKHCDO data provided to the Inquiry indicate that 13 patients were infected with HIV up to 1988. One person tested positive in 1984, nine people tested positive in 1985 and three people tested positive in 1986 (INQY0000250)

Other issues

49. As with other Haemophilia Centres, it appears to have been standard practice to inform Treloar Haemophilia Centre whether or not a local patient had been treated with blood products in Norfolk and Norwich during the holidays (TREL0000032; TREL0000095_007).

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